



Eu – US PFI

# Safety and Toxicity of Excipients for Paediatric [STEP]

User Guide

European Paediatric Formulation Initiative (EuPFI)

UCL School of Pharmacy

29-39 Brunswick Square, London WC1N 1AX

www.eupfi.org

Introduction

Page | 1

## CONTENTS

1	]	Introduction
	1.1	Overview
	1.2	Scope
	1.3	Purpose
2	(	Getting started
	2.1	Log in
	2.2	New user registration
	2.3	Existing User
	2.4	Forgot Password
	2.5	Regular User
	2.6	Website links
3	ç	Session expiration
4	Ι	Logout
5	S	Search BY Excipients
	5.1	Search BY Excipients
6	S	Search FOR Excipients
	6.1	Clinical Data
	6.2	Non-Clinical Data
7	I	Excipient(s) Intermediate Details:
8	ç	Search Results
	8.1	General Information
	8.2	Clinical Data
	8.3	Non Clinical Data
	8.4	Invitro data

Eu – U	S PFI User Guide	Version- 1.0
8.5	Regulatory & other information	
8.6	Reviews	
8.7	Customization using Filters	
8.8	Show/Hide Columns	
8.9	Navigations in Search Results page	
8.10	Filtered Data Export	
8.11	No records found	
8.12	Back Link Functionality	
9 E	xport	
9.1	Export to Excel	
9.2	Export to PDF	
9.3	Cancel Export	
10 H	elp	
11 G	lossary	

## **1** Introduction

### 1.1 Overview

European Paediatric Formulation Initiative (EuPFI) is a consortium working in a pre-competitive way on paediatric drug formulations. Members are from academia, hospital pharmacies, pharmaceutical industry (Innovators, Generics, Contract Research Organizations (CRO), Specials and Excipient Manufacturers) with European Medicine Agency (EMA) as an observer.

Its main aim and objective is to identify/scope issues and challenges in paediatric formulation development in order to raise awareness and facilitate preparation of better/safe medicines for children.

As there is no central repository in public domain that resides all the information on safety and toxicity of Excipients for the paediatric drug development. The Eu-US PFI has established that there is a pressing need for a single authoritative comprehensive database of adverse effects of excipients for paediatrics.

STEP **S**afety and **T**oxicity of **E**xcipients for **P**aediatric [STEP] Database holds all the animal toxicity and human health data, regulatory information and toxicological reviews of excipients. STEP acts as repository for all the scientific communities to share the data for better understanding and paediatric drug development.

### 1.2 Scope

STEP database is intended to provide the data availability for the paediatric formulation development by the implementation of freely accessible online source which will provide easy access to authoritative comprehensive database of adverse effects of excipients for paediatrics from a key resource. Its main compass is to provide all the regulatory information and toxicological reviews of excipients.

STEP accomplishes a high-level scientific literature review of the pharmacology, toxicology and safety data of a prioritized group of excipients likely to be used in paediatric formulations.

#### Introduction

## 1.3 Purpose

STEP main rationale is to afford the public access of an evidence database of safety and toxicity of excipients for the pharmaceutical industry academics, clinicians and regulators to make informed decisions. This also enhances the prospects of identifying potential safety issues at earlier stages of the development process when excipients are being screened and selected.

STEP also establishes a fine relationship between exposure and evidence of clinically significant toxicity in the paediatric subpopulations and also assists in need of generating new data for paediatric medicines.

## 2 Getting started

Currently most of the existing databases are focusing in providing Safety and Toxicity related information related only to adults and animals. But very few include the paediatric information related to children. Consequently, there is an acute need for a single repository to capture, archive, validate, manage, maintain and provide access to safety, tolerability and toxicity data that have been generated for excipients available world-wide for paediatric drug development.

In order to address this need, the European (Eu) and United States (US) Paediatric Formulation Initiatives (PFIs) are working together to create and maintain a database of Safety and Toxicity of Excipients for Paediatrics (STEP).

## 2.1 Log in

Enter the user credentials in the login page and click "Login" as shown below.

EUPF	Database of safety and toxicity of excipients for paediatrics	United Btates Pediatric Initiative
Existing User If you already hav	e an account, please login below	Revision Date: 10/29/2012
Login Email * Password *	venkata.bodhanapu@gvkbio.com •••••• Log In Forqot Password ? (Your login session will expire after 30 minutes of inactivity)	
* Indicates manda New User - <u>F</u>		Need help? Click <u>Here</u>
Developed by GV	Contact Feedback Disclaimer	

"Search BY Excipients" page appears as shown below.

	STEP database Database of safety and toxicity of excipients for paediatrics	US Porter Durand States
bodhanapu venkata reddy (Your login t	session will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
Search BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate  Select Accoulfame K Accohol Aspartame Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. sobvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoyams. For Multiple Excipient/Function Selection: Please use "Ctff" or "Mouse click & drag" to select multiple search terms.08 please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	" icon to open excipients list hos for selection. Progressive search with Be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provide
Function	Select from drop down or enter minimum of 3 characters to populate	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Antiseptic	age or effect.

When user clicks "Log in" without entering the email id then the below alert message appears.



When user enters invalid email address then the below alert message appears



When user clicks "Log in" without entering password, the below alert message appears



If user logins with unregistered Login Email then the message appears as shown below.

	Database of safety and toxicity of excipients for paediatrics	United States Pediatric Initial States
Existing User Login If you already have an account, please	login below Email ID not yet registered. Please register before login.	Revision Date: 10/29/2012
	Password ? ill expire after 30 minutes of inactivity)	
* Indicates mandatory field(s). New User - <u>Register User</u>		Need help? Click <u>Here</u>
Developed by GVR BIO	Contact Feedback Disclaimer	GOSTAR GOBIOM

If user is already registered and trying to login with the incorrect credentials then the message appears as shown below.

	STEP database Database of safety and toxicity of excipients for paediatrics	United States Politice Pormulation
Existing User Login If you already have an account, plea	ise login below Unable to login, Please enter valid Login Email/Password.	Revision Date: 10/29/2012
	r <u>qot Password ?</u> n will expire after 30 minutes of inactivity)	
* Indicates mandatory field(s). New User - <u>Register User</u>		Need help? Click <u>Here</u>
	Contact Feedback Disclaimer	GOSTAR GOBION
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#### Version- 1.0

If user needs any help in STEP Database login process then, clicks on Need help? Click Here (Link), it will displays one window with the details,



In Login page, the Revision Date indicates that the recent/last database updation (addition/deletion of data) date in 'MM/DD/YYYY' format.

## 2.2 New user registration

STEP facilitates user to create a new user in a simple way by using the "Register User" link from

the login page. Click "Register User" link from the login page as shown below.

	STEP database Database of safety and toxicity of excipients for paediatrics	United States Promotion Initiative
Existing User Login If you already have an account, please login b	elow	Revision Date: 10/29/2012
Login Email * Password * Log In <u>Forqot Passw</u> (Your login session will expire	<u>vord ?</u> re after 30 minutes of inactivity)	
* Indicates mandatory field(s). New User - <u>Register User</u>		Need help? Click <u>Here</u>
	Contact Feedback Disclaimer	
etting started		Page   9

**Note:** "New User - Register User" page appears, here "I've read the Disclaimer and accepted the Terms & Conditions" checkbox appears in selected mode by default and cursor is at first name field by default.

Click "Why Registration?" link then the benefits for registration information appears as shown below.

Use of the STEP database is subject to the STEP database Terms of Use and the disclaimer  STEP DATABASE - DISCLAIMER & TERMS OF USE  This End User License Agreement shall be governed by the United Kingdom laws, without giving effect to principles of conflict of laws. You hereby consent to the exclusive jurisdiction and venue of the courts sitting in London, United Kingdom to resolve any disputes arising under this End User License Agreement. This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EuPFI to exercise anv of its rights under this End User License Agreement or upon any breach of this End User License Agreement I've read the Disclaimer and accept the Terms & Conditions	New User Reg	istration (Why Registration	Database of safety and toxicity of e for paediatrics		Initiative
<ul> <li>This End User License Agreement shall be governed by the United Kingdom laws, without giving effect to principles of conflict of laws. You hereby consent to the exclusive jurisdiction and venue of the courts sitting in London, United Kingdom to resolve any disputes arising under this End User License Agreement.</li> <li>This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EuPFI to exercise anv of its rights under this End User License Agreement or upon any breach of this End User License Agreement</li> <li>I've read the Disclaimer and accept the Terms &amp; Conditions</li> </ul>	Use of the STEP da	tabase is subject to the STE	P database Terms of Use and the	disclaimer	
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Login Email*     Your email address is your username     Confirm Login Email*       Contact Number     Country*     Select	and the second second	and income Announced and	ains the complete agreement bet	ween the parties with respect to	the subject matter
Contact Number Country* Select	hereof, and that any var you in relati exercise any	supersedes all prior or con rying or additional terms or on to The ONLINE STEP DA of its rights under this En	temporaneous agreements or un ontained in any purchase order or ATABASE licensed hereunder shall d User License Agreement or upo	derstandings, whether oral or wi other written notification or doo be of no effect. The failure or d	ritten. You agree sument issued by elay of EuPFI to
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Register Reset * Indicates mandatory field(s).	hereof, and that any var you in relati exercise any ✓ I've read the Dise First Name * Login Email* Contact Number	supersedes all prior or con rying or additional terms or on to The ONLINE STEP DA of its rights under this En claimer and accept the Term Your email address is you	temporaneous agreements or uniontained in any purchase order or ATABASE licensed hereunder shall d User License Agreement or upoins & Conditions Last Name Confirm L Country*	derstandings, whether oral or wi other written notification or doo be of no effect. The failure or d n anv breach of this End User Li e ogin Email*	ritten. You agree sument issued by elay of EuPFI to cense Agreement
Need help with this process? Click Here for more information	hereof, and that any var you in relati exercise any ✓ I've read the Dise First Name * Login Email* Contact Number	supersedes all prior or con rying or additional terms or on to The ONLINE STEP DA of its rights under this En claimer and accept the Term Your email address is you	temporaneous agreements or uniontained in any purchase order or ATABASE licensed hereunder shall d User License Agreement or upoins & Conditions Last Name Confirm L Country*	derstandings, whether oral or wi other written notification or doo be of no effect. The failure or d n anv breach of this End User Li e ogin Email* Select	ritten. You agree sument issued by elay of EuPFI to cense Agreement

If user clicks on Why Registration (Link) then it will display one window like below,

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	Database of safety and toxicity of excipients for paediatrics	
New User Registration (Why Registration) Use of the STEP database is subject to the STEP STEP DATABASE - DISCLAIMER & TEI • This End User License Agreement shall b conflict of laws. You hereby consent to th to resolve any disputes arising under this • This End User License Agreement contair hereof, and supersedes all prior or conte that any varying or additional terms cont you in relation to The ONLINE STEP DAT exercise any of its rights under this End I've read the Disclaimer and accept the Terms First Name * Login Email* Vour email address is your Contact Number Organization/Sector Select	<ul> <li>Benefits of registration -apart from the access to the database, help and literature</li> <li>Provide an opportunity for the users to test new data &amp; new features of dat full release.</li> <li>Give users an opportunity to provide your requirements on what you need toxicity database and software application.</li> <li>Support, Training and Feedback:</li> <li>Help and support available</li> </ul>	tabase and applications prior to and want in an ideal safety and ure enhancements to the STEP t number, organization and s. These purposes include
Register       Reset         Need help with this process? Click Here for more in         Developed by	simply asking a question. Your information is privileged and confidential and w any organization or business entity other than those affiliated with or working in database development.	rill not be shared or released to

To get help on user creation click on link "Here". Help page is displayed as shown below.

EUPFI L'OCHAR PRESERTC <sup>P</sup> OTFUSSORI (FEET - F	Database o	(G) (2) http://eupfi.org, ρ - 2 C × (2) eupfi.org ×
Use of the STEP data	for paediat stration (Why Registration?) abase is subject to the STEP database T E - DISCLAIMER & TERMS OF (	How to Register to get access to the STEP database The final step in the registration process is the page to confirm your registration is successfully comple You will then be sent back to database login page. All registrations must be personal registrations using your email address. Generic group or comp
conflict of law to resolve an • This End Use hereof, and s that any vary you in relatic exercise any	r License Agreement shall be governed vs. You hereby consent to the exclusiv y disputes arising under this End User r License Agreement contains the com supersedes all prior or contemporane ing or additional terms contained in a in to The ONLINE STEP DATABASE lice of its rights under this End User Licens laimer and accept the Terms & Conditio	accounts, or use thereof, are not permitted. Improper, inaccurate or duplicate registrations may be remo without notice. Please do not re-register yourself if you have previously registered, unless you are not able to retrieve y previous registration email. If you have forgotten your password, use the forgot password link on to reset For registration follow the steps below: 1. Read the disclaimer and terms and conditions.
First Name * Login Email* Contact Number Organization/Sector	Your email address is your user name Select Register Reset	<ol> <li>Check the box - I have read the disclaimer and terms and conditions</li> <li>Fill in the registration form. Please note that the fields marked as * in the registration form mandatory and need to be completed.</li> <li>Click the register button and you will forwarded to confirmation page.</li> <li>Click the register button and you will forwarded to confirmation page.</li> </ol>
Need help with this p	rocess? Click <mark>Here</mark> for more information	<ol> <li>6. Click âOKâ and you will then be sent back to database login page.</li> </ol>

Getting started

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Fill the required information for new user creation in the "New User Registration" page, click on "Register" button.

	Database of saf for paediatrics	ty and toxicity of excipients	United Duates Formulation
New User Regi	stration (Why Registration?)		
Use of the STEP dat	abase is subject to the STEP database Term	of Use and the disclaimer	
STEP DATABAS	E - DISCLAIMER & TERMS OF USE		
to resolve al	ny disputes arising under this End User Lice		
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<ul> <li>This End Use hereof, and that any var you in relati exercise any</li> <li>I've read the Disc</li> <li>First Name *</li> <li>Login Email*</li> <li>Contact Number</li> </ul>	A conditions of the second sec	e agreement between the pa irreements or understanding urchase order or other writte hereunder shall be of no ef irreement or upon any bread Last Name	s, whether oral or written. You agree en notification or document issued by ffect. The failure or delay of EuPFI to the of this End User License Agreement

After successful creation, below page appears containing user information.

	0	
	Database of safety and toxicity of excipients for paediatrics	United States Production Initiative
New user registered	a successionly	Registration details are also mailed to you)
Login Email :	mounika.dugyala@gvkbio.com	Registration details are also mailed to you)
Login Email : Password :	mounika.dugyala@gvkbio.com Mounika@123	Registration details are also mailed to you)
Login Email : Password : First Name :	mounika.dugyala@gvkbio.com Mounika@123 Mounika	Registration details are also mailed to you)
Login Email : Password : First Name : Last Name :	mounika.dugyala@gvkbio.com Mounika@123 Mounika Dugyala	Registration details are also mailed to you)
Login Email : Password : First Name : Last Name : Organization/Sector :	mounika.dugyala@gvkbio.com Mounika@123 Mounika Dugyala Professional Society	Registration details are also mailed to you)
Login Email : Password : First Name : Last Name :	mounika.dugyala@gvkbio.com Mounika@123 Mounika Dugyala	Registration details are also mailed to you)
Login Email : Password : First Name : Last Name : Organization/Sector : Country :	mounika.dugyala@gvkbio.com Mounika@123 Mounika Dugyala Professional Society India 9553114252	Registration details are also mailed to you)
Login Email : Password : First Name : Last Name : Organization/Sector : Country : Contact Number :	mounika.dugyala@gvkbio.com Mounika@123 Mounika Dugyala Professional Society India	

An email is sent to user containing registration details.

Close Reply Reply to All Forward Delete Spam					
Eupfi Registration Details					
From: donotreply@eupfi.com					
To: mounika dugyala					
Dear Mounika,					
You are successfully registered. Please find your login credentials below, Login Email : mounika.dugyala@gvkbio.com Password : Mounika@123					
Thank you, The STEP database Support Team					
Disclaimer: This is a system generated mail. Please do not reply to this email ID					

## 2.3 Existing User

When user tries to register with already registered email ID, then an error message displayed as show below.

Getting started

New User Registration (Why Registration?)         Use of the STEP database is subject to the STEP database Terms of Use and the disclaimer         STEP DATABASE - DISCLAIMER & TERMS OF USE         • This End User License Agreement shall be governed by the United Kingdom laws, without giving effect to principles of conflict of laws. You hereby consent to the exclusive jurisdiction and venue of the courts sitting in London, United Kingdom to resolve any disputes arising under this End User License Agreement.         • This End User License Agreement contains the complete agreement between the parties with respect to the subject matter hereof, and supersedes all prior or contemporaneous agreements or understandings, whether oral or written. You agree that any varying or additional terms contained in any purchase order or other written notification or document issued by you in relation to The ONLINE STEP DATABASE licensed hereunder shall be of no effect. The failure or delay of EUPF1 to exercise anv of its rights under this End User License Agreement or upon any breach of this End User License Agreement.         If I've read the Disclaimer and accept the Terms & Conditions         First Name *       Venkata         Last Name       Reddy         Login Email*       venkata.bodhanapu@gvkbio.com         Confirm Login Email*       venkata.bodhanapu@gvkbio.com         Organization/Sector       Professional Society       *         I'Register       * Indicates mandatory fle         Need help with this process? Click Here for more information       * Indicates mandatory fle			ety and toxicity of excipients	United States
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Login Email*       venkata.bodhanapu@gvkbio.com       Confirm Login Email*       venkata.bodhanapu@gvkbio.com         Contact Number       9966623713       Country*       India         Organization/Sector       Professional Society <ul> <li>Register</li> <li>Reset</li> <li>Need help with this process? Click Here for more information</li> </ul> <ul> <li>Need help with this process? Click Here for more information</li> </ul> <ul> <li>India</li> <li>India</li> <li>India</li> <li>India</li> <li>Indicates mandatory fie</li> </ul>	to resolve an This End Use hereof, and that any var	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p	ense Agreement. e agreement between the pa greements or understanding: purchase order or other writte	s, whether oral or written. You agree en notification or document issued by
Contact Number       9966623713       Country*       India         Organization/Sector       Professional Society <ul> <li>Register</li> <li>Reset</li> <li>* Indicates mandatory fie</li> </ul> Need help with this process? Click Here for more information	to resolve an This End Usi- hereof, and that any var you in relati- exercise any	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p on to The ONLINE STEP DATABASE license v of its rights under this End User License A	ense Agreement. e agreement between the pa greements or understandings urchase order or other writte d hereunder shall be of no eff	s, whether oral or written. You agree en notification or document issued by ffect. The failure or delay of EuPFI to
Organization/Sector Professional Society  Register Reset  Need help with this process? Click Here for more information	to resolve an This End Us, hereof, and that any var you in relati exercise any I've read the Disc First Name *	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p on to The ONLINE STEP DATABASE license of its rights under this End User License A claimer and accept the Terms & Conditions Venkata	ense Agreement. e agreement between the pa greements or understandings ourchase order or other writte d hereunder shall be of no eff areement or upon any breac Last Name	s, whether oral or written. You agree en notification or document issued by fect. The failure or delay of EuPFI to ch of this End User License Agreement Reddy
Register       Reset       * Indicates mandatory fie         Need help with this process? Click Here for more information	to resolve au • This End Us, hereof, and that any var you in relati exercise any ✓ I've read the Diso First Name * Login Email*	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p on to The ONLINE STEP DATABASE license of its rights under this End User License A claimer and accept the Terms & Conditions Venkata venkata.bodhanapu@gvkbio.com	ense Agreement. e agreement between the pa greements or understandings uurchase order or other writte d hereunder shall be of no eff areement or upon any breac Last Name Confirm Login Email*	s, whether oral or written. You agree en notification or document issued by fect. The failure or delay of EuPFI to the of this End User License Agreement Reddy venkata.bodhanapu@gvkbio.com
	to resolve ai This End Usi- hereof, and that any var you in relati- exercise any I've read the Diso First Name * Login Email* Contact Number	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p on to The ONLINE STEP DATABASE license of its rights under this End User License A claimer and accept the Terms & Conditions Venkata venkata.bodhanapu@gvkbio.com 9966623713	ense Agreement. e agreement between the pa greements or understandings uurchase order or other writte d hereunder shall be of no eff areement or upon any breac Last Name Confirm Login Email* Country*	s, whether oral or written. You agree en notification or document issued by fect. The failure or delay of EuPFI to the of this End User License Agreement Reddy venkata.bodhanapu@gvkbio.com
	to resolve au • This End Us, hereof, and that any var you in relati exercise any I've read the Disc First Name * Login Email* Contact Number Organization/Sector	er License Agreement contains the complet supersedes all prior or contemporaneous a rying or additional terms contained in any p on to The ONLINE STEP DATABASE license of its rights under this End User License A claimer and accept the Terms & Conditions Venkata venkata.bodhanapu@gvkbio.com 9966623713 Professional Society Register Reset	ense Agreement. e agreement between the pa greements or understandings uurchase order or other writte d hereunder shall be of no eff areement or upon any breac Last Name Confirm Login Email* Country*	s, whether oral or written. You agree en notification or document issued by fect. The failure or delay of EuPFI to the of this End User License Agreement Reddy venkata.bodhanapu@gvkbio.com

## 2.4 Forgot Password

User can retrieve the password using "Forgot Password" in the "Login" page by clicking on "Forgot Password" link as shown below

Existing Us	er Login ave an account, please login below	🔁 🛛 User Guide
n you alleauy na	we an account, please login below	
Login Email '		
Password *		
	Log In Forgot Password ?	
	(Your login session will expire after 30 minutes of inactivity)	
* Indicates man	datory field(s).	Need help? Click Here
New User -	Register User	

"Forgot Password" page appears as shown below.

Eu – US PFI User Guide		Version- 1.0
	Database of safety and toxicity of excipients for paediatrics	United States Pediatric Formulation Initiative
Forgot Password: • Please enter the Login Er • Your account information • If you can't remember you		* Indicates mandatory field(s). please contact us at <u>admin@eupfi.org</u>
Login Email:* Submit	Go Back to Login	
	<u>Contact</u> <u>Feedback</u> Disclaimer	

Enter the registered login email id and click on "Submit" button to get the password details as shown below.

	r the Login Email you registered with. It information will be emailed to you.
<ul> <li>If you can't</li> </ul>	remember your login email, please re-register or if you have any further problems please contact us at admin@eupfi.
Login Email:*	venkata.bodhanapu@gvkbio.com
	Submit Go Back to Login

Then a message appears indicating the password has been sent to your login email as shown below.

Eu – US PFI User	Guide Version- 1.0
<ul> <li>Your account</li> </ul>	1:       * Indicates mandatory field(s).         he Login Email you registered with.         information will be emailed to you.         emember your login email, please re-register or if you have any further problems please contact us at <u>admin@eupfi.org</u>
Login Email:*	venkata.bodhanapu@gvkbio.com Submit Go Back to Login
	Your password has been sent to your login email.

Use the received password to login into the STEP Database application.

### Example mail content:

Close Reply Reply to All Forward Delete Spam 📇 🕶 🖉 🕶 Actions 🔻
Eupfi Password Details
From: donotreply@eupfi.com
To: venkata bodhanapu
Dear bodhanapu,
Please find your login details below, Login Email : venkata.bodhanapu@gvkbio.com Password : venkat
Thank you, The STEP database Support Team
Disclaimer: This is a system generated mail. Please do not reply to this email ID

If entered email id in 'Login Email' field is not yet registered, then the application will display an error message like below.

<ul> <li>Your account</li> </ul>	the Login Email you registered with. information will be emailed to you. emember your login email, please re-register or if you have any furth <mark>i.org</mark>	er problems please contact us at
Login Email:*	mounika@gvkbio.com Submit Go Back to Login	
	Email Id not registered, Please try again.	]

### <u>Note</u>:

- If user enters incorrect Login Email and clicks "Submit" button then the application prompts the below message.
- If user clicks on 'Go back to Login' button, application will navigate to login page.

## 2.5 Regular User

STEP provides a new option for the regular user who ever are visited more than 10 times can provide Feedback on the application using feedback form

Whenever user logins into the application for 10th time then feedback appears. User is recommended to fill the feedback form with the relevant information and click "Submit" as shown below.



**Note:** Once if the user **Closes** this sub window/iframe, then it indicates that the user is entered feedback and this feedback form will be displays for the next 10<sup>th</sup> time.

And the application will navigates to Search BY Excipients page as shown below.

	Database of safety and toxicity of excipients for paediatrics	United States Printers
<mark>dhanapu venkata reddy —</mark> (Your login s	session will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
arch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate Select Accesufame K A(cohol Aspantame Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number ( eg 57-55-6), by synonym ( eg 1,2 propanediol) o by function ( eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propylene Glycol 1,2-Propylengkylol (German)	Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipien name box, try searching in synoymms. For Multiple Excipient/Function Selection: Please use "Ctt" or "Mouse click & drag" to select multiple search terms.0R please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate  Select 100-51-6  22639-47-8  22639-47-0  532-32-1	I con to open excipients list box for selection Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provid.
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients	

### Note:

- When user skips the "Feedback Form" and continues the work and logged out of the application and login to the application again then again this Feedback Form page will not appears.
- It is user responsibility (choice) to fill the Feedback Form this "Feedback Form" will appear for every 10<sup>th</sup> login.

## 2.6 Website links

In the STEP application user can access the related websites using the icons in the page throughout the application. When user clicks required logo then the corresponding website appears as shown below



## **3** Session expiration

If the user keeps the application idle/inactive for more than 30 minutes then the session automatically gets expired and displays the below message/page.

	Database of safety and toxicity of excipients for paediatrics	Used States Prices
Session expired due to 30 minutes inactivity. Please login a	gain.	
	Click <u>Here</u> to login.	
	<u>Contact Feedback</u> Disclaimer	GOSTAR G.BOM

To login to the application click "Here" link which automatically opens the application's login page.

Eu – US PFI User Guide		Version- 1.0
	Database of safety and toxicity of excipients for paediatrics	United States Polistoic Formulation Initiative
Existing User Login	gin below	Revision Date: 10/29/2012
	<u>our Password?</u> expire after 30 minutes of inactivity)	
* Indicates mandatory field(s). New User - <u>Register User</u>		Need help? Click <u>Here</u>
Developed by GVK BIO	Contact Feedback Disclaimer	GOSTAR GOBIOM

## 4 Logout

Click Logout link as shown below

EuPFi		STEP database Database of safety and toxicity of excipients for paediatrics			United States Revealed
🚨 bodhanapu venkata reddy	(Your login session will expire after 30 minutes of inactivity)		Search BY Excipients	Search FOR Excipients	User Guide   Help   Logout

Then the application logouts and navigates to the below page, If user desires to login to the application can click "Login" link as shown below

	Database of safety and toxicity of excipients for paediatrics	USER FARE
Logout		
	You're logged out Click here to " <u>Login</u> "	
Developed by GVK <sup>7</sup> BIO	Contact Feedback Disclaimer	GOSTAR GOBIOM
Logout		Page   20

Then the application's login page appears as shown below

EU OCHAN PARCIAICE PORTUGASONIN FAILIR BUIOCHAN PARCIAICE PORTUGASONIN FAILIR	Database of safety and toxicity of excipients for paediatrics	United States Podiatele Initiative
Existing User Log If you already have an a	zin ccount, please login below	Revision Date: 10/29/2012
Login Email * Password * Log (Your	In <u>Forqot your Password?</u> login session will expire after 30 minutes of inactivity)	
* Indicates mandatory fi New User - <u>Regis</u>		Need help? Click <u>Here</u>
Developed by GVR	Contact Feedback Disclaimer	

## 5 Search BY Excipients

Enter the valid user credentials in the "Login" page and click "Login" as shown below.

Eurocean Paesatre formulas	Database of safety and toxicity of excipients for paediatrics	United States Pediatric Formulation Initiative
Existing Use	r Login e an account, please login below	Revision Date: 10/29/2012
Login Email * Password *	venkata.bodhanapu@gvkbio.com  Log In Forgot your Password?	
* Indicates manda	(Your login session will expire after 30 minutes of inactivity)	Need help? Click Here
New User - I	<u>Contact</u> <u>Feedback</u> Disclaimer	GÖSTAR GOBION

Search BY Excipients

Then click "Login" button, application navigates user to "Search" page as shown below

	Database of safety and toxicity of excipients for paediatrics	United Otates Promote La Contraction Contr
hanapu venkata reddy (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
rch BY Excipients		
ch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate  Constrained to the select	Instructions on Search BY Excipients page: Three are several ways you can search for the excipients. You can search they excipient name strain the second second second second second straints of the second second second second second by function ( e.g. solver).
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymms. For Multiple Excipient/Function Selection: Please use "CH" or "Mouse click & drog" to select multiple search term.Obt please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate ** Select from drop down or enter minimum of 3 characters to populate 100-51-6 120-47-8 22839-47-0 532-32-1 *	"icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the essuits could take some time to load. Befine your search by using the filters provide
Function	Select from drop down or enter minimum of 3 characters to populate Select Select Antimicrobial green value Antimicrobial green value Disinfectant	on the results page or there is also a Saarch FOR excipients option where you can find the excipients by study type, age, or effects or excipients by study type, age, or effects or age or effect.
	Submit Reset Search FOR Excipients	

In the STEP application by default "Search BY Excipients" page appears wherein user is allowed to select the required data and view the results. Search page provides results based on "Excipient Name, CAS Registry Number, Synonyms and Function."

	Database of safety and toxicity of excipients for prediatrics		United States
hanapu venkata reddy (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients	Search FOR Excipients   User Guide   Help
and DV Evainiants			
arch BY Excipients			
ch BY Excipients			
Excipient Name	Select from drop down or enter minimum of 3 characters to populate		Instructions on Search BY Excipients page:
	Select A Acsulfame K Alcohol Aspartame Benzalkonium Chloride		There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg 57-55-6), by synonym (eg 1,2 propanediol) o by function (eg. solvent)
Synonyms as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate		Select from drop down or enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient
	Select A 1,2-Dihydroxypropane (E) 1,2-Propanediol 1,2-Propylene Glycol		name box , try searching in synonyms. For Multiple Excipient/Function Selection:
CAS Registry Number	1,2-Propylenglykol (German)		Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use " " icon to open excipients list box for selection
CAS Registry Number	Select 100-51-6		Progressive search will be based and filtered on the values already selected in dropdowns.
	120-47-8 22839-47-0 532-32-1		If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate		Refine your search by using the filters provide on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or
	Select      Antimicrobial agent     Antimicrobial preservative     Antiseptic     Disinfectant     T		excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients		

Search BY Excipients

## 5.1 Search BY Excipients

**Excipients** in medicines are ingredients other than the active drug that are essential for their manufacture, stability and function. Superlatively, an excipient is pharmacologically inactive, non-toxic, and does not interact with the active ingredients or other excipients. However, in practice few excipients meet these criteria.

### 5.1.1 Excipient Name

STEP endow with Excipient based search functionality for the end users to attain relevant results.

In the "Search BY Excipients" page user can select the required excipient name from the "Excipient Name" drop down as shown below.

Search BY Excipients		
Search BY Excipients		
Excipient Name	Aspartame	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylme glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoyrums. For Multiple Excipient/Function Selection: Please use "Ctt" or "Mouse click & drag" to select multiple search terms.OR please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	" icon to open excipients list box for selection. " icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

User can get the suggestions after entering minimum of 3 characters in Excipient Name text box. If the data is available then it will display like below,

	Database of safety and toxicity of excipients for paediatrics	Lined Bases
dhanapu venkata reddy (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
arch BY Excipients		
rch BY Excipients		
Excipient Name Synonyms (as per the Handbook of Excipients) CAS Registry Number	ben       +         Benzalkonium Chloride       E         Benzoi Acid       E         Select from drop down or enter minimum of 3 characters to populate       +        Select       I         12-Propylene Givcol       II         12-Propylene Givcol       III         120-17-8       III         122-12-12       III	Instructions on Search BY Excipients page: There are several ways you can search for th excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (e 57-55-6), by synonym (eg 1,2 propanedio) o by function (eg. solvent) Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipien name box, try searching in synonyms. For Multiple Excipient/Function Selection: Please use "Ctf" or "Mouse click & drag" to select multiple search terms.OR please use " " icon to open excipients list box for selection Progressive search will be hased and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provid
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant  Submit Reset Search FOR Excipients	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients		
Search BY Excipients		
Excipient Name	test Sorry No Matches,try searching by synonyms	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-0), by synonym, (eg. 1,2 propanetioi) or
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	by function (eg. solvent) Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box , try searching in synoynms.
CAS Registry Number	1,2-Propanediol 1,2-Propyleng (lycol 1,2-Propyleng (lycol 1,2-Propyleng (lycol 1,2-Propyleng (lycol 1,2-Propyleng (lycol 1,2-Propanediol 1,2-Propanediol 1,2-Propyleng (lycol 1,2-Propyleng (lycol 1,2	For Multiple Excipient/Function Selection: Please use "CHI" or "Mouse click & drag" to select multiple search terms.OR please use " + " icon to open excipients list box for selection.
	Select  100-51-5 ED 120-47-8 22839-47-0 532-32-1	Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial preservative A	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients	

Based on this user can go for the alternative to get the desired results.

### 5.1.1.1 Multiple Excipient selection

Use "CTRL" key from the keyboard to select the excipients from the drop down either continuously or randomly as shown below

EuPFi	Database of safety and toxicity of excipients for paediatrics	US Pfi
🚨 bodhanapu venkata reddy 🛛 (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Search BY Excipients Search BY Excipients		
Excipient Name	Acesulfame K  Aspartame  Benzalkonium Chloride  Select Acesulfame K Alcohol Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (e.g. propylene glycol), or by CAS Number (e.g. 57-55-0), by synonym (eg 1,2 propanediol) or by function (eg. solver).
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate 3-Amino-N-(alpha-Carboxyphenethyl)Succinamic Acid N-Methyl Est Alkyl Dimethyl Bezyl Ammonium Chloride Alkyl dimethyl (Phenylmethyl) Quaternary Ammonium Chlorides Alpha Aspartame	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymes. For Multiple Excipient/Function Selection: Please use "CH" or "Mouse click & drag" to select multiple search terms.0R please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate 22839-47-0 8001-54-5	"icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant	Refine your search by using the filters provided on the results page or three is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
Developed by	Submit Reset Search FOR Excipients	G <sup>©</sup> ST∕-R G∵BIOM

## 5.1.1.2 Excipient selection based on the category

In the basic search page user only has the privilege of selecting "Excipients" of one category at a time but there is an another option of selecting multiple category related excipients at a time using "+" symbol. When user clicks "+" symbol besides the "Excipient Name" text box then the below pop up window appears.

* Please enter minimum of three characters		
Acesulfame K Alcohol	s.	
Alconol Aspartame Benzalkonium Chloride Benzoic Acid		
	OK)	

Auto search is available in the pop-up window, when user specifies 3 or more characters in the excipient name then the relevant excipient names appears as shown below.

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES	
Excipient Name ber * Please enter minimum of three characters. Benzalkonium Chloride Benzyi Alcohol Benzyl Paraben Butylparaben OK	
	~

Then user is allowed to select the required excipients from the list and can click ">" button then the selected excipient name appears in the empty text box as shown below to

🧭 Select Multiple Excipients - Microsoft Intern	et Explorer provided by WK BIOSCIENCES	
Excipient Name ben * Please enter minimum of three characters. Benzoic Acid Benzylparaben	Benzalkonium Chloride Benzyl Alcohol	~
Ethylparaben Isobutylparaben Isopropylparaben	Butylparaben	
	OK	
		~

If user needs to select any other excipient from another category can again enter the excipient name then the relevant excipients list appears as shown below

Eu – US PFI User Guide		Version- 1.0
Excipient Name	nternet Explorer provided by GVK BIOSCIENCES	
* Please enter minimum of three charact Isopropylparaben Propylene Glycol Propylparaben	Senzalkonium Chloride Benzyl Alcohol Butylparaben	
	OK	~

Then user can select the required excipient from the list and click ">" button to add it then it appears along with the earlier selected excipient as shown below

🧭 Select Multiple Excipients - Microsoft Internet E	xplorer provided by GVK BIOSCIENCES	
Excipient Name	<ul> <li>Benzalkonium Chloride</li> <li>Benzyl Alcohol</li> <li>Butylparaben</li> <li>Propylene Glycol</li> <li>OK</li> </ul>	

Click "Ok" button then the selected search criteria appears in the "Search BY Excipients" page as shown below

Search BY Excipients						
ch BY Excipients						
Excipient Name Synonyms as per the Handbook of Excipients)	Benzalkonium Chloride  Benzyl Alcohol  Butylparaben  Propylene Glycc Benzalkonium Chloride Benzoic Acid Benzylparaben Butylparaben Butylparaben Select from drop down or enter minimum of 3 characters to populate 1,2-Propyleng (kol (Serman))	Instructions on Search BY Excipients page: There are several ways you can search for th excipients. You can search by excipient namu (eg. propylene glycol), or by CAS Number (e 57-55-6), by synonym (eg 1,2 propanediol) by function (eg. solvent) Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipien name box, try searching in synoymms. For Multiple Excipient/Function Selection:				
CAS Registry Number	2-Hydroxypropanol <ul> <li>Select from drop down or enter minimum of 3 characters to populate</li> <li>100-51-6</li> <li>57-55-6</li> <li>8001-54-5</li> </ul>	Please use "Cht" or "Mouse click & drag" to select multiple sarch terms.OR please use " "icon to open excipients list box for selectio Progressive search will be based and filtered on the values already selected in dropdowns If you've selected a large dataset the results could take some time to load.				
Function	Select from drop down or enter minimum of 3 characters to populate	Refine your search by using the filters provid on the results page or there is also a Search excipients by study type, age, or effects or restrict your search to particular study type, age or effect.				

User can select "CAS Registry Number and Synonyms" also along with the selected "Excipient Name" to retrieve the results as shown below

Search BY Excipients		
Search BY Excipients		
Excipient Name Synonyms (as per file Handbook of Excipients) CAS Registry Number	Benzalkonium Chloride  Benzyl Alcohol  Butylparaben  Propylene Glyct Benzol Acid Benzyl Aciolol Benzyl Aciolol Butylparaben Butylparaben Alkyl Dimethylbenzyl Ammonium Chloride  Alkyldimethyl (Phenylmethyl Alkyl Dimethylbenzyl Ammonium Chloride Alkyldimethyl Benzyl Ammonium Chloride Alkyldimethyl (Phenylmethyl) (Phenylmethyl Bool-54-5	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-53-63), by synonym (eg 1,2 propanediol) or by function (eg. solvent). Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box , try searching in synonyms. For Multiple Excipient/Function Selection: Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use " + " icon to open excipients list box for selection:
Cho negisiry namber	00154-5 57-55-6 8001-54-5	Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided
Function	Select from drop down or enter minimum of 3 characters to populate	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Then click "Submit" button to retrieve the search results considering the search criteria.

					_						0
	Å				-	f afety and toxicity of				United States	Pediatric Formulation Initiative
bodhanapu venka	<mark>ta reddy</mark> (Your logi	in session will expire	after 30 minutes of in	activity)			Search BY Exc	ipients   Search F	FOR Excipients   E	xport   User Guide	Help
Search Resul	ts <u>Back</u>					Total Reference	s: 15			R	lecord 1 d
										Excipient	Navigati
General Informatic	on al Name: Benzalkoni	ium Chloride									
CAS Registry Nur											
Excipient Catego	ory/Function :										
Pharmacopoeial											
Regulatory Statu	JS:										
Synonyms:											
= oynonyme.											
Acceptable Daily	y Intake:										
	y Intake:										
Acceptable Daily	y Intake: Non Clinical Data	(3) Invitro Data	(1) Regulatory a	and other informatior	1 (5) Reviews (3	i)			Different co	lors indicates Unique R	Referenc
Acceptable Daily     Revision Date:     Clinical Data (3)		(3) Invitro Data	(1) Regulatory a	and other informatior	1 (5) Reviews (3	•)		Clear All Filt	Different co		
Acceptable Daily     Revision Date:     Clinical Data (3)	Non Clinical Data	(3) Invitro Data Study Type	(1) Regulatory a	and other information	n (5) Reviews (3 Age Units	) Gender	Route of Exposure or Administration				cal Data
Acceptable Daily     Revision Date:     Clinical Data (3)     Show/Hide Clinical	Non Clinical Data						Route of Exposure or Administration		ers on Clinical Data	Export Filtered Clinic	cal Data It Dura
Acceptable Daily     Revision Date:     Clinical Data (3)     Show/Hide Clini     Ref ID	Non Clinical Data nical Columns 🏵 Excipient Name	Study Type	Age Category	Age	Age Units	Gender		Dose	ers on Clinical Data	Export Filtered Clinic	t Dura
Acceptable Daily Clinical Data (3) Show/Hide Clinical Data (1) Ref IDSelect	Non Clinical Data nical Columns ® Excipient Name Select v Benzalkonium	Study Type	Age Category	Age	Age Units	Gender	Select	Dose	Dose Units	Export Filtered Clinic Duration of Treatment	cal Data
Acceptable Daily Clinical Data (3) Clinical Data (3) Show/Hide Clin Ref IDSelect 121	Non Clinical Data nical Columns ® Excipient Name Select V Benzalkonium Chloride Benzalkonium	Study Type	Age Category Select v Adult	Age Select 34 (Mean age)	Age Units	Gender Select 💌 Male	Select V	Dose	vers on Clinical Data Dose Units Select V	Export Filtered Clinic Duration of Treatment Select	t Dura Sel
Acceptable Daily Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clin Ref IDSelect 121 171	Non Clinical Data ical Columns 🕫 Excipient Name Select V Benzalkonium Chloride Benzalkonium Chloride Benzalkonium	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Age Category Select V Adult Adult	Age Select 34 (Mean age) Unspecified	Age Units Select V Years Unspecified	Gender Select V Male	Select V Topical	Dose          Select         ▼           0.5; 1         0.5	ers on Clinical Data Dose Units Select V % aq % % % % % % % % % % % % %	Export Filtered Clinic Duration of Treatment Select v 48	t Dura Sel Hours
Acceptable Daily Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clin Ref IDSelect 121 171	Non Clinical Data ical Columns 🕫 Excipient Name Select V Benzalkonium Chloride Benzalkonium Chloride Benzalkonium	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Age Category Select V Adult Adult	Age Select 34 (Mean age) Unspecified	Age Units Select V Years Unspecified	Gender Select V Male	Select V Topical	Dose          Select         ▼           0.5; 1         0.5	ers on Clinical Data Dose Units Select V % aq % % % % % % % % % % % % %	Export Filtered Clinic Duration of Treatment Select v 48	t Dura .t Dura Se Hours
Acceptable Daily Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clin Ref IDSelect 121 171	Non Clinical Data ical Columns 🕫 Excipient Name Select V Benzalkonium Chloride Benzalkonium Chloride Benzalkonium	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Age CategorySelect Adult Adult Adult	Age Select 34 (Mean age) Unspecified	Age Units Select V Years Unspecified	Gender Select V Male	Select V Topical	Dose          Select         ▼           0.5; 1         0.5	ers on Clinical Data Dose Units Select V % aq % % % % % % % % % % % % %	Export Filtered Clinic Duration of Treatment Select v 48	t Dura Sel Hours

But here based on the selected "Excipient Name" the "CAS Registry Number and Synonyms" gets progressively filtered. User is allowed to select the combination of the "CAS Registry Number" and "Synonyms".

In search results count of the references appears as shown below.

E⊍₽F	Ă				S	TEP datak	@8€			us	pf
EU-SCHAR - SHOARCE STRUKS	A Male of				Database o for paediati	f safety and toxicity of rics				United States	Formulation
oodhanapu venka	<mark>ata reddy</mark> (Your log	jin session will expire	after 30 minutes of ina	activity)			Search BY Exc	cipients   Search F	OR Excipients   E	Export   User Guide	Help
Search Resul	ts Back					Total Reference	s: 15				Record 1
										Excipier	nt Naviga
Seneral Information Excipient Chemic CAS Registry Nur	al Name: Benzalkor	ium Chloride									
Excipient Catego											
<ul> <li>Pharmacopoeial</li> <li>Regulatory Statu</li> </ul>											
<ul> <li>Regulatory Statt</li> <li>Synonyms:</li> </ul>	us.										
Acceptable Daily	y Intake:										
E Revision Date:											
_		_									
Clinical Data (3)		(3) Invitro Data	(1) Regulatory a	nd other information	(5) Reviews (3	)			Different co	olors indicates Unique	Referen
Show/Hide Cli	nical Columns 🗉		(1) Regulatory a	nd other informatior	(5) Reviews (3	9			Different co	Export Filtered Clin	nical Data
			(1) Regulatory a	nd other information	(5) Reviews (3 Age Units	) Gender	Route of Exposure or Administration			-	nical Data
Show/Hide Cli	nical Columns II						Route of Exposure or Administration		ers on Clinical Data	Export Filtered Clin	nical Data
Show/Hide Cli	nical Columns II	Study Type	Age Category	Age	Age Units	Gender		Dose	ers on Clinical Data	Export Filtered Clin	nt Dur
Show/Hide Clin Ref ID	Excipient Name Select ✓ Benzalkonium	Study Type	Age Category	Age Select 💌	Age Units	Gender	Select	Dose	ers on Clinical Data Dose UnitsSelect	Export Filtered Clin Duration of Treatme	nt Dur Si Hour
Show/Hide Clin Ref ID Select v 121	Rical Columns ® Excipient Name Select V Benzalkonium Chloride Benzalkonium	Study Type Select  Other study type Other study type - Lab/Drug de	Age Category	Age Select V 34 (Mean age)	Age Units	Gender Select 💌 Male	Select V Topical	Dose	ers on Clinical Data Dose Units Select V	Export Filtered Clin       Duration of Treatme      Select       48	nt Dur
Show/Hide Clir Ref ID Select ¥ 121 171	nical Columns ® Excipient Name Select V Benzalkonium Chloride Benzalkonium Benzalkonium	Study Type Select- V Other study type - Lab/Drug de (More)	Age CategorySelect Adult Adult Adult	Age Select V 34 (Mean age) Unspecified	Age UnitsSelect Years Unspecified	GenderSelect Male Male	Select V Topical Topical	Dose Select V 0.5; 1 0.5	ers on Clinical Data Dose Units Select V % aq %	Export Filtered Clin       Duration of Treatme      Select-       48       48	nical Data nt Dur Se Hour
Show/Hide Clir Ref ID Select ¥ 121 171	nical Columns ® Excipient Name Select V Benzalkonium Chloride Benzalkonium Benzalkonium	Study Type Select- V Other study type - Lab/Drug de (More)	Age Category Select V Adult	Age Select V 34 (Mean age) Unspecified	Age UnitsSelect Years Unspecified	GenderSelect Male Male	Select V Topical Topical	Dose Select V 0.5; 1 0.5	ers on Clinical Data Dose Units Select V % aq %	Export Filtered Clin       Duration of Treatme      Select-       48       48	nical Data nt Dur Se Hour

### Note:

- Based on the selected "Excipient Name" remaining data in the "CAS Registry Number", "Synonyms" appears.
- When user selects "Excipient Name" and "CAS Registry Number" then based on both those values data in the "Synonyms" appears.
- The progressive filtering will populate the data by 'Contains' search, with that particular entered search string in the respective text fields.
- The above functionality is applicable when user selects any of the value among "Excipient Name, CAS Registry Number, Synonyms" based on that remaining data appears. If user selects any other value in addition to the initially selected one then considering both those values remaining data appears.

## 5.1.2 Synonyms

Synonyms includes other chemical names, trade names, common or general names, foreign language names (with the language in parentheses), or codes. Only the key synonyms would be displayed and for details it would be linked to other source

**Example**: The privilege of selecting the required synonyms using the Synonyms is also facilitated. When user selects synonyms using "Synonyms" then based on that selected synonyms remaining data in the "Excipient Name, CAS Registry Number" appears as shown below

#### Search BY Excipients page before selecting the Synonyms

EUPFi	Database of safety and toxicity of excipients for paediatrics	US Print
C bodhanapu venkata reddy (Your legin s Search BY Excipients Search BY Excipients	eession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (e.g. propylene glycol), or by CAS Number (e.g. 57-55-6), by synopym (eg 1,2 propanediol) or by function (e.g. solven)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propanedia 1,2-Propylete Glycol 1,2-Propylete glycol 1,2-Propylete glycol (German)  +	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in eynoymes. For Multiple Excipient/Function Selection: Please use "Cut" or "Mouse click & drag" to select multiple search terms.OR please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate  Select from drop down or enter minimum of 3 characters to populate  Solution of the select for the sele	"icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to lead. Refine your search by using the filters provided
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial agent Antisetic Disinfectant  Submit Reset Search FOR Excipients	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
Developed by GVK BIO	<u>Contact</u> <u>Feedback</u> Disclaimer	GOSTAR GOBIOM

#### Search BY Excipients page after selecting the Synonyms

User can get the suggestions after entering minimum of 3 characters in Synonyms text box. If the data is available then it will display like below,

rch BY Excipients		
ch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page:
Excipient Name		
	Acesulfame K	There are several ways you can search for the excipients. You can search by excipient name
	Alcohol Aspartame	(eg. propylene glycol), or by CAS Number ( eg 57-55-6), by synonym ( eg 1,2 propanediol) o
	Benzalkonium Chloride	by function ( eg. solvent)
Svnonvms		Select from drop down or enter enter minimu
(as per the Handbook of Excipients)	ben	of 3 characters to populate suggestions.
	Select	If you don't find the excipient in the excipien name box , try searching in synoynms.
	4 Hydroxybenzoic Acid Methyl Ester	For Multiple Excipient/Function Selection:
	4-Hydroxy- Methyl Ester Benzoic Acid	Please use "Ctrl" or "Mouse click & drag" to
	4-Hydroxy- Propyl Ester Benzoic Acid	select multiple search terms.OR please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	" icon to open excipients list box for selection
	Select 🔺	Progressive search will be based and filtered on the values already selected in dropdowns.
	100-51-6 (E) 120-47-8	
	22839-47-0	If you've selected a large dataset the results could take some time to load.
	532-32-1	Refine your search by using the filters provid
Function	Select from drop down or enter minimum of 3 characters to populate	on the results page or there is also a Search FOR excipients option where you can find the
	Select	excipients by study type, age, or effects or
	Antimicrobial agent	restrict your search to particular study type, age or effect.
	Antiseptic	
	Disinfectant	

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients		
Search BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg., propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg.1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	test Sorry No Matches,try searching by excipients name	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoynms. For Multiple Excipient/Function Selection:
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use " + " icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns.
Function	120-47-8 22839-47-0 532-32-1	If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the
	Select Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant  Submit Reset Search FOR Excipients	excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

Eu – US PFI User	Guide	Version- 1.0
Search BY Excipients		
Search BY Excipients		
Excipient Name Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate Propylene Glycol  1,2-Propanediol  1,2-Propylenglykol (German)  2-Hydroxypropanol 1,2-Propanediol 1,2-Propylenglykol (German) 1,2-Propanediol	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-53-63), by synonym (eg 1,2 propanadiol) or by function (eg. solvent) Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synonyms. For Multiple Excipient/Function Selection: Please use "Ch!" or "Mouse click & drag" to select multiple search terms. OR please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate 57-55-6	" icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided
Function	Select from drop down or enter minimum of 3 characters to populate	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the restrict your study type, and, or effects or restrict your search to particular study type, age or effect.

After selecting the entire required values click "Submit" button then the search results page appears as shown below.

eneral Informatio										Excipient Naviga
Excipient Chemica CAS Registry Nun	al Name: Propylene aber: 57-55-6	Glycol								
Excipient Catego	ry/Function :									
Pharmacopoeial	Status:									
Regulatory Statu	S:									
Synonyms:										
Acceptable Daily	Intake:									
Revision Date:										
Oliniaal Data (00)	Neg Oligiaal Dat	a (158) Invitro Data (95)	Desulations and	ather information (	EE) Deviewe (40			Diff	ferent colore indic	ates Unique Referer
			Regulatory and	outer information (c	(10) Reviews (10	/				
snow/Hide Clir	ical Columns 🗉					13	Clea	r All Filters on Clin	ical Data Export	Filtered Clinical Dat
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatm
Select	Select 💌	Select	Select	Select	Select	Select 💌	Select	Select	Select 💌	Select
2	Propylene Glycol	Unspecified	Adult	18 to 83	Years	Male/Female	Parenteral	128 (cumulative)	g	36
	Propylene Glycol	Unspecified	Paediatric age group and adult	6 to 66	Years	Male/Female	Topical	20	%	1
10			(More)							
<u>10</u> 15	Propylene Glycol	Case study	Adult	49	Years	Male	Unspecified	Unspecified	Unspecified	Unspecified
	Propylene Glycol Propylene Glycol			49 Unspecified	Years Unspecified	Male Unspecified	Unspecified Topical	Unspecified	Unspecified	Unspecified
<u>15</u>			Adult Unspecified							

## 5.1.3 CAS Registry Number

CAS Registry Number is a numeric designation assigned by the "Chemical Abstracts Service" of the American Chemical Society that uniquely identifies a specific chemical compound, regardless of the name or nomenclature system used.

#### Example:

57-55-6 for propylene glycol) only a single excipient may be associated with a single CAS registry number

The privilege of selecting the required CAS numbers using the CAS Registry number is also facilitated. When user selects CAS registry number using "CAS Registry Number" then based on that selected CAS Registry Number remaining data in the "Excipient Name, Synonyms" appears as shown below

### Search BY Excipients before selecting the CAS Registry Number

	Database of safety and toxicity of excipients for paediatrics	Search BY Excipients   Search FOR Excipients   User Guide   Help
earch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate + Select Accesulfame K Accohol Appartame Benzalkonium Chloride +	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propythem eglycal), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propylene Glycol 1,2-Propyleng kylol (German)	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoynms. For Multiple Excipient/Function Selection: Please use "Cth" or "Mouse click & drag" to select multiple search terms.08 please use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate  Select 100-51-6  22839-47-0 532-32-1	" icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial agent Antimicrobial preservative Antiseptic Disinfectant  Submit Reset Search FOR Excipients	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
Developed by GVK BIO	Submit Reset Search FOR Excipients	GSTAR GB

### Search BY Excipients after selecting the CAS Registry Number

User can get the suggestions after entering minimum of 3 characters in CAS Registry Number text box. If the data is available then it will display like below,

rch BY Excipients		
CO BY Excipients		
h BY Excipients		
xcipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page:
	Select Acesulfame K (#) Alcohol (#) Aspartame Berzalkonium Chloride *	There are several ways you can search for th excipients. You can search by excipient name (eg. propylene slycol), or by CAS Number (e 37-53-6), by synonym (eg 1,2 propanedio)) by function (eg. solvent)
Bynonyms as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter minimu of 3 characters to populate suggestions.
	Select * 1,2-Dihydroxypropane 1,2-Propanediol	If you don't find the excipient in the excipien name box , try searching in synoynms. For Multiple Excipient/Function Selection:
	1,2-Propylene Glycol 1,2-Propylenglykol (German)	Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use " " icon to open excipients list box for selectio
AS Registry Number	900 ** Select	Progressive search will be based and filtered on the values already selected in dropdowns.
	9005-64-5 9005-65-6 9005-66-7 *	If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate	Refine your search by using the filters provid on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or
	Antimicrobial agent (E) Antimicrobial preservative Antiseptic Disinfectant *	restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients		
Search BY Excipients		
Excipient Name Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate Select Accsulfame K Alcohol Aspartame Berzalkonium Chloride Select from drop down or enter minimum of 3 characters to populate Select 1,2-Poparediol 1,2-Poparediol	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 37-53-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent) Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synonyms. For Multiple Excipient / Function Selection:
CAS Registry Number	1.2-Propylene Glycol 1.2-Propylenglykol (German)	Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use " + "icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to pairoular study type,
	Antimicrobial preservative Antiseptic Disinfectant • Submit Reset Search FOR Excipients	age or effect.

Based on this user can go for the alternative to get the desired results.

Search BY Excipients		
Search BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate <b>+ Ethylparaben</b>	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-95-9), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  4-Hydroxy- Ethyl Ester Benzoic Acid 4-Hydroxybenzoic Acid, Ethyl Ester 4-Hydroxybenzoic Acid, Ethyl Ester, Sodium Salt Ben Benzoic Acid, 4-Hydroxy-, Ethyl Ester	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymus. For Multiple Excipient/Function Selection: Please use "Cth" or "Mouse click & drag" to
CAS Registry Number	120-47-8     Image: Control of the second seco	select multiple search terms.OR please use " + " icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate Select Antimicrobial agent Antimicrobial agent E Disinfectant	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients	

Click "Submit" then the search results appears as shown below.

eneral Informatior										Excipient I	lavigat
	I Name: Ethylparab										
AS Registry Num											
Excipient Categor	ry/Function :										
Pharmacopoeial §	Status:										
Regulatory Status	s:										
Synonyms:											
Acceptable Daily	Intake:										
Revision Date:											
Clinical Data (4)	Non Clinical Data	(14) Invitro Data	(13) Regulator	y and other informat	ion (0) Reviews	(0)			Different co	lors indicates Unique R	aferend
	ical Columns 🗉							Clear All Filt	ers on Clinical Data	Export Filtered Clinica	al Data
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Dur
Select 🔽	Select 💌	Select 💌	Select 💌	Select 💌	Select 💌	Select 💌	Select	Select 🔽	Select 💌	Select	Se
<u>14</u>	Ethylparaben	Case study	Adult	67	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	47	Years	Female	Topical	5; 1; 0.1	%	Unspecified	Unsp
14	Ethylparaben	Case study	Adult	56	Years	Male	Topical	5; 1; 0.1	%	Unspecified	Unsp
											•

## 5.1.4 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

Search BY Excipients before selecting the Function
	Database of safety and toxicity of excipients for paediatrics	Listed Gates Printed
dhanapu venkata reddy (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
arch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populateSelect Accesufame K Alcohol Acpantame Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search to the xcipient name (eg. propylene glycol), or by CAS Number ( eg 57-55-6), by synonym ( eg 1,2 propanediol) o by function ( eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propylene Giy(col 1,2-Propyleng/kxd (German)	Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymms. For Multiple Excipient / function Selection: Please use "Cth" or "Mouse click & drag" to select multiple search terms,0R please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populateSelect 100-51-6 120-47-8 22839-47-0 532-32-1	"icon to open excipients list box for selection Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provid.
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial agent Antipetic Bisinfectant  Submit Reset Search FOR Excipients	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

#### Search BY Excipients after selecting the Function

User can get the suggestions after entering minimum of 3 characters in Function text box. If the data is available then it will display like below,

rch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene slycol), or by CAS Number (eg 57-53-6), by synonym (eg 1,2 propanedio) o by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propylene Glycol 1,2-Propylenglykol (German)  +	Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymms. For Multiple Excipient/Function Selection: Please use "Cth" or "Mouse click & drog" to select multiple search terms.OR please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate  Select 100-51-5 100-51-5 22839-47-0 532-32-1	" icon to open excipients list box for selection Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provide
Function	ant +) Select Antimicrobial preservative Antineptic Disinfectant +	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Among the available data user can select and then clicks on Submit button to get the Search Results page.

If data is not available for the given 3 characters then it will display the message like below.

Search BY Excipients		
Search BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate  Select 1,2-Dihydroxypropane 1,2-Propyleng divol 1,2-Propyleng kykol (German)  *	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoynms. For Multiple Excipient/Function Selection: Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR elease use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate  Select 100-51-6 120-47-8 22839-47-0 532-32-1	* icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provided
Function	Itest Sorry No Matches	Remie your search by Using the inters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Based on this user can go for the alternative to get the desired results.

Search BY Excipients		
Search BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate  Select Accesulfame K Alcohol Aspartame Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propythene glycol), or by CAS Number (eg. 57-55-6), by synonym (eg 1,2 propanediol) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoyams. For Multiple Excipient/Function Selection: Please use "Ctfl" or "Mouse click & drag" to
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	select multiple search terms.OR please use " + " icon to open excipients list box for selection. Progressive search will be based and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Antiseptic  Disinfectant	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

Click "Submit" then the search results appears as shown below.

Search Resul	S Back							Total Reference	es: 21						Record 1
														Excipier	nt Naviga
General Informatio	n														
Excipient Chemic	al Name: Ethylparab	en													
CAS Registry Nur	nber: 120-47-8														
Excipient Catego	vrv/Function :														
Pharmacopoeial															
Regulatory Statu															
Synonyms:															
	Intake:														
Acceptable Daily	Intake:														
Acceptable Daily     Revision Date:															
<ul> <li>Acceptable Daily</li> <li>Revision Date:</li> </ul>	Intake: Non Clinical Data	(14) Invitro	Data (13) Re	gulatory	/ and other infi	ormation (	)) Review	/s (0)				Differe	nt colors indic	ates Unique	Referen
Acceptable Daily     Revision Date:     Clinical Data (4)		(14) Invitro	Data (13) Reg	gulatory	/ and other infi	formation (	)) Review	rs (0)			Clear All	Differe Filters on Clinical		ates Unique t Filtered Clin	
Acceptable Daily     Revision Date:     Clinical Data (4)	Non Clinical Data	(14) Invitro Study Type			y and other inf		)) Review Age Units	rs (0) Gender	Route of Expo	osure or Administration			Data Export	-	nical Data
-	Non Clinical Data	Study Type		gory				Gender	Route of Expo	_	Dose	Filters on Clinical	Data Export	t Filtered Clin	nical Data
Acceptable Daily     Acceptable Daily     Revision Date:     Clinical Data (4)     Show/Hide Clin     Ref ID	Non Clinical Data nical Columns ® Excipient Name	Study Type	Age Cate	gory	Age		Age Units	Gender	_	_	Dose	Filters on Clinical Dose Unit	Data Export	t Filtered Clin	nical Data ent Dur
Acceptable Daily     Acceptable Daily     Revision Date:     Clinical Data (4)     Show/Hide Clin     Ref ID    Select     V	Non Clinical Data nical Columns ® Excipient Name	Study Type	Age Cate	gory	Age		Age Units Select 🗸 🗸	Gender	_	_	Dose	Filters on Clinical Dose Unit	Data Export	t Filtered Clin n of Treatme t	nical Data ent Dur
Acceptable Daily     Acceptable Daily     Revision Date:     Clinical Data (4)     Show/Hide Clin     Ref ID    Select     V	Non Clinical Data nical Columns @ Excipient Name Select	Study Type	Age Cate	gory	Age Select		Age Units Select 🗸 🗸	Gender	Select	_	Dose	Filters on Clinical Dose Unit	Data Export	t Filtered Clin n of Treatme t	ent Dur
Acceptable Daily     Acceptable Daily     Revision Date:     Clinical Data (4)     Show/Hide Clin     Ref ID    Select     V	Non Clinical Data nical Columns @ Excipient Name Select	Study Type	Age Cate	gory	Age Select		Age Units Select 🗸 🗸	Gender	Select	_	Dose	Filters on Clinical Dose Unit	Data Export	t Filtered Clin n of Treatme t	ent Dur
Acceptable Daily     Acceptable Daily	Non Clinical Data nical Columns @ Excipient Name Select	Study Type	Age Cate	gory	Age Select		Age Units Select ♥	Gender	Select	_	Dose	Filters on Clinical Dose Unit	Data Export	t Filtered Clin n of Treatme t v	nical Data ent Dur Si Unsp
Acceptable Daily     Revision Date:     Clinical Data (4)     Show/Hide Clin     Ref ID    Select ♥	Non Clinical Data nical Columns @ Excipient Name Select V Ethylparaben	Study Type Select Case study	Age Cate	gory	Age Select 67	Yez	Age Units Select ♥	Gender	Select Topical	_	Dose Select 5; 1; 0.1	Filters on Clinical Dose Unit Select %	Data Export s Duration •Select Unspecif	t Filtered Clin n of Treatme t v	ent Dur
Clinical Data Ref ID  Show/Hide Clin Ref ID  -Select  14	Non Clinical Data nical Columns @ Excipient Name Select V Ethylparaben	Study Type Select Case study	Age Cate	gory	Age Select 67	Yez	Age Units Select ♥	Gender	Select Topical	_	Dose Select 5; 1; 0.1	Filters on Clinical Dose Unit Select %	Data Export s Duration •Select Unspecif	t Filtered Clin n of Treatme t v	nical Data ent Dur Se Unsp

Note: Progressive filtering functionality is available for Excipient Name, CAS Registry Number and Synonyms fields. And Function field is an individual field.

# 6 Search FOR Excipients

Search FOR Excipients supports user in selecting the search criteria in an easy manner. User can access the Search FOR Excipients using "Search FOR Excipients" link in the main menu bar or from the "Search FOR Excipients" link in the "Search BY Excipients" page at the bottom as shown below.

hanapu venkata reddy (Your login :	session will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
arch BY Excipients		
ch BY Excipients		
Excipient Name	Select from drop down or enter minimum of 3 characters to populate	Instructions on Search BY Excipients page:
	Select	There are several ways you can search for the excipients. You can search by excipient name (e.g. propylene glycol), or by CAS Number (e 57-55-6), by symowrm (eg 1,2 propanedio) by function (e.g. solven)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate	Select from drop down or enter enter minimu of 3 characters to populate suggestions.
	Select A 1,2-Dihydroxypropane (I) 1,2-Propanediol	If you don't find the excipient in the excipient name box, try searching in synoyms.
	1,2-Propylene Glycol 1,2-Propylenglykol (German)	For Multiple Excipient/Function Selection: Please use "Ctrl" or "Mouse click & drag" to select multiple search terms.OR please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate	" icon to open excipients list box for selection Progressive search will be based and filtered
	100-51-6 (E) 120-47-8 (E)	on the values already selected in dropdowns. If you've selected a large dataset the results
	22839-47-0 532-32-1	could take some time to load. Refine your search by using the filters provid
Function	Select from drop down or enter minimum of 3 characters to populate	on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type,
	Antimicrobial preservative Antiseptic Disinfectant	age or effect.
	Submit Reset Search FOR Excipients	

Search FOR Excipients

Click "Search FOR Excipients" link either from main menu bar or from the "Search BY Excipients" page "Search FOR Excipients" page appears as shown below.

C Dodtanapu verkata reddy (Your login s	Database of safety and toxicity of excipients for paediatrics	Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Search FOR Excipients Clinical Data Non Clinical Data Search For Excipients		
Study Type	Select     A block randomization procedure     A single-blind crossover     ADME/bharmacoknetics studies     Blocked parallel randomised trial	
Age Category	Select Adolescents (12 to 16-18 years) Adult Children (2 to 11 years) Infants and toddlers (28 days to 23 months)	
Route of Exposure / Administration	Select A Inhalation E Nasal Oral Parenteral •	
Function	Select Antimicrobial agent (E) Antimicrobial preservative Antiseptic Disinfectant •	
Effect by Organ / System	Select Appette 前 Cardiovascular System Digestive System Endocrine System	
	Submit Reset Search BY Excipients	
Developed by GVK BIO	<u>Contact</u> <u>Feedback</u> Disclaimer	G BIOM

Search FOR Excipients facilitates user to select the search criteria based on the below aspects

- ✓ Clinical Data
- ✓ Non- Clinical Data

### 6.1 Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Clinical Data. This provides complete optional environment depending on the "Clinical Data" attributes.

Clinical Data attributes listed in the STEP database under "Search FOR Excipients" are

- 1. Search FOR Excipients
  - ✓ Study Type
  - ✓ Age Category
  - ✓ Route of Exposure / Administration
  - ✓ Function
  - ✓ Effect by Organ / System

#### 6.1.1 Search FOR Excipients

Search FOR Excipients includes all the data related to the excipient related to the Study Type, Age Category, Route of Exposure/Administration and Function. Based on the data selected under the above categories then relevant Excipients and its related data appears in the search results.

#### 6.1.1.1 Study Type

"Study Type" provides the nature of investigations like randomized controlled, cohort, case studies etc. Depending on the Study Type selected the results page data appears.

Search FOR Excipients		
Clinical Data Non Clinical Data		
Search For Excipients		
Study Type	Select     A block randomization procedure     A single-bind crossover     ADMP(Pharmacokinetics studies     Blocked parallel randomised trial     v	
Age Category	Select Adolescents (12 to 16-18 years) Adult Children (2 to 11 years) Infants and toddlers (28 days to 23 months) •	
Route of Exposure / Administration	Select ^ Inhalation III Nasal Oral Parenteral *	
Function	Select Antimicrobial agent (E) Antimicrobial preservative Antiseptic Disinfectant +	
Effect by Organ / System	Select Appetite (E) Cardiovascular System (E) Digestive System tendocrine System v	
	Submit Reset Search BY Excipients	

#### 6.1.1.2 Age Category

"Age Category" indicates is classified as per ICH classification (CPMP/ICH/2711/99). Based on the age category the relevant group name in indicated here a few group names are

- ✓ Adolescents (12 to 16-18 years; dependent on the region)
- ✓ Adults
- ✓ Children (2 to 11 years)
- ✓ Infants
- ✓ Pre-school Children
- ✓ School Children
- ✓ Unspecified

All the above appears in the "Age Category" drop down based on the selected "Age Category" corresponding excipients and the data appears in the search results page.

Search FOR Excipients		
Clinical Data Non Clinical Data		
Search For Excipients		
Study Type	Select A A block randomization procedure EII A single-bind crossover ADME/Pharmacokinetics studies Blocked parallel randomised trial	
Age Category	Select Adolescents (12 to 16-18 years) Adult Children (2 to 11 years) Infrants and toddlers (28 days to 23 months) *	
Route of Exposure / Administration	Select A A A A A A A A A A A A A A A A A A	
Function	Select Antimicrobial agent Ell Antimicrobial preservative Antiseptic Disinfectant V	
Effect by Organ / System	Select A Appetite El Cardiovascular System Digestive System Endocrine System *	
	Submit Reset Search BY Excipients	

#### 6.1.1.3 Route of Exposure / Administration

"Route of Exposure/ Administration" indicates the part of the body through or into which, or the way in which, the excipient is introduced.

**Example:** Cutaneous, IV, Oral, Inhalation, Dermal, Implantation, Parenteral, Topical, Ocular, rectal, Intranasal.

Considering the selected Route of Exposure/Administration values the search results appears.

Search FOR Excipients	
Clinical Data Non Clinical Dat	
Search For Excipients	
Study Type	Select A block randomization procedure A single-bind crossover ADME/Pharmacokinetics studies Blocked parallel randomised trial
Age Category	Select Adolescents (12 to 16-18 years)
Route of Exposure / Administration	Select     Inhalation       Inhalation     Image: Comparison of the select of t
Function	Select Antimicrobial greervative Antimetrobial preservative Antiseptic Disinfectant
Effect by Organ / System	Select Appetite Cardiovascular System Digestive System Endocrine System
	Submit Reset Search BY Excipients

#### 6.1.1.4 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

– US PFI User	Guide	Version- 1.0
earch FOR Excipients		
Clinical Data Non Clinical Data		
Search For Excipients		
Study Type	Select A block randomization procedure EII A single-blind crossover ADME/Pharmacokinetics studies Blocked parallel randomised trial	
Age Category	Select Adolescents (12 to 16-18 years) E Adult Children (2 to 11 years) Infants and toddlers (28 days to 23 months) V	
Route of Exposure / Administration	Select A Inhalation Inhalatii Inhalation Inhalation Inhalation Inhalation Inhalati	
Function	Select Antimicrobial agent El Antimicrobial preservative Antiseptic Disinfectant v	
Effect by Organ / System	Select Appetite El Cardiovascular System El Digestive System Endocrine System *	
	Submit Reset Search BY Excipients	

### 6.1.1.5 Effect by Organ / System

Indicates on which organ or system the effects are observed

Search FOR Excipients	
Clinical Data Non Clinical Data	
Search For Excipients	
Study Type	Select A block randomization procedure (E) A single-blind crossover ADME/Pharmacokinetics studies Blocked parallel randomised trial
Age Category	- Select Adolescents (12 to 16-18 years) E Addite (2 to 11 years) E Infants and toddlers (28 days to 23 months) T
Route of Exposure / Administration	Select A A A A A A A A A A A A A A A A A A
Function	Select Antimicrobial agent Antimicrobial preservative Antimicrobial preservative Disinfectant
Effect by Organ / System	Select
	Submit Reset Search BY Excipients

Based on the selected data the search results appears

# 6.2 Non-Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Non-Clinical Data. This provides complete optional environment depending on the "Non-Clinical Data" attributes.

Below are the Non-Clinical Data attributes

- Search by Excipients
  - Study Type
  - Species
  - Age Category
  - Route of Exposure/Administration
  - Function
  - Organ/System

## 6.2.1 Search FOR Excipient

Search FOR Excipients includes all the data related to the excipient related to the Study Type, Species, Age Category, Route of Exposure/Administration and Organ/System. Based on the data selected under the above categories then relevant Excipients and its related data appears in the search results.

## 6.2.1.1 Study Type

Study Type helps in providing the nature of investigations like Acute Toxicity, Experimental Animal Study, Eye Irritation, Ocular Toxicity etc;

Εı	u – US PFI User	Guide	Version- 1.0
	Search FOR Excipients Clinical Data Search For Excipients		
	Study Type	Select ADME/Pharmacokinetics/Toxicokinetics Adulte toxicity (0-14days) Carcinogenicity Developmental toxicity / teratogenicity	
	Species	- Select A Cat E Catte Chicken Chicken Chinchilla	
	Age Category	- Select Adult and Juvenile Juvenile Juvenile and Adult	
	Route of Exposure / Administration	- Select Implantation E Inhalation Nasal Opthalmic •	

#### 6.2.1.2 Species

Species indicates the animal species used in the experiment.

Example: rabbit, rat, sheep, cat, cattle, dog, gerbil, guinea pig, hamster, monkey, mouse, pig and other

E	Search FOR Excipients		
	Clinical Data Non Clinical Data		
	Search For Excipients		
	Study Type	Select ADME/pharmacokinetics/Toxicokinetics (E) Acute toxicity (0-14days) Carcinogenicity Developmental toxicity / teratogenicity (Carcinogenicity)	
	Species	Catte Chicken Chinchilla	
	Age Category	Select Adult Adult Select Adult Select Adult Select	
	Route of Exposure / Administration	Select A Implantation I Inhalation Nasal Opthalmie *	

### 6.2.1.3 Age Category

Age Category" indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated here a few group names are **Example**: Adults, Juvenile etc;

ı – US PFI 🛛 User Gui	de	Version- 1.0
Search FOR Excipients		
Clinical Data Non Clinical Data		
Search For Excipients		
Study Type	Select ADME/Pharmacokinetics/Toxicokinetics (E) Acute toxicity (0-14days) Carcinogenicity Developmental toxicity / teratogenicity	
Species	Select (E) Cat Catte Catte Chicken Chicken	
Age Category	Adult Adult and Juvenile Juvenile Juvenile Adult	
Route of Exposure / Administration	Select A Implantation Inhalation Inhalation Inhalation Inhalation Inhalation Inhalation Implantation Im	
Function	Select Antimicrobial agent (E) Antimicrobial preservative Antiseptic Disinfectant T	
Organ / System	Select Analgesia (E) Cardiovascular System Cellular Digestive System *	

### 6.2.1.4 Route of Exposure / Administration

Route of Exposure/Administration indicates the part of the body through or into which, or the way in which, the excipient is introduced.

Example: Oral, Inhalation, Dermal, Implantation, Parenteral, Topical, Ocular, rectal other.

5	Search FOR Excipients		
	Clinical Data Non Clinical Data		
	Search For Excipients		
	Study Type	Select ADME/Pharmacokinetics/Toxicokinetics Ell Acute toxicity (0-14days) Carcinogenicity Used to the second	
	Species	- Select → Cat Cat Catte Chicken Chinchilla v	
	Age Category	Select Adult # Adult and Juvenile # Juvenile Juvenile #	
	Route of Exposure / Administration	Select Implantion Inhalation Resal Opthalmic v	
	Function	Select A Antmicrobial agent Ell Antmicrobial preservative Antiseptic Disinfectant T	
	Organ / System	Select Analgesia EI Cardiovascular System Cellular Digestive System +	

#### 6.2.1.5 Function

Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It

facilitates user to access the data based on the function values as shown below

Search FOR Excipients	
Clinical Data Non Clinical Data	
Search For Excipients	
Study Type	Select ADME/Pharmacokinetics/Toxicokinetics ADME/Volative/Uo-14days) Carcinogenicity Developmental toxicity / teratogenicity
Species	Select A Cat (E) Cattle Chicken Chinchilla
Age Category	Select Adult Adult E Adult and Juvenile Juvenile and Adult V
Route of Exposure / Administration	Select Implantation E Implantation E Inhalation Nasal Opthalmic
Function	Select Antimicrobial agent     Antimicrobial preservative     Antimicrobial preservative     Antiseptic     Disinfectant
Organ / System	Select Analgesia Cardioascular System Calular Digestive System +
	Submit Reset Search BY Excipients

### 6.2.1.6 Organ/System

Effect is any undesired action or effect of an Excipient. User can view the search results based on

the effect. Indicates on which organ or system the effects are observed

**Example**: Kidney, Brian, Cellular System, Renal, Liver, Cardiovascular etc.

– US PFI User (	Guide	Version- 1.0
earch FOR Excipients		
Clinical Data Non Clinical Data		
earch For Excipients		
Study Type	Select ADNE/Pharmacokinetics/Toxicokinetics Acute toxicity (0-14days) Carcinogenicity Developmental toxicity / teratogenicity	
Species	Select  Cat Cat Cat Cat Chicken Chinchilla	
Age Category	Select A Adult Adult and Juvenile Juvenile Juvenile and Adult *	
Route of Exposure / Administration	Select A Implantation E Inhalation E Opthalmic •	
Function	Select Antimicrobial agent [E] Antimicrobial preservative Antiseptic [E] Disinfectant *	
Organ / System	Select Analgesia El Cardiovascular System Cellular Digestive System	
	Submit Reset Search BY Excipients	

When user provides any search criteria in the "Non-Clinical Data" page and clicks "Submit" button as shown below

	Database of safety and toxicity of excipients for paediatrics	US PARA
odhanapu venkata reddy (Your login s	ession will expire after 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients   User Guide   Help
earch FOR Excipients		
Clinical Data Non Clinical Data earch For Excipients		
Study Type	Select     ADME/Pharmacokinetics     Advecte toxicity (0-1/4days)     Carcinogenicity     Developmental toxicity / teratogenicity	
Species	Select Cat III Cat III Catile Chicken Chinchilla	
Age Category	Select Adult Adult and Juvenile Juvenile Juvenile Adult	
Route of Exposure / Administration	Select A Implantation Implantation Implantation Implantation Implantation Implantation Nasal Opthalmic *	
Function	Select Antimicrobial agent III Antimicrobial preservative Antiseptic Disinfectant *	
Organ / System	Select Analgesia El Cardiovascular System Cellular Digestive System *	
	Submit Reset Search BY Excipients	

Then "Search Results" page appears with the corresponding results. But if there are more than one excipient exists for the given search criteria then the below page appears

Excipient(s) Intermedia	e Page <u>Back</u>			
Number of Excipient	s found: 2			
II All				
Aspartame Propylene Glycol				
Submit				

Then the "Search Results" page appears considering the selected excipient as shown below.

	interactive					database	ts			United States Polatic Initiation
bodhanapu venka	<mark>ita reddy</mark> (Your log	in session will expire after 30	minutes of inactivity)				Search BY Excipients	Search FOR Exc	cipients   Export	User Guide   Help
Search Resul	ts <u>Back</u>				Total	References: 316				Record 2
<mark>General Information</mark> Excipient Chemic CAS Registry Nur	al Name: Propylene	Glycol						3	2 Go 4 First	Excipient Naviga
Excipient Categ     Pharmacopoeia     Regulatory State     Synonyms:	Status:									
Acceptable Dail:     Revision Date:	y Intake:									
Acceptable Dail     Revision Date:     Clinical Data (98)	Non Clinical Dat	a (158) Invitro Data (9:	5) Regulatory and	other information (	55) Reviews (16	)				ficates Unique Referen
Acceptable Dail     Revision Date:     Clinical Data (98)		a (158) Invitro Data (9) Study Type Select V	5) Regulatory and Age Category Select V	other information ( Age Select v	55) Reviews (16 Age Units Select V	) Gender Select V	Route of Exposure or Administration	Clear All Filters on (		dicates Unique Referen ort Filtered Clinical Data Duration of Treatmen Select V
Acceptable Dail     Acceptable Dail     Revision Date:     Clinical Data (98)     Show/Hide Cli     Ref ID	Non Clinical Dat nical Columns 🗷 Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Clear All Filters on C Dose	Clinical Data Expo	ort Filtered Clinical Data
Acceptable Dail Acceptable Dail Revision Date: Clinical Data (98) Show/Hide Cli Ref IDSelect	Non Clinical Dat nical Columns ® Excipient Name Select	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Clear All Filters on C Dose Select	Clinical Data Exp Dose Units Select	ort Filtered Clinical Data
Acceptable Dail     Revision Date:     Clinical Data (98)     Show/Hide Cli     Ref ID    Select     Y  1015	Non Clinical Dat nical Columns ® Excipient Name Select v Propylene Glycol	Study Type Select  Unspecified Cohort (Incidence,	Age Category Select	Age Select V 18 to 61	Age Units Select 💙 Years	Gender Select 💙 Male	Route of Exposure or Administration	Clear All Filters on C Dose Select ¥ 100 (15)	Clinical Data Expo Dose Units Select V % (µl/Finn Chamber)	ort Filtered Clinical Data Duration of Treatmen Select v 48
Acceptable Dail     Acceptable Dail     Acceptable Dail     Revision Date:     Clinical Data (98)     Show/Hide Cli     Ref ID    Select     Y  1015 186	Non Clinical Dat Trical Columns ® Excipient Name Select- Propylene Glycol Propylene Glycol	Study TypeSelect Unspecified Cohort (Incidence, Longitudina(Hore) Cohort (Incidence,	Age Category Select  Adult Adult	Age Select 💙 18 to 61 48	Age Units Select  Years Years	Gender Select 💙 Male Male	Route of Exposure or AdministrationSelect- Topical Parenteral	Clear All Filters on 0 Dose Select V 100 (15) 444	Dose Units Select V % (µl/Finn Chamber) 9	Duration of Treatment Select V 48

#### Note:

- If user gave the search criteria from Search BY Excipients or Clinical Data section of Search FOR Excipients then the Search Results will display with Clinical Data section by default.
- If user gave the search criteria from Non Clinical Data section of Search FOR Excipients then the Search Results will display with Non Clinical Data section by default.
- User can give the combination of all the fields on sections wise (Clinical and Non Clinical), based on the given inputs the search results will display.
- On each field name mouse hover, the respective field description will be displayed as tool tip.

# 7 Excipient(s) Intermediate Details:

User can select the search criteria from Search BY Excipients or Search FOR Excipients to get the Multiple Excipients like below,

**Excipient**(s) Intermediate Details:

ı – US PFI User	Guide	Version- 1.
arch BY Excipients		
Excipient Name	Acesulfame K Alcohol  Aspartame  Benzalkonium Chloride  Benzoic Ar	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name 57-55-6), by synonym (eg 1,2 propanediol) o by function (eg, solvent)
Synonyms (as per the Handbook of Excipients)	A-Toluenol  Alkohol  Alkyl Dimethyl Benzyl Ammonium Chloride Alkyl Dimethyl Benzyl Ammonium Chloride Alkyl Dimethyl Chloride Alkyl Almethyl (Pherylmethyl) Quaternary Ammonium Chlorides Alpha Aspartame Alpha Tydraxytoluene	Select from drop down or enter enter minimu of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoyrms. For Multiple Excipient/Function Selection: Please use "CtH" or "Mouse click & drag" to select multiple search terms.08 please use "
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate 100-51-6 64-17-5 8001-54-5	* Icon to open excipients list hox for selection Progressive search will be based and fittered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate  Select Antimicrobial agent Antimicrobial preservative Antinesptic Disinfectant  +	Refine your search by using the filters provid on the results page or there is also a Search FOR excipients option where you can find th excipients by sludy type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients	

In search results if more than one Excipients are selected in the 'Search BY Excipients' or 'Search FOR Excipients' then "Excipient(s) Intermediate Page" appears as shown below.

	Database of safety and toxicity of excipients for paediatrics		United State	Pediatric Formulation bitUative	
2 bodhanapu venkata reddy (Your login session will expire af	er 30 minutes of inactivity)	Search BY Excipients   Search FOR Excipients	User Guide	Help   Lo	jout
Excipient(s) Intermediate Page Back Number of Excipients found: 3 All Alcohol Benzyl Alcohol Benzyl Alcohol Submit					
Developed by GVK BIO	Contact Feedback Disclaimer		S STAR	GOBIOM	

Select the required excipients using checkboxes and click "Submit" to retrieve the search results and search results appears as shown below.

#### Version- 1.0

earch Result	ts <u>Back</u>					Total Referen	ces: 1			F	Record 1 of
										Excipient	t Navigatio
eneral Informatio	m								1 Go	IFirst < Previous >	Next IN a
xcipient Chemica AS Registry Nun											
Excipient Catego	ory/Function :										
Pharmacopoeial	Status:										
Regulatory Statu	IS:										
Synonyms:											
Acceptable Daily	Intake:										
Revision Date:											
Ref ID	nical Columns ⊞ Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Export Filtered Clini Duration of Treatmer	
Select 💌	Select 💌	Select 💌	Select 💌	Select 🔽	Select	Select 💌	Select	Select	Select 💌	Select 💌	Sel
126	Alcohol	Other study type - Lab/Drug de (More)	Adult	Unspecified	Unspecified	Male	Topical	1.5; 0.2	ml	5	Minute

Based on the user selection of Excipients, the search results will be displayed for those Excipients.

# 8 Search Results

Based on the search criteria given in the "Search BY Excipients or Search FOR Excipients" as shown below.

arch BY Excipients		
rch BY Excipients		
Excipient Name	Benzyl Alcohol    Propylene Glycol	Instructions on Search BY Excipients page: There are several ways you can search for th excipients. You can search by excipient nam 57-55-6), by synorym ( eg 1,2 proparedioi) by function ( eg. solver)
Synonyms (as per the Handbook of Excipients)	A-Tolueno   Alpha Hydroxytoluene  Benzenemethano   Benzylic Alcoho Benzylic Alcoho Phenylearbinol Phenylearbinol Phenylearbinol	Select from drop down or enter enter minim of 3 characters to populate suggestions. If you don't find the excipient in the excipien name box, try searching in synoyams. For Multiple Excipient/Function Selection: Please use "Ctrl" or "Mouse click & drag" to
CAS Registry Number	100-51-6 100-51-6 17-55-5	select multiple search terms.OR please use " " icon to open excipient list box for selectio Progressive search will be based and filterer on the values already selected in dropdowns If you've selected a large dataset the results could take some time to load. Refine your search by using the filters provi
Function	Antimicrobial gent  Antimicrobial preservative	on the results page or there is also a Search FOR excipients option where you can find th excipients by study type, age, or effects or restrict your search to particular study type, age or effect.

#### Version- 1.0

Search results page appears considering the search criteria. STEP provides the Data in the search results page in a user friendly manner. Search Results page is universal when user selects the search criteria either from "Search BY Excipients or from Search FOR Excipients". Then the Search Results page appears displaying the corresponding information as shown below.

	Å				-	database Ind toxicity of excipien	ts			United States
bodhanapu venkata	a reddy (Your log	in session will expire after 30	minutes of inactivity)				Search BY Excipients	Search FOR Exc	cipients   Export	User Guide   Help   Log
Search Results	Back				Tota	al References: 93				Record 1 of 1
General Information Excipient Chemica CAS Registry Num	- I Name: Benzyl Alc	ohol								Excipient Navigation
Excipient Categor     Pharmacopoeial 5     Regulatory Status     Synonyms:     Acceptable Daily     Revision Date:	Status: 3: Intake:									
Clinical Data (10) Show/Hide Clini	Non Clinical Dat	a (73) Invitro Data (21)	Regulatory and	other information (7)	Reviews (2)			Clear All Filters on (		ndicates Unique References port Filtered Clinical Data
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
<u>64</u>	Benzyl Alcohol	Case study	Adult	Unspecified	Unspecified	Male/Female	Topical	1	%	Unspecified
<u>933</u>	Benzyl Alcohol	ADME/Pharmacokinetics studies	Preterm newborn infants (born <u>(More)</u>	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified
933	Benzyl Alcohol	ADME/Pharmacokinetics studies	Term newborn infants (0 to 27 (More)	Unspecified	Unspecified	Unspecified	Parenteral	Unspecified	Unspecified	Unspecified
•			III							F
Developed by G					Contact Feed	back Disclaimer				GOSTAR GOBIOM

Search Results provides the result information in a categorical manner for that the information is categorized into the below data

- ✓ General Information
- ✓ Clinical Data
- ✓ Non Clinical Data
- ✓ Invitro Data
- ✓ Regulatory & other information

✓ Reviews

Among those "General Information" and "Clinical Data" information appears by default as shown below.

Search Results Back	Total References: 93	Record 1 of 1
		Excipient Navigation
General Information		
Excipient Chemical Name: Benzyl Alcohol		
CAS Registry Number: 100-51-6		
Excipient Category/Function :		
Pharmacopoeial Status:		
Regulatory Status:		
Synonyms:		
Acceptable Daily Intake:		
Revision Date:		

### 8.1 General Information

In the "Search Results" page considering the search criteria "General Information" provides the information about the corresponding Excipient along with the CAS Registry Number as shown below.

Search Results Back	Total References: 93	Record 1 of 1
		Excipient Navigation
General Information		
Excipient Chemical Name: Benzyl Alcohol		
CAS Registry Number: 100-51-6		
Excipient Category/Function :		
Pharmacopoeial Status:		
Regulatory Status:		
E Synonyms:		
Acceptable Daily Intake:		
Revision Date:		

In the "General Information" along with "Excipient Chemical Name and CAS Registry Number" details regarding "Excipient Category/Function, Pharmacopoeial Status, Regulatory Status, Synonyms, Acceptable Daily intake, Revision Date" data is also available in the Collapsed mode by default in "Search Results" page as shown below.

Search Results Back	Total References: 93	Record 1 of 1
		Excipient Navigation
General Information		
Excipient Chemical Name: Benzyl Alcohol		
CAS Registry Number: 100-51-6		
Excipient Category/Function :		
Pharmacopoeial Status:		
Regulatory Status:		
E Synonyms:		
Acceptable Daily Intake:		

#### Version- 1.0

Whenever user clicks [+] symbol before the fields then the corresponding data appears as shown below.

Search R	esults Back				Total References: 93		Record 1 c
							Excipient Navigati
<u>Seneral Info</u>	mation						
Excipient Cl	hemical Name: Benzyl Alcohol						
AS Regist	ry Number: 100-51-6						
- Evenient	Category/Function :						
	I preservative; Disinfectant; Solvent						
	poeial Status:						
IP XV; USP:	32?NF27; PhEur 6.5;						
= Regulator	y Status:						
Agency	Description	Permitted Functionalit	y Use I	limits	Reference		Source URL
Japan	listed in the Japanese Compreh(	in the Japanese Compreh(More) -		t for use of ( <u>More)</u>	Japanese Comprehensive Licensi(More)	:	
EU	-	preservative		up to the cc <u>(Morc)</u>	Ash, Michael, and Irene Ash. H(More)	http://www.knovel.com/k	novel2/Toc.jsp?BookID=2978.
US	-	preservative		up to the ce(More)	Ash, Michael, and Irene Ash. H(More)	http://www.knovel.com/k	novel2/Toc.jsp?BookiD=2978.
FDA	-	Synthetic flavoring substances(More)			Title 21 of the U.S. Code of F(More)	http://www.accessdata.fo fr=172.515&SearchTerm	la.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm? =benzyl%20alcohol
Synonyma	ter and a second a second a	• •			The second second second second		
A-Toluenol		Alpha Hydroxytoluene			Benzenemethanol	Hydroxymel	hylbenzene
Phenylcarbi	nol	Phenylmethanol			Phenmethylol	Benzylic Alo	
Acceptabl	le Daily Intake:						
General Acc	ceptable Daily Intake						
	Source	Limit	Yea	ar	Reference		Source URL
EC SCF		0-5 mg/kg bw.	2002	2 SCF (	Scientific Committee on F(More)	Http://ec.	europa.eu/food/fs/sc/scf/out138_en.pdf
Joint FAOA	WHO Expert Committee(More)	0 5 mg/kg bw ; No safety conce <u>(Mor</u>	2002	2 Summ	ary of Evaluations Perform(More)	Http://ww	w.inchem.org/documents/jecfa/jeceval/jec 194.htr
Acceptable	Daily Intake for Pediatrics						
	Source	Limit		Year	Reference		Source URL
					No Data Found		
Revision [	Date:						
V/A							

In the "Search Results" the count of the references for a particular excipient appears as shown below.

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dara	Dose Units
1000 Contraction (1990)			Age Category			10 In 10			Dose onits
*	×	<b></b>	*	×	¥	¥	<b>•</b>	*	
<u>29</u>	Sodium Benzoate	Case Study	Adult	64	Years	Female	Oral	750	Mg
<u>64</u>	Sodium Benzoate	Case Study	Adult	Unspecified	Unspecified	Male/Female	Topical	5	%
<u>79</u>	Sodium Benzoate	Case Study	Children (2 To 11 Years)	5	Years	Male	Topical	4	%

## 8.2 Clinical Data

Clinical data provides complete Clinical information of the excipient.

### 8.2.1 Reference ID

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicates that the records with the unique Reference ID.
- Click "Ref ID", to get the complete reference information appears in a tabular format as shown below

Mg
Mg
Mg/Kg/Day
Mg/Kg/Day
En Malka
e Type Year
_

### 8.2.2 Excipient Name

Based on the search criteria the relevant "Excipient Name" appears in the "Excipient Name" column as shown below.

Clinical Data(		ta(2) Invitro Data(	7) Regulatory R	eterence(7) Rev	views(1)				
how/Hide C	Clinical Columns 🗉								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units 🧉
	<b>Y</b>				<b>~</b>			<b>~</b>	
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
<u>.14</u>	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
.14	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
<b>1</b> 4	Codium	Dharmacokinotics	A duite	Upperceified	Unpresided	Unencoified	Oral	120-150	Malka

### 8.2.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant "Study Type" appears in the column types as shown below.

now/Hide Clin	ical Columns 🗉								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
~	Y	~	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>		<b>~</b>	
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day

### 8.2.4 Age Category

"Age Category" indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated. Depending upon the search criteria the corresponding age category information will appear under "Age Category" column

Eu – US PFI	User Guide
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Show/Hide	Clinical (	Columns 🗉								
Ref ID	Б	xcipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
		<b>~</b>			<b>~</b>	<b>~</b>	<b>~</b>		<b>~</b>	
<u>112</u>		odium enzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114		odium enzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
<u>114</u>		odium enzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day
124	S	odium	Pharmacokinetics	Adult	Unspecified	Unspecified	Unspecified	Oral	130; 150	Mg/Kg

## 8.2.5 Age

Age provides numerical entry for age in its corresponding column as shown below

Ref ID									
(et ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
<b>~</b>	~	<b>~</b>	×	~	~	~		~	
	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day
	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Female	Unspecified	600	Mg/Kg/Day

# 8.2.6 Age Units

Displays the unit for Age- provides in years, months etc; as shown below

now/Hide Clini	cal Columns 🗉								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
~	<b>~</b>	<b>~</b>	~	~	<b>~</b>	~		~	
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
<u>112</u>	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

### 8.2.7 Gender

Displays the gender based on the search criteria in the relevant column as shown below.

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
~	<b>~</b>	<b>~</b>	<b>×</b>	<b>~</b>	<b>~</b>	<b>~</b>		<b>~</b>	
<u>110</u>	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
<u>114</u>	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

### 8.2.8 Route of Exposure or Administration

"Route of Exposure/Administration" indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

ef ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
~		×	<b>~</b>	<b>~</b>	~	<b>~</b>		<b>~</b>	
<u>10</u>	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
<u>12</u>	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
<u>14</u>	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

### 8.2.9 Dose

Dose(s) or concentration(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)) will be displayed based on the searched criteria as shown below.

how/Hide Clini	cal Columns 🗉								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose	Dose Units
~	I	<b>~</b>	~	~	~	~		~	
110	Sodium Benzoate	Case Study	Adult	75	Years	Female	Oral	100	Mg
112	Sodium Benzoate	Case Study	Adult	67	Years	Male	Oral	800	Mg
114	Sodium Benzoate	Case Study	Unspecified	Unspecified	Unspecified	Male	Unspecified	600	Mg/Kg/Day

### 8.2.10 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

now/Hide Clini	ical Columns 🗉							
Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Referenc
~		×	<b>~</b>	~				
Mg/Kg	Unspecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K <u>(More)</u>	NA, K. Oyanagi, Kuniya, A (More)
Mg	1	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (More)	NA, Netti Colanarc MC, Fe (More)
1g	Unspecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (More)	NA, D. A MONERE VAUTRIN (More)
Unspecified	Unspecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(More)	NA, Tom E, Rapos

## 8.2.11 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

how/Hide Clinica	al Columns 🗉							
Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Referenc
<b>~</b>	<b>~</b>	×	<b>~</b>	<b>~</b>	<b>~</b>			
Mg/Kg	Unspecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K <u>(More)</u>	NA, K. Oyanagi, Kuniya, / (More)
Mg	1	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (More)	NA, Netti Colanarc MC, Fe (More)
Mg	Unspecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (More)	NA, D. A MONERE VAUTRIN (More)
Unspecified	Unspecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(More)	NA, Tom E, Rapos

## 8.2.12 Duration Units

Displays duration of the dose in units

5how/Hide Clinica		Carl Contraction (Contraction Contraction)				The second se	and the second	
tion Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
~	<b>~</b>		<b>~</b>	<b>•</b>				<b>~</b>
ecified	Unspecified	Unspecified	Multiple Organs/Systems	No Adverse Effects	Unspecified	Period 1: VmaxD 152 G/MI/H K <u>(More)</u>	NA, K. Oyanagi, Y. Kuniya, A. <u>(More)</u>	C
	Days	Unspecified	Integumentary System	Urticaria	Capsule	Hypersensitive Reactions To So (More)	NA, Nettis E, Colanardi MC, Fe (More)	L
ecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (More)	NA, D. A. MONERET- VAUTRIN, R. (More)	L
ecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge(More)	NA, Tomaz- E, Raposo-	J

### 8.2.13 Frequency of Administration

This indicates the administration of doses to the test species as shown below.

now/Hide Clinica	I Columns 🗉							
ion Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
			<b>~</b>					<b>~</b>
						(More)	Hsien-Yuan (More)	
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjiev S <u>(More)</u>	J
	Hours	Every 3 Hours	Unspecified	Agitation; Confusion; Kussmaul (More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjiev S <u>(More)</u>	J
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul (More)	Injection	Not Applicable	NA, Praphanphoj V, Boyadjiev S <u>(More)</u>	J

### 8.2.14 System/Organ

Indicates on which organ or system the effects were observed as shown below.

Show/Hide Clinica	l Columns 🗉							
tion Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
<b>~</b>	<b>~</b>	<b>~</b>	<b>•</b>					<b>~</b>
						(More)	MC, Fe (More)	
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory <u>(More)</u>	NA, D. A. MONERET- VAUTRIN, R. (More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge <u>(More)</u>	NA, Tomaz- E, Raposo- MS, Santos (More)	J
	Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (More)	NA, Chien- Han Lai, Hsien-Yuan (More)	3

## 8.2.15 Safety / Tolerability / Adverse Effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Clinical	Data (10) Non Clinical	Data (73) Invitro	o Data (21) Regulatory and o	ther information (7)	Reviews (2)			Differ	ent colors indicate	s Unique Referenc
Show/I	Hide Clinical Columns	; 🕀					Clear All Filte	ers on Clinica	I Data Export Fil	tered Clinical Data
Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
💌	Select	Select 💌	Select	Select 💌		Select 💌			Select 💌	
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec <u>(More)</u>	NA, Schnuch A, Lessmann H, Gei (More)	J	2011
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	د	1988
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	J	1988
•							III			4

#### Version- 1.0

When user clicks "More" link then the complete information about the adverse effects appears as shown below.

Clinical	Data (10) Non Clinical	Data (73) Invitro	Data (21) Regulatory and o	her information (7)	Reviews (2)			Differ	ent colors indicate	s Unique Refere
Show/I	Hide Clinical Columns	: 🗄					Clear All Filte	ers on Clinica	l Data Export Fil	tered Clinical Da
nits	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Yea
- 🖌	Select 🔽	Select 💌	Select	Select 💌		Select			Select 🔽	
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec <u>(More)</u>	NA, Schnuch A, Lessmann H, Gei <u>(More)</u>	3	2011
ed	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine than in term newborns as hippuric acid formation is deficient in preterm neonates (Less)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	]	1988
					Larger percentages of benzyl alcohol			NA, LeBel		

Mouse hover on "More" link also displays the complete information of the "Adverse Effects" in a tool tip as shown below.

Clinical Da	ta (10) Non Clinical Da	ta (73) Invitro D	ata (21) Regulatory and othe	r information (7)	Reviews (2)			Different	colors indicates U	nique Referenc
Show/Hid	le Clinical Columns 🗄	]					Clear All Filters	on Clinical Da	ata Export Filter	ed Clinical Data
se Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Ye
ect 🔽	Select 🔽	Select 🔽	Select	Select 🔽		Select 🔽			Select 🔽	
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec <u>(More)</u>	NA, Schnuch A, Lessmann H, Gei (More)	J	2011
cified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (More) Larger percentages of in urine as benzoic ac			NA, LeBel M, Ferron L, Masson (More)	J	1988
cified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentag hippuric acid appeare doses were found newborns as hippuric acid in preterm b in preterm neonates hippuric acid appeares in their units	d in their urine than	in term	NA, LeBel M, Ferron L, Masson (More)	1	1988
•							III			- F

### 8.2.16 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

Clinical Da	ta (10) Non Clinical Da	ta (73) Invitro D	ata (21) Regulatory and other	r information (7)	Reviews (2)			Different	colors indicates L	Inique References
Show/Hic	le Clinical Columns 🗉						Clear All Filters	on Clinical Da	ata Export Filter	ed Clinical Data
se Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Yei
ect 🔽	Select	Select 💌	Select 💌	Select 💌		Select 💌			Select 💌	E
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec <u>(More)</u>	NA, Schnuch A, Lessmann H, Gei (More)	J	2011
cified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	J	1988
cified	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	J	1988
•							III			4

## 8.2.17 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

Non Clinical Data	2) Invitro Data(7) Regula	tory Reference(7)	Reviews(1)				
Columns 🗉							
Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
~							<b>~</b>
Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory <u>(More)</u>	NA, D. A. MONERET- VAUTRIN, R. (More)	J
Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge <u>(More)</u>	NA, Tomaz- E, Raposo- MS, Santos <u>(More)</u>	J
Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (More)	NA, Chien- Han Lai, Hsien-Yuan <u>(More)</u>	<u>=</u>
Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul	Injection	Not Applicable	NA, Pranhannhoi	J ~
	Columns ® Duration Units Unspecified Unspecified Weeks	Columns ® Duration Units Frequency Of Administration Unspecified Unspecified Unspecified Unspecified Weeks Unspecified	Columns ®       Duration Units     Frequency Of Administration     System/Organ       Image: System     Image: System     Image: System       Unspecified     Unspecified     Integumentary System       Umspecified     Unspecified     Integumentary System       Weeks     Unspecified     Nervous System	Columns ®       Duration Units     Frequency Of Administration     System/Organ     Safety / Tolerability / Adverse Effects       Image: System     Image: System     Image: System     Image: System       Unspecified     Unspecified     Integumentary System     Image: System       Weeks     Unspecified     Nervous System     Tolerated       Hours     Continuous Infusion     Unspecified     Agitation; Confusion; Kussmaul	Columns (9)       Duration Units     Frequency Of Administration     System/Organ     Safety / Tolerability / Adverse Effects     Dosage Form       Image: System     Image:	Columns (?)     Frequency Of Administration     System/Organ     Safety / Tolerability / Adverse Effects     Dosage Form     Conclusion / Comments       Image: Stress of the stress of	Columns ®         Duration Units       Frequency Of Administration       System/Organ       Safety / Tolerability / Adverse Effects       Dosage Form       Conclusion / Comments       Reference         Image: Columns (B)       Image: Column (Column)       Image: Column (Column)

Click "More" link then complete comments data appears as shown below.

Show/Hide	Clinical Columns 🗉								
ation Of Trea	tment Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Ty	ре
~									*
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory Flow Rate Of 50% Was Demonstrated With Oral Sodium Benzoate 100 Mg. The Anaphylactoid Reaction Was Due To Sodium Benzoate Given With The Diazepam. (Less)	NA, D. A. MONERET- VAUTRIN, R. (More)	J	
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge Tests Resulted In Urticaria. (Less)	NA, Tomaz- E, Raposo- MS, Santos (More)	J	

## 8.2.18 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

Clinical Data(14)	Non Clinical Data	(2) Invitro Data(7) Regula	tory Reference(7)	Reviews(1)				
Show/Hide Clinica	il Columns 🗉							
tion Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
~	<b>~</b>							<b>~</b>
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (More)	NA, D. A. MONERET- VAUTRIN, R. (More)	J
pecified	Unspecified	Unspecified	Integumentary System	Urticaria	Unspecified	Sodium Benzoate Oral Challenge Tests Resulted In Urticaria. (Less)	NA, Tomaz- E, Raposo- MS, Santos (More)	J
	Weeks	Unspecified	Nervous System	Tolerated	Unspecified	No Side Effects Related To Sod (More)	NA, Chien- Han Lai, Hsien-Yuan (More)	J
	Hours	Continuous Infusion	Unspecified	Agitation; Confusion; Kussmaul	Injection	Not Applicable	NA, Pranhannhoi	د د

Search Results

Click "More" link then complete reference information appears as shown below.

Show/Hid	le Clinical	l Columns ⊞							
tion Of Tr	reatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>				~
ecified		Unspecified	Unspecified	Integumentary System	Drug Eruption	Patch	No Evidence Of Sodium Benzoate( <u>More</u> )	NA, J. V ILAPLANA, C. R. OMAGUERA. Fixed Drug Eruption From Sodium Benzoate. Contact Dermatitis. 2003 Dec;49 (6):290-1, NA, 2003, NA (Less)	1
ecified		Unspecified	Unspecified	Integumentary System	Drug Eruption	Solution	No Evidence Referring To Sodiu(More)	NA, J. V ILAPLANA, C.	J

### 8.2.19 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

Show/Hide Clini	al Columns 🗉							
		F 0(41.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.1.	5 1 10		р. г.		<b>D</b> (	р <i>(</i> т
ation Of Treatmen	t Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
<b>~</b>			<b>~</b>	<b>•</b>				<b>~</b>
pecified	Unspecified	Q6h	Multiple Organs/Systems	Impaired Renal Function And H (More)	Injection	VdD0.14§ 0.07 L/Kg (0.086?0.2 <u>(More)</u>	NA, Green TP, Marchessault RP, <u>(More)</u>	J
pecified	Unspecified	Q6h	Genitourinary System	Renal Failure	Injection	Use Ofsodium Benzoate In Newbo (More)	Thomas P Green And B L Mirkin (More)	0
pecified	Unspecified	Unspecified	Integumentary System	Pruritis	Capsule	Sodium Benzoate Induces A Rela (More)	NA, R. Asero. Sodium Benzoate- (More)	ſ
pecified	Unspecified	Unspecified	Integumentary	Acute Leukocytoclastic Vasculi	Capsule	Sodium Benzoate Is	NA, Thomas	J

### 8.2.20 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical	Data (10) Non Clinical	Data (73) Invitro	Data (21) Regulatory and o	ther information (7)	Reviews (2)			Differ	ent colors indicate	s Unique Referer
how/	Hide Clinical Columns	; ±					Clear All Filte	ers on Clinica	I Data Export Fil	tered Clinical Data
nits	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
	Select 👻	Select	Select	Select 💌		Select			Select	
	Unspecified	Unspecified	Unspecified	Integumentary System	Leg dermatitis	Patch	Epidemiologically relevant dec <u>(More)</u>	NA, Schnuch A, Lessmann H, Gei (More)	j	2011
	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl a (More)	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	J	1988
	Unspecified	Unspecified	Unspecified	Genitourinary system	Larger percentages of benzyl alcohol doses were found in urine as benzoic acid in preterm babies, while less hippuric acid appeared in their urine	Solution	Not Available	NA, LeBel M, Ferron L, Masson (More)	J	1988

**Note:** For any field, the data is more than 30 characters in the cell, then the data will display 30 characters and followed by "(...More)". If user clicks on "More" link then user is able to see the full information for that particular cell. In that case the link will be "(...Less)" as shown above. More over user is able to see the full text of that particular cell as a tooltip (Mouse hover). This is applicable for overall application in the search results page.

### 8.3 Non Clinical Data

STEP application provides the data of the excipients based on the various aspects one among them is the Non-Clinical Data. This provides complete optional environment depending on the "Non-Clinical Data" attributes.

### 8.3.1 Ref ID

Non-Clinical data provides complete Non-Clinical information of the excipient.

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicate Unique References.
- Click "Ref ID", complete reference information appears in a tabular format as shown below

Clinical Data(98)	Non Clinical Dat	ta(102) Invitro Data(18) Regu	ilatory Refer	ence(59	9) Reviews(21)						
Show/Hide Non	Clinical Columns [	÷									
Ref ID	Excipient Name	Study Type	Species		Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units	
~	<b>~</b>			~	<b>×</b>	<b>~</b>	<b>~</b>	~			
5	Aspartame	Repeated Dose Toxicity	Rat		Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw	
5	Aspartame	Acute Toxicity (0-14days)	Rat		Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw	
27	Aspartame	Specific Investigations: Other (More)	Rat		Adult	Unspecified	Unspecified	Unspecified	200	Mg	
<u>96</u>	Aspartame	Pharmacokinetcs/Toxicokinetics	Rat		Adult	14	Weeks	Male	34	Mg/Kg	~
•1											
Ref ID		Reference				Title		Author	Reference Type	Year	
27		AB, Manion CV. Treatment of osteo; Clin Pharmacol Ther. 1998 May;63( ), NA-NA	E)-E90-02		dson AB, Manion C ame. Clin Pharmac				J	1998	

### 8.3.2 Excipient Name

Based on the search criteria the relevant "Excipient Name" appears in the "Excipient Name" column as shown below.

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
	×	<b>~</b>	~	~	~	<b>~</b>	<b>~</b>	<b>~</b>	
ž	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other (More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96	Aspartame	Pharmacokinetcs/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg

### 8.3.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant "Study Type" appears in the column types as shown below.

Clinical Data(98)	Non Clinical Dat	a(102) Invitro Data(18) Regu	latory Reference(5	9) Reviews(21)					
Show/Hide Non	Clinical Columns	•							
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units 🧁
·			<b>~</b>	×	×			<b>~</b>	
5	Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5	Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27	Aspartame	Specific Investigations: Other (More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
<u>96</u>	Aspartame	Pharmacokinetcs/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg 🔽
<		1111							>

## 8.3.4 Species

Species displays the information about the species name of the excipient as shown below.

now/Hide No	n Clinical Columns	Ŧ							
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender Dose / Concentration		n Dose Units
•			×		<b>~</b>	<b>~</b>	<b>~</b>		
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw
212	Aspartame	Reproductive Toxicity And	Rabbit	Adult	14-18	Weeks	Female	2	G/Kg/Day

Version- 1.0

Eu – US PFI User Guide

### 8.3.5 Age Category

"Age Category" indicates is classified as per ICH classification (CPMP/ICH/2711/99). Based on the age category the relevant group name in indicated. Depending upon the search criteria the corresponding age category information will appear under "Age Category" column as shown below.

		Clinical Columns B								
Ref ID		Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
	~			<b></b>						
5		Aspartame	Repeated Dose Toxicity	Rat	Juvenile	Unspecified	Unspecified	Male	10, 250	Mg/Kg Bw
5		Aspartame	Acute Toxicity (0-14days)	Rat	Juvenile	Unspecified	Unspecified	Male	250	Mg/Kg Bw
27		Aspartame	Specific Investigations: Other (More)	Rat	Adult	Unspecified	Unspecified	Unspecified	200	Mg
96		Aspartame	Pharmacokinetcs/Toxicokinetics	Rat	Adult	14	Weeks	Male	34	Mg/Kg

## 8.3.6 Age

Age provides numerical entry for age in its corresponding column as shown below

207 Aspart		Reproductive Toxicity And Deve <u>(More)</u>	Rabbit	Adult	~9	Months	Female		
207 Aspart			Rabbit	Adult	~9	Months	French		
							remaie	0.86; 1.45; 1.26	G/Kg/Day
09 Aspart	ame R	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210 Aspart	ame G	Senotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw

## 8.3.7 Age Units

Displays the unit for Age- provides in years, months etc; as shown below

~			Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
				<b>~</b>		×			
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw

Search Results

### 8.3.8 Gender

Displays the gender based on the search criteria in the relevant column as shown below.

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dece Units
					ABG	_			Dose onits
	<b>•</b>		✓	<b>~</b>		<b>~</b>	<b>~</b>		
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw

## 8.3.9 Dose/Concentration

Dose(s) or concentration(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)) will be displayed based on the searched criteria as shown below.

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
				× Interest of the second seco					
207	Aspartame	Reproductive Toxicity And Deve(More)	Rabbit	Adult	~9	Months	Female	0.86; 1.45; 1.26	G/Kg/Day
209	Aspartame	Repeated Dose Toxicity	Mouse	Adult	<17	Years	Male/Female	Approx. 50	Mg/Kg
210	Aspartame	Genotoxicity	Rat	Adult	23	Weeks	Male	2000	Mg/Kg Bw

## 8.3.10 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
	✓							
G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa <u>(Mo</u>
Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Expo Aspartame <u>(</u>
Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam()

Search Results

# 8.3.11 Route of Exposure or Administration

"Route of Exposure/Administration" indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

	inical Columns 🗉								
Dose Units	Route Of Exposu	ure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
~	×	l		<b>~</b>					
G/Kg/Day	Oral		13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Adm Of Aspa(M
Mg/Kg	Oral		6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Exp Aspartame(.
Mg/Kg Bw	Oral		1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Surviva Aspartam(

# 8.3.12 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

٦O	w/Hide Non Clir	nical Columns 🗉							
D	Oose Units	Route Of Exposure / Administration	<b>Duration Of Treatment</b>	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
IC	~								<u>.</u>
G	6/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa <u>(Mc</u>
м	1g/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Expo Aspartame <u>(</u>
м	lg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam <u>()</u>
6	G/Kg/Day	Oral	13	Days	B.i.d. (Every 2 Hours)	Reproductive	No Adverse Effects	Powder	SC-18862 Wa

# 8.3.13 Duration Units

Displays duration of the dose in units

Image: Normal system         Image: Normal system         Image: Normal system         Image: Normal system         Normal syst	Pellet	Dietary Adm Of Aspa(M
Mg/Kg Oral 6-17 Weeks Unspecified Disorders Elevated Fasting	Pellet	
Disorders Elevated Fasting		
(More)	Solution	Lifetime Exp Aspartame <u>(.</u>
Mg/Kg Bw Oral 1 Days B.i.d. Genetic System No Adverse Effect	Suspension	The Survival Aspartam <u>(</u>

Search Results

### 8.3.14 Frequency of Administration

This indicates the administration of doses to the test species as shown below.

Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
<b>~</b>			<b>~</b>	<b>•</b>				
G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa <u>(Mc</u>
Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Expo Aspartame <u>(</u>
Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam <u>()</u>

# 8.3.15 System/Organ

Indicates on which organ or system the effects were observed as shown below.

Dose Units	Route Of Exposure / Administration	Duration of Transformer						
		Duration of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion /
×			<b>~</b>	<b>×</b>	~			
G/Kg/Day	Oral	13	Days	Continuous Feeding	Multiple Organs/Systems	No Adverse Effect	Pellet	Dietary Admi Of Aspa <u>(Mc</u>
Mg/Kg	Oral	6-17	Weeks	Unspecified	General Disorders	Weight Gain, Elevated Fasting (More)	Solution	Lifetime Expo Aspartame <u>(</u>
Mg/Kg Bw	Oral	1	Days	B.i.d.	Genetic System	No Adverse Effect	Suspension	The Survival Aspartam <u>()</u>

## 8.3.16 Adverse effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Clinical Data (10)	Non Clinical Data (73)	Invitro Data (21)	Regulatory and other informat	tion (7) Reviews	(2)			Differ	ent colors indicate	s Unique Referen
how/Hide Non (	Clinical Columns 🗉						Clear All Filters o	on Non Clinical Dat	a Export Filtered	l Non Clinical Data
or Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
	Select 💌	Select 💌	Select 💌	Select 🗸		Select 🗸			Select 🔽	
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot <u>(More)</u>	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ <u>(More)</u>	L	1986
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot <u>(More)</u>	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ <u>(More)</u>	ι	1986
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp (More)	Gel	Benzyl alcohol did not cause a(More)	NA, Thomas R Moench, Russell J <u>(More)</u>	J	2010
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, <u>(More)</u>	J	1979
				Interumentary				NA, Motoyoshi		
							III			•

### 8.3.17 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

Clinical Data (10)	Non Clinical Data (73)	Invitro Data (21)	Regulatory and other informat	tion (7) Reviews	(2)			Differ	ent colors indicate	s Unique References
Show/Hide Non (	Clinical Columns 🗉						Clear All Filters of	on Non Clinical Dat	ta Export Filtered	l Non Clinical Data
e or Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
	Select	Select 🗸	Select	Select 🗸		Select 💌			Select 💌	
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot <u>(More)</u>	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ <u>(More)</u>	J	1986
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(More)	Solution	Benzyl alcohol, on a dose/body(More)	NA, McCloskey SE, Gershanik JJ <u>(More)</u>	J	1986
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp (More)	Gel	Benzyl alcohol did not cause a(More)	NA, Thomas R Moench, Russell J <u>(More)</u>	J	2010
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, <u>(More)</u>	J	1979
				Integumentary				NA, Motoyoshi		-
•										4

### 8.3.18 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

w/Hide N	Non Clinical Columns 🗉									
istration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	<b>~</b>	<b>~</b>			<b>~</b>				~	
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects	Powder	SC-18862 Was Neither Embryotox <u>(More)</u>	Schroeder R. E, Mitchell A, Ra <u>(More)</u>	0	
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weig <u>(More)</u>	Powder	Continuous Dietary Administrat <u>(More)</u>	R. E. Schroeder, K. S. Rao, G. <u>(More)</u>	0	
	Unspecified	Unspecified	Continuous Feeding	Multiple Organs/Systems	Hepatocellular Carcinoma; Alve (More)	Pellet	Aspartame Is A Carcinogenic Ag (More)	NA, Morando Soffritti, Fiorell <u>(More)</u>	J	
	4	Weeks	Continuous Feeding	Multiple Organs/Systems	No Adverse Effects- 100% Survi(More)	Powder	No Adverse Physical/Behavioura (More)	KS Rao, TB Martinez, And RG Mc	0	

Click "More" link then complete comments data appears as shown below.

	how/Hide Non Clinical Columns 🗄										
inistration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type		
		<b>~</b>		<b>~</b>					<b>~</b>		
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects		SC-18862 Was Neither Embrytoxic Nor Teratogenic To The Albino Rabbit Fetus, When Administered Intragastrically At A Dosage Of 2 G/Kg/Oay During The Mid-Portion Of Gestation. Likewise, It Lacked Notabit, Adverse Effects On The Maternal Animal. (Less)	Schroeder R. E, Mitchell A, Ra <u>(More)</u>	0		
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weig (More)	Powder	Continuous Dietary Administrat (More)	R. E. Schroeder, K. S. Rao, G.	0		
#### 8.3.19 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

w/Hide N	Ion Clinical Columns 🗉								
nistration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
	<b>~</b>	<b>~</b>		<b>~</b>	<b>~</b>				<b>~</b>
	13	Days	B.i.d. (Every 2 Hours)	Reproductive System	No Adverse Effects	Powder	SC-18862 Was Neither Embryotox (More)	Schroeder R. E, Mitchell A, Ra <u>(More)</u>	0
	8	Days	Continuous Feeding	Reproductive System	Decrease In Maternal Body Weig <u>(More</u> )	Powder	Continuous Dietary Administrat <u>(More)</u>	R. E. Schroeder, K. S. Rao, G. <u>(More)</u>	0
	Unspecified	Unspecified	Continuous Feeding	Multiple Organs/Systems	Hepatocellular Carcinoma; Alve (More)	Pellet	Aspartame Is A Carcinogenic Ag (More)	NA, Morando Soffritti, Fiorell <u>(More)</u>	J
	4	Weeks	Continuous Feeding	Multiple Organs/Systems	No Adverse Effects- 100% Survi(More)	Powder	No Adverse Physical/Behavioura (More)	KS Rao, TB Martinez, And RG Mc	0

Click "More" link then complete reference information appears as shown below.

	Clinical Columns 🗉						
Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
<b>~</b>		<b>•</b>	<b>~</b>				
Unspecified	Unspecified	Reproductive System	A Slight Elevation In Maternal (More)	Solution	Administration Of Aspartame At <u>(More)</u>	Rao KS, McConnell RG, SC-18862: Experiments In Mated And Pregnant Rhesus Monkeys. 1975 May;1-29; <u>(Less)</u>	0
Days	OD	Cellular	Chromosomal Aberration	Solution	Aspartame Significantly Induce (More)	NA, AlSuhaibani ES. In Vivo Cytogenetic Studies On Aspartame. Comp Funct Genomics. 2010. Pii: 605921, NA, 2010, NA(NA), NA-NA ( <u>Less)</u>	J
Days	OD	Not Applicable	Mean Body Weight In The Offspr (More)	Powder	The Study Shows That Levels Of <u>(More)</u>	Lennon HD, Metcalf L, Mares SE, Smith JH. Effects Of SC-18862 On Lactation In Rats. 1973 Sep;1-67; (Less)	0
Days	OD	Cellular	No Adverse Effects	Unspecified	No Mutagenic Effects Were Obse(More)	Mutagenic Study In Rats. SC-18(More)	0
Days	OD	Endocrine	No Adverse Effects	Suspension	Intact Male Rats Have	Mares SE, Berg JR. Effects Of (More)	0

## 8.3.20 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

Clinical Data(98)	Non Clinical Data(102)	vitro Data(18) F	egulatory Reference(5	i9) Reviews	(21)		
Show/Hide Non	Clinical Columns 🗉						
Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference T
<b>~</b>							
Unspecified	Unspecified	Reproductive System	A Slight Elevation In Maternal (More)	Solution	Administration Of Aspartame At <u>(More)</u>	Rao KS, McConnell RG. SC-18862 (More)	0
Days	OD	Cellular	Chromosomal Aberration	Solution	Aspartame Significantly Induce (More)	NA, AlSuhaibani ES. In Vivo Cy (More)	J
Days	OD	Not Applicable	Mean Body Weight In The Offspr (More)	Powder	The Study Shows That Levels Of(More)	Lennon HD, Metcalf L, Mares SE (More)	0
Davs	OD	Cellular	No Adverse Effects	Unspecified	No Mutagenic Effects Were Obse(More)	Mutagenic Study In Rats. SC-18(More)	0

### 8.3.21 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical Data (10)	Non Clinical Data (73)	Invitro Data (21)	Regulatory and other informat	ion (7) Reviews	(2)			Differ	ent colors indicate	s Unique Referen
how/Hide Non (	Clinical Columns 🗄						Clear All Filters o	n Non Clinical Dat	a Export Filtered	d Non Clinical Data
or Administration	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
	Select 🔽	Select 🔽	Select 💌	Select 🗸		Select 🗸			Select 🔽	
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot <u>(More)</u>	Solution	Benzyl alconol, on a	NA, McCloskey SE, Gershanik JJ <u>(More)</u>	J	1986
	4	Hours	Single	Nervous System	Sedation, Dyspnea, Loss of mot(More)	Solution		NA, McCloskey SE, Gershanik JJ <u>(More)</u>	ı	1986
	Unspecified	Unspecified	Unspecified	Reproductive System	Susceptibility to genital herp (More)	Gel	Benzyl alcohol did not cause a(More)	NA, Thomas R Moench, Russell J <u>(More)</u>	ı	2010
	24 to 48	Hours	Once	Integumentary System	No irritation observed	Unspecified	Not Available	NA, Motoyoshi K, Toyoshima Y, <u>(More)</u>	t	1979
				Interumentary				NA, Motoyoshi		
										•

## 8.4 Invitro data

Invitro Data provides the complete information about the

### 8.4.1 Ref ID

Invitro provides complete Invitro information of the excipient.

- Ref ID accommodates the reference ID information of the selected excipient.
- Different colors indicate Unique References.
- Click "Ref ID", complete reference information appears in a tabular format as shown below

ef ID	Excipient Nan	ne Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	on Duration Of Treatmen	t Duration
		<b>v</b>		<b>v</b>				
2	Aspartame	Immunotoxicity	Human	10-3	M		45	Minutes
2	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minutes
2	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	м		10	Minutes
Z	Aspartame	Genotoxicity	Salmonell Typhimuri		Ug/Plate		2	Days
						1		>
Ref ID	)	Reference			Title	Author	Reference Type	Year

### 8.4.2 Excipient Name

Based on the search criteria the relevant "Excipient Name" appears in the "Excipient Name" column as shown below.

Clinical Dat	ta(98) Non Clinica	al Data(	(102) Invitro Data(18)	Regulat	ory Reference(59)	Reviews(21)				
Show/Hide	Invitro Columns 🛙	-								
Ref ID	Excipient Na	ime S	Study Type	5	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
			<b>~</b>		<b>~</b>	<b>~</b>	<b></b>			
<u>39</u>	Aspartame	I	mmunotoxicity	ł	Human	10-3	М		45	Minutes
<u>39</u>	Aspartame	I	mmunotoxicity	'	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minutes
<u>39</u>	Aspartame	I	mmunotoxicity	'	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		10	Minutes
<u>377</u>	Aspartame	•	Genotoxicity		Salmonella Typhimurium	100-10000	Ug/Plate		2	Days
<	1							1		>

### 8.4.3 Study Type

Study Type provides the nature of investigations like randomized controlled, cohort, case studies etc in this field considering the search criteria given the relevant "Study Type" appears in the column types as shown below.

Clinical Data	a(98) Non Clinical Dat	a(102) Invitro Data(18)	Regulatory Reference(59	) Reviews(21)				
how/Hide	Invitro Columns 🗈							
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duratio
	· ·	<b>×</b>		<b>~</b>	<b>•</b>	<b>×</b>		
<u>39</u>	Aspartame	Immunotoxicity	Human	10-3	м		45	Minutes
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minutes
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		10	Minutes
<u>377</u>	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

## 8.4.4 Species

Species displays the information about the species name of the excipient as shown below.

how/Hide Inv	itro Columns 🗉							
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
~			×	<b>~</b>	<b>~</b>			
39	Aspartame	Immunotoxicity	Human	10-3	М		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minutes
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

## 8.4.5 Dose

Dose(s) tested/administered including unit (e.g. '0, 112, 220, 523 mg/kg bw/day (m/f)' or '0, 112, 220, 523 mg/kg bw/day (m)) will be displayed based on the searched criteria as shown below.

Clinical Da	ata(98)	Non Clinical Dat	a(102) Invitro Data(18) Regu	ulatory Reference(59)	Reviews(21)				
Show/Hide	e Invitr	o Columns ⊞							
Ref ID		Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration
	~	<b>~</b>			<b>~</b>	<b>~</b>			
<u>39</u>		Aspartame	Immunotoxicity	Human	10-3	М		45	Minutes
<u>39</u>		Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, ( <u>More)</u>	М		30	Minutes
<u>39</u>		Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	м		10	Minutes
<u>377</u>		Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days
¢									2

Search Results

### 8.4.6 Dose Units

Dose Units represents the relevant dose unit terms of the dose based on the selected search criteria as shown below.

Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duratio
			_					Duracio
	✓			<b>~</b>				
<u>39</u>	Aspartame	Immunotoxicity	Human	10-3	М		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	м		30	Minutes
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	м		10	Minutes
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

### 8.4.7 Route of Exposure or Administration

"Route of Exposure/Administration" indicates the part of the body through or into which, or the way in which, the excipient is introduced will be displayed as shown below.

Show/Hide	e Invitro Columns 🗉							
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administrati	on Duration Of Treatment	Duration
	<b>v</b>		<b>×</b>	<b>~</b>	<b>~</b>	<b>×</b>		
<u>39</u>	Aspartame	Immunotoxicity	Human	10-3	М		45	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minutes
39	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		10	Minutes
<u>377</u>	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

## 8.4.8 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below.

Clinical Data	98) Non Clinical Dat	a(102) Invitro Data(18) R	legulatory Reference(59)	Reviews(21)				
Show/Hide I	nvitro Columns 🗉							_
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duratio
	✓	<b>~</b>	<b>•</b>	<b>~</b>	<b></b>			
<u>39</u>	Aspartame	Immunotoxicity	Human	10-3	м		45	Minutes
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		30	Minute
<u>39</u>	Aspartame	Immunotoxicity	Mouse	10-3, 10-4, 10- 5, 10-6, 10-7, (More)	М		10	Minute
377	Aspartame	Genotoxicity	Salmonella Typhimurium	100-10000	Ug/Plate		2	Days

## 8.4.9 Duration Units

Displays duration of the dose in units

how/Hide Invitro C	olumns 🗉							
e Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
								<b>~</b>
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc(More)	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment), 48 (Post-T <u>(More)</u>	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treate(More)	NA, Sherertz EF, Sloan KB, McT (More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos <u>(More)</u>	NA, Xiaorong Huang, Ping Zhuan <u>(More)</u>	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When (More)	NA, Seki S, Kouya T, Tsuchiya (More)	J

#### System/Organ 8.4.10

Indicates on which organ or system the effects were observed as shown below.

now/Hide Invitro C	olumns ±							
e Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
		<b>~</b>	<b>~</b>					
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc <u>(More)</u>	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment), 48 (Post-T <u>(More)</u>	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treate <u>(More)</u>	NA, Sherertz EF, Sloan KB, McT (More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (More)	NA, Xiaorong Huang, Ping Zhuan <u>(More)</u>	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When (More)	NA, Seki S, Kouya T, Tsuchiya (More)	J

Search Results

Page | 78

## 8.4.11 Safety/Tolerability/Adverse Effects

It displays the adverse effects that are in the excipient appears in this column as shown below.

Show/Hide Invitro	Columns 🗉					Clear All	Filters on Invitre	Data Export Fil	tered Invitro Dat
ure or Administration	Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
4	Select 💌	Select 💌	Select		Select 💌			Select 🔽	
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl (More)	NA, Placzek M, Krosta I, Gaube (More)	1	2005
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat (More)		Not Available	NA, Ball JC, FoxallNot Availab (More)	J	1984
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up (More)		Not Available	NA, SainteNot AvailableMarie J <u>(More)</u>	J	1990
	3, 60	Minutes	Reconstructed epidermis ESTNot(More)	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007;	0	2007

## 8.4.12 Dosage Form

Dosage form provides the information about the form of the dosage as shown below.

how/Hide Invitro	o Columns 🗉					Clear All	Filters on Invitr	o Data Export Fil	ltered Invitro Dat
re or Administratio	n Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	Reference Year
	Select	Select 💌	Select		Select 💌			Select	
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl <u>(More)</u>	NA, Placzek M, Krosta I, Gaube (More)	3	2005
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat (More)		Not Available	NA, Ball JC, FoxallNot Availab (More)	J	1984
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up (More)		Not Available	NA, SainteNot AvailableMarie J <u>(More)</u>	t	1990
	3, 60	Minutes	Reconstructed epidermis ESTNot(More)	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007;	o	2007

## 8.4.13 Conclusions/Comments

Conclusions/Comments indicate the overall remarks of the references. Any remarks or concluding statement could be entered in this section. It will be a free text editor field for creating formatted text and tables or inserting any excerpt from a reference as shown below.

how/Hide Invitro C	olumns 🗉							
e Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
		~	~					<b>~</b>
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc <u>(More)</u>	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment), 48 (Post-T <u>(More)</u>	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treate <u>(More)</u>	NA, Sherertz EF, Sloan KB, McT (More)	J
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos <u>(More)</u>	NA, Xiaorong Huang, Ping Zhuan <u>(More)</u>	J
	30	Minutes	Immature Oocytes	No Adverse Effects		Hatched Embryos Obtained When (More)	NA, Seki S, Kouya T, Tsuchiya (More)	J

Search Results

Page | 79

Click "More" link then complete comments data appears as shown below.

w/Hide Invitro C	olumns 🗉							
Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>				<b>~</b>
							Bergh (More)	
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc (More)	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment), 48 (Post-T <u>(More)</u>	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treated With Propylene Glycol And Then Applied With Theophylline In A Diffusion Cell System Shows Increased Theophylline Flux (Less)	NA, Sherertz EF, Sloan KB, McT (More)	3
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (More)	NA, Xiaorong Huang, Ping	J

### 8.4.14 References

A reference indicates the source from which the information is extracted. The references would be linked to their original source through DOI. When possible the references would be linked to their original source through DOI. The users who need the details of the study will be able to access the abstract or full text depending upon their subscription/copyrights limitations as shown below.

now/Hide Invitro C	olumns 🗉							
e Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	<b>~</b>	<b>~</b>	<b>~</b>					~
	24	Hours	Abdominal Skin	No Adverse Effects		Steady State Penetration Rate (More)	NA, Fasano WJ, Ten Berge WF, B <u>(More)</u>	ſ
	Unspecified	Unspecified	Sperm	No Adverse Effect		The Study Shows That The Combi <u>(More)</u>	NA, Yildiz C, Ottaviani P, Law (More)	J
	30	Minutes	Embryo	Significantly Good Survival Ra (More)		Ethylene Glycol Does Not Appea(More)	NA, Emiliani S, Van Den Bergh <u>(More)</u>	J
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc (More)	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment),	Hours	Skin	No Adverse Effects		Hairless Mouse Skin	NA, Sherertz EF,	J

Click "More" link then complete reference information appears as shown below.

iow/Hide Invitro C	olumns 🗉							
Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
	<b>~</b>	<b>~</b>	<b>~</b>	<b>~</b>				<b>~</b>
							On Sperm Quality, Nuclear DNA Integrity, In Vitro Fertilization, And In Vitro Embryo Development In The Mouse. Reproduction. 2007 Mar;133 (3):585-95, NA, 2007, NA(NA), NA-NA (Less)	
	30	Minutes	Embryo	Significantly Good Survival Ra (More)		Ethylene Glycol Does Not Appea(More)	NA, Emiliani S, Van Den Bergh <u>(More)</u>	J

Search Results

### 8.4.15 Reference Type

Reference Type Indicator specifies the type of reference, e.g. 'Study report' or 'Publication'. Choices include study report, company data, publication, review article or handbook, other;

e Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
		<b>~</b>	<b>~</b>					· · · · · · · · · · · · · · · · · · ·
	30	Minutes	Oocytes	Exposing Cat Oocyte To 0.75 M (More)		The Study Performed On Cat Ooc (More)	NA, Comizzoli P, Wildt DE, Puk (More)	J
	48 (Pre-Treatment), 48 (Post-T <u>(More)</u>	Hours	Skin	No Adverse Effects		Hairless Mouse Skin Pre-Treated With Propylene Glycol And Then Applied With Theophylline In A Diffusion Cell System Shows Increased Theophylline Flux (Less)	NA, Sherertz EF, Sloan KB, McT (More)	I
	30	Minutes	Embryos	Embryonic Toxicity		Cleavage And Blastula Embryos (More)	NA, Xiaorong Huang, Ping	1

### 8.4.16 Reference Year

Reference Year Indicator specifies the year of that particular reference

Show/Hide Invitro	Columns 🗉					Clear All	Filters on Invitro	o Data Export Fil	tered Invitro Da
sure or Administration	Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Conclusion / Comments	Reference	Reference Type	Reference Yea	
	Select 🗸	Select 🔽	Select		Select 💌			Select 💌	
	1	Hours	Erythrocytes	No adverse effects		The study reveals that benzyl <u>(More)</u>	NA, Placzek M, Krosta I, Gaube (More)	J	2005
	Unspecified	Unspecified	Bacteria	Genotoxicity test showed negat (More)		Not Available	NA, Ball JC, FoxallNot Availab (More)	J	1984
	Unspecified	Unspecified	Leukemic B lymphocytes	Benzyl alcohol inhibits the up (More)		Not Available	NA, SainteNot AvailableMarie J <u>(More)</u>	L	1990
	3, 60	Minutes	Reconstructed epidermis ESTNot(More)	Corrosive to skin		Not Available	Vohr (Bayer AG). 2007;	0	2007

## 8.5 Regulatory & other information

'Regulatory & other information' includes the references to the regulations, and regulatory requirements for a specific substance.

### 8.5.1 Ref ID

All references will be given a unique Reference ID. This will help users to identify the references where two or more studies are discussed in one reference. When user clicks "Ref ID" link in the "Regulatory & other information" table, entire information of the reference appears as a tabular

#### Version- 1.0

separate with the "Ref ID, Reference, Title, Author, Reference Type and Year information as shown

Ref ID	D Excipient Nam	e Reference	Source		Source URL			Reference Yea
<u>550</u>	Benzyl Alcohol	Opinion of the Scientific Comm(Mor <u>e)</u>		http://ec.europa.eu/	/food/fs/sc/scf/out138_en.pdf			2002
578	Benzyl Alcohol	Benzyl alcohol - Report(Source(Mor e)		http://iter.ctcnet.ne	t/publicurl/p_report_l2_non.cfm?crn=100-51-6&type=NCO;http://	/toxnet.nlm.nih.gov/cgi	-bin/sis/search	
79	Benzyl Alcohol	Benzyl alcohol regulatory data(More)		http://ec.europa.eu/	consumers/cosmetics/cosing/index.cfm?fuseaction=search.details8	id=28294		
13	Benzyl Alcohol	A survey and health assessment(Mor <u>e)</u>		http://www2.mst.dk 8/html/kap06_eng.h	/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/pub .tm	lications/2007/978-87-7	7052-638-	2007
<u>i43</u>	Benzyl Alcohol	white paper(Source: unknown )((Mo re)		http://legacy.library	.ucsf.edu/tid/khl05c00/pdf			1997
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(More)		http://www.techstre	et.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf			2004
577	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		http://www.efsa.eur	opa.eu/en/efsaiournal/doc/2176.pdf			2011
	Ref ID	Reference			Title	Author	Reference Type	Year
650	C 2	pinion of the Scientific Committee on Food or pinion of the Scientific Committee on Food or 002)(URL: http://ec.europa.eu/food/fs/sc/sc// e Scientific Committee on Food on Benzyl al	n Benzyl al out138_en.	cohol)(Year: Opi	nion of the Scientific Committee on Food on Benzyl alcohol(Source: nion of the Scientific Committee on Food on Benzyl alcohol)(Year: 2)(URL: http://ec.europa.eu/food/fs/sc/sc/fout138_en.pdf)		0	2002

### 8.5.2 Excipient Name

Based on the search criteria the relevant "Excipient Name" appears in the "Excipient Name" column as shown below.

Clinical I	Data (10) Non Cl	inical Data (73) Invitro Data (21) R	egulatory &	other information (7) Reviews (2) Different colors indicate	s Unique Referenc
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Yea
<u>650</u>	Benzyl Alcohol	Opinion of the Scientific Comm <u>(Mor</u> <u>e)</u>		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
<u>678</u>	Benzyl Alcohol	Benzyl alcohol - Report(Source(Mor e)		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crn=100-51-68type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search	
<u>679</u>	Benzyl Alcohol	Benzyl alcohol regulatory data(More)	۱.	http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
<u>513</u>	Benzyl Alcohol	A survey and health assessment(Mor e)		http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-638- 8/html/kap06_eng.htm	2007
<u>543</u>		white paper(Source: unknown )((Mo re)		http://legacy.library.ucsf.edu/tid/kh105c00/pdf	1997
<u>572</u>	Benzyl Alcohol	Benzyl alcohol Oral risk asses(More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf	2004
577	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

### 8.5.3 References

References indicate the source from which the information is extracted. Bibliographic source of the study report or publication will be provided. The references would be linked to their original source through DOI. The users who need the details of the study will be able to access the full text, if available with their subscription or will be able to access the abstract.

Clinical I	Data (10) Non Cl	inical Data (73) Invitro Data (21) R	egulatory &	her information (7) Reviews (2)	Different colors in	dicates Unique Referenc
Ref ID	Excipient Name	Reference	Source		Source URL	Reference Yea
<u>650</u>	Benzyl Alcohol	Opinion of the Scientific Comm <u>(Mor</u> <u>e)</u>		ttp://ec.europa.eu/food/fs/sc/scf/out138	<u>en.pdf</u>	2002
<u>678</u>	Benzyl Alcohol	Benzyl alcohol - Report(Source <u>(Mor</u> <u>e)</u>		tp://iter.ctcnet.net/publicurl/p_report_l	2_non.cfm?crn=100-51-6&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search	
<u>679</u>	Benzyl Alcohol	Benzyl alcohol regulatory data(More)		tp://ec.europa.eu/consumers/cosmetics	/cosing/index.cfm?fuseaction=search.details&id=28294	
<u>513</u>	Benzyl Alcohol	A survey and health assessment(Mor e)		ttp://www2.mst.dk/common/Udgivramm /html/kap06_eng.htm	e/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-638-	2007
<u>543</u>	Benzyl Alcohol	white paper(Source: unknown )( <u>(Mo</u> <u>re)</u>		tp://legacy.library.ucsf.edu/tid/khl05c0	0/pdf	1997
<u>572</u>	Benzyl Alcohol	Benzyl alcohol Oral risk asses <u>(More)</u>		tp://www.techstreet.com/direct/nsf/ber	zyl alcohol Exec Summ 081204.pdf	2004
<u>577</u>	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		tp://www.efsa.europa.eu/en/efsajourna	l/doc/2176.pdf	2011

Search Results

### 8.5.4 Source

Source indicates from which the Reference information is extracted.

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Ye
<u>650</u>	Benzyl Alcohol	Opinion of the Scientific Comm(Mor e)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
<u>678</u>	Benzyl Alcohol	Benzyl alcohol - Report(Source(Mor e)		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crm=100-51-6&type=NCO ; http://toxnet.nlm.nih.gov/cgi-bin/sis/search	
<u>679</u>	Benzyl Alcohol	Benzyl alcohol regulatory data(More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
<u>513</u>	Benzyl Alcohol	A survey and health assessment $(\dots$ Mor <u>e</u> )		http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-638- 8/html/kap06_eng.htm	2007
<u>543</u>	Benzyl Alcohol	white paper(Source: unknown )((Mo		http://legacy.library.ucsf.edu/tid/khl05c00/pdf	1997
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf	2004
<u>577</u>	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

## 8.5.5 Source URL

Source URL indicates from which the Reference information is extracted.

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Yea
<u>650</u>	Benzyl Alcohol	Opinion of the Scientific Comm <u>(Mor</u> <u>e)</u>		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
<u>678</u>	Benzyl Alcohol	Benzyl alcohol - Report(Source(Mor e)		http://iter.ctcnet.net/publicurl/p_report_l2_non.cfm?crn=100-51-6&type=NCO : http://toxnet.nlm.nih.gov/cgi-bin/sis/search	
<u>679</u>	Benzyl Alcohol	Benzyl alcohol regulatory data(More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
<u>513</u>	Benzyl Alcohol	A survey and health assessment(Mor e)		http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-638- 8/html/kap06_eng.htm	2007
<u>543</u>	Benzyl Alcohol	white paper(Source: unknown )((Mo re)		http://leqacy.library.ucsf.edu/tid/khl05c00/pdf	1997
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf	2004
577	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

## 8.5.6 Reference Year

Reference Year Indicator specifies the year of that particular reference

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Ye
<u>650</u>	Benzyl Alcohol	Opinion of the Scientific Comm <u>(Mor</u> <u>e)</u>		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
<u>678</u>	Benzyl Alcohol	Benzyl alcohol - Report(Source(Mor e)		http://iter.ctcnet.net/publicurl/p_report_12_non.cfm?cm=100-51-6&tvpe=NCO; http://toxnet.nlm.nih.gov/cgi-bin/sis/search	
<u>679</u>	Benzyl Alcohol	Benzyl alcohol regulatory data(More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
<u>513</u>	Benzyl Alcohol	A survey and health assessment(Mor $\underline{e}$ )		http://www2.mst.dk/common/Udqivramme/Frame.asp?http://www2.mst.dk/Udqiv/publications/2007/978-87-7052-638- 8/html/kap06 eng.htm	2007
<u>543</u>	Benzyl Alcohol	white paper(Source: unknown )((Mo re)		http://legacy.library.ucsf.edu/tid/khl05c00/pdf	1997
572	Benzyl Alcohol	Benzyl alcohol Oral risk asses(More)		http://www.techstreet.com/direct/nsf/benzyl_alcohol_Exec_Summ_081204.pdf	2004
<u>577</u>	Benzyl Alcohol	Scientific Opinion on Flavouri(More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

## 8.6 Reviews

This includes the references to the general safety and toxicological reviews and specific reviews

Ex: IPCS, IARC monograph reviews, ASTDR reviews etc.

#### 8.6.1 Ref ID

All references will be given a unique Reference ID. This will help users to identify the references where two or more studies are discussed in one reference. When user clicks "Ref ID" link in the "Reviews" table, entire information of the reference appears as a tabular separate with the "Ref ID, Reference, Title, Author, Reference Type and Year information as shown below

ef ID	Excipient Name	Reference	Source	Source URL			Reference
	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(More)	http://wv	ww.sciencedirect.com/science/referenceworks/9780444510051			2006
	Benzyl Alcohol	Summary data of benzyl alcohol(More)	http://tob	baccodocuments.org/lor/89233462-3493.html?zoom=750&ocr position=ab	ove foramatted☆	t page=1&end page=32	1993
	Ref ID	Reference		Title	Author	Reference Type	Year

#### 8.6.2 Excipient Name

Based on the search criteria the relevant "Excipient Name" appears in the "Excipient Name" column as shown below.

Ref ID Exc	cipient Name	Reference	Source	Source URL	Reference Year
	-	Benzyl alcohol, In: Editor: J(More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
758 Ben:	enzyl Alcohol	Summary data of benzyl alcohol(Mor	2)	http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

### 8.6.3 References

References indicate the source from which the information is extracted. Bibliographic source of the study report or publication will be provided. The references would be linked to their original source

through DOI. The users who need the details of the study will be able to access the full text, if available with their subscription or will be able to access the abstract.

Clinical I	Data (10) Non Cli	nical Data (73) Invitro Data (21) Regula	atory & oth	ar information (7) Reviews (2) Different colors indicates	Unique References
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
<u>704</u>	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
<u>758</u>	Benzyl Alcohol	Summary data of benzyl alcohol(More)		http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

### 8.6.4 Source

Source indicates from which the Reference information is extracted.

Reference Yea
2006
=1&end page=32 1993
s

## 8.6.5 Source URL

Source URL indicates from which the Reference information is extracted.

Z04         Benzyl Alcohol         Benzyl alcohol, In: Editor: J(More)         http://www.sciencedirect.com/science/referenceworks/9780444510051           758         Benzyl Alcohol         Summary data of benzyl alcohol(More)         http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr position=above feetility	2006
758 Benzyl Alcohol Summary data of benzyl alcohol(More) http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr position=above f	2000
	pramatted&start_page=1&end_page=32 1993

## 8.6.6 Reference Year

Reference Year Indicator specifies the year of that particular reference

Clinical [	Data (10) Non Cli	nical Data (73) Invitro Data (21) R	egulatory & oth	er information (7) Reviews (2) Different colors indicate	s Unique References
Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
<u>704</u>	Benzyl Alcohol	Benzyl alcohol, In: Editor: J(More)		http://www.sciencedirect.com/science/referenceworks/9780444510051	2006
<u>758</u>	Benzyl Alcohol	Summary data of benzyl alcohol ( Mo	re)	http://tobaccodocuments.org/lor/89233462-3493.html?zoom=750&ocr_position=above_foramatted&start_page=1&end_page=32	1993

Version- 1.0

### 8.7 Customization using Filters

In the STEP application user is allowed to customize the excipient selection by selecting more than one excipient using "Search BY Excipients" as shown below using CTRL key

Search BY Excipients		
Search BY Excipients		
Excipient Name	Acesulfame K  Alcohol  Aspartame  Benzalkonium Chloride	Instructions on Search BY Excipients page: There are several ways you can search for the excipients. You can search by excipient name (eg. propylene glycol), or by CCS Number (eg. 57-55-6), by synonym (eg 1,2 propanedioi) or by function (eg. solvent)
Synonyms (as per the Handbook of Excipients)	Select from drop down or enter minimum of 3 characters to populate 3-Amino-N-(alpha-Carboxyphenethyl)Succinamic Acid N-Methyl Est Alcohol Alkohol Alkyl Dimethyl Benzyl Ammonium Chloride	Select from drop down or enter enter minimum of 3 characters to populate suggestions. If you don't find the excipient in the excipient name box, try searching in synoymms. For Multiple Excipient/Function Selection Plasae uss "Ctri" or "Mouse click & drag" to select multiple search terms.08 plasae use " +
CAS Registry Number	Select from drop down or enter minimum of 3 characters to populate 22839-47-0 64-17-5 8001-54-5	" icon to open excipients list box for selection. Progressive search will be leaded and filtered on the values already selected in dropdowns. If you've selected a large dataset the results could take some time to load.
Function	Select from drop down or enter minimum of 3 characters to populate	Refine your search by using the filters provided on the results page or there is also a Search FOR excipients option where you can find the excipients by study type, age, or effects or restrict your search to particular study type, age or effect.
	Submit Reset Search FOR Excipients	

Then click "Submit" button then below page appears

	Database of safety and toxicity of excipients for paediatrics	United Prates Pharters in the states
Bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)		Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Excipient(s) Intermediate Page Back          Number of Excipients found: 4         All         Acesuifame K         Acoda         Aspartame         Benzalkonium Chloride         Submit		
	Contact Feedback Disclaimer	GOSTAR GOBIOM

In the above page user is allowed to select one or more than one excipient name using check boxes

As shown below

Eu – US PFI User Guide		Version- 1.0
EuPFi	Database of safety and toxicity of excipients for paediatrics	US PART
bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)		Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Excipient(s) Intermediate Page Back Number of Excipients found: 4 All Acesultame K Acotol Benzalkonium Chloride Submit		
	Contact Feedback Disclaimer	

Click "Submit" to retrieve the results. Then the "Search Results" page appears as shown below

	a reddy (Your log	in session will expire a	after 30 minutes of in	activity)			Search BY Exc	ipients   Search F	OR Excipients   E	xport   User Guide	Help
earch Result	B Back					Total Reference	s: <b>15</b>				Record 1
										Excipien	nt Naviga
eneral Informatio	1										
	I Name: Benzalkon	ium Chloride									
AS Registry Num	ber: 8001-54-5										
Excipient Catego	y/Function :										
Pharmacopoeial											
Regulatory Statu	8:										
Synonyms:											
Acceptable Daily Revision Date:	Intake:										
Clinical Data (3)	Non Clinical Data	(3) Invitro Data	(1) Regulatory	and other information	n (5) Reviews (3	i)			Different co	lors indicates Unique	Referen
	Non Clinical Data ical Columns 🖽	(3) Invitro Data	(1) Regulatory	and other informatior	n (5) Reviews (3	)		Clear All Filt	Different co ers on Clinical Data		
		(3) Invitro Data	(1) Regulatory	and other information	n (5) Reviews (3 Age Units	) Gender	Route of Exposure or Administration	Clear All Filt Dose			nical Data
-	ical Columns 🗉						Route of Exposure or Administration		ers on Clinical Data	Export Filtered Clin	nical Data
Show/Hide Clin Ref ID	ical Columns 🗉 Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Select	Dose	ers on Clinical Data Dose Units	Export Filtered Clin	nical Data ent Dur S
how/Hide Clin Ref ID Select 💉	ical Columns ⊞ Excipient Name Select ✓ Benzalkonium	Study Type	Age Category	Age	Age Units	Gender	Select	Dose	Dose Units	Export Filtered Clin Duration of Treatme Select	nical Data ent Dui S Hour
Show/Hide Clin Ref ID Select 💌	ical Columns  Excipient NameSelect Benzalkonium Benzalkonium	Study Type	Age Category	Age Select 34 (Mean age)	Age Units Select 💙 Years	Gender Select 🗸	Select 💌	Dose	ers on Clinical Data Dose Units Select	Export Filtered Clin Duration of Treatme Select	nical Data
Ref ID Select V 121 171	Excipient Name Select ♥ Benzalkonium Chloride Benzalkonium Chloride Benzalkonium	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Age CategorySelect Adult Adult	Age Select 34 (Mean age) Unspecified	Age Units	Gender Select V Male Male	Topical	Dose          Select         •           0.5; 1         0.5	Provide     Provide       Provide     Provide       %     Provide       %     Provide       %     Provide	Export Filtered Clim Duration of Treatmee Select V 48	nical Data nt Dur S Hour Hour
Ref ID Select V 121 171	Excipient Name Select ♥ Benzalkonium Chloride Benzalkonium Chloride Benzalkonium	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Age CategorySelect Adult Adult	Age Select 34 (Mean age) Unspecified	Age Units	Gender Select V Male Male	Topical	Dose          Select         •           0.5; 1         0.5	Provide     Provide       Provide     Provide       %     Provide       %     Provide       %     Provide	Export Filtered Clim Duration of Treatmee Select V 48	nical Data nt Dur Si Hour Hour

Here user can able to filter the data in all 3 (Clinical Data, Non Clinical Data and Invitro Data) tabs in 2 ways.

- a. Horizontally (Row wise) Filtering.
- b. Vertically (Column wise) Filtering.

EUPF	Ă				EP databa			United States	Pediatric Permulation Initiative
bodhanapu venk	kata reddy (Your k	ogin session will expire	e after 30 minutes of i	inactivity)	Search BY	Excipients   Sea	arch FOR Excipients   Export	User Guide   Help	Log
Search Result	ts <u>Back</u>				Total References	15		R	lecord 1 o
Excipient Chemic CAS Registry Nur									
CAS Registry Num  Description: Excipient Categor  Description: Pharmacopoelal  Regulatory State  Synonyms: Acceptable Daily Revision Date:	nber: 8001-54-5 ory/Function : I Status: us: y Intake:	(3) Invitro Data	(1) Perulatory	and other information	n (5) Penjewe (3	-	Different es	lors indicatos Unique Pe	foronces
CAS Registry Num  Description: Excipient Categor  Description: Pharmacopoelal  Regulatory State  Synonyms: Acceptable Daily Revision Date:	nber: 8001-54-5 ory/Function : IStatus: Js: y Intake: Non Clinical Data	(3) Invitro Data	(1) Regulatory a	and other information	n (5) Reviews (3	•	Officiant so	lors indicator Universe a Export Filtered Clinic	foroncos al Data
CAS Registry Num     Excipient Catego     Pharmacopoelal     Regulatory Statt     Synonyms:     Acceptable Daily     Revision Date:     Clinical Data (3)	nber: 8001-54-5 ory/Function : IStatus: Js: y Intake: Non Clinical Data	(3) Invitro Data Study Type	(1) Regulatory a	ind other information	n (5) Reviews (3 Age Units	) Gender	Clear All Filters on Clinical Dat Route of Exposure or Administ		former es al Data Dos
CAS Registry Num Excipient Catege Pharmacopoeial Regulatory Statu Synonyms: Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clinical	nber: 8001-54-5 ory/Function : I Status: Js: y Intake: Non Clinical Data								
CAS Registry Num Excipient Catege Pharmacopoelal Regulatory Statt Synonyms: Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clin Ref ID	nber: 8001-54-5 ory/Function : I Status: Js: Vintake: Non Clinical Data nical Columns Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administ	ration Dose	Dos
CAS Registry Num     Excipient Catege     Pharmacopoeial     Regulatory Statu     Synonyms:     Acceptable Daily     Revision Date:     Clinical Data (3)     Show/Hide Clin     Ref ID    Select	nber: 8001-54-5 ory/Function : Status: Istatus: Intake: Non Clinical Data Excipient NameSelect Benzalkonium	Study Type	Age Category	Age Select 💌	Age Units	Gender	Route of Exposure or Administ	Select V	Dos Sele

#### A. Horizontal (Row wise) Filtering:

For example user is trying to apply the filters on Clinical Data tab;

a. User is applying the filtering criteria on any one of the columns, say Ref ID as shown below.

	Å			Database of sa	EP databa			United States	Pediato
🚨 bodhanapu ven	kata reddy (Your I	ogin session will expir	e after 30 minutes of i	for paediatrics		Excipients   Se	arch FOR Excipients   Export   Us	ser Guide   Help	
Search Resu	lts <u>Back</u>				Total References	: 15		R	ecore
Excipient Cnemic     CAS Registry Nu     Excipient Categ     Pharmacopoeia     Regulatory Stat     Synonyms:     Acceptable Dat     Revision Date:	jory/Function : il Status; tus:	ium Chionde							
Clinical Data (3)	Non Clinical Data		(1) Regulatory a	and other information	n (5) Reviews (3	)		ndicates Unique Re	
Clinical Data (3)	Non Clinical Data inical Columns 👁 Excipient Name		(1) Regulatory a	and other informatio	n (5) Reviews (3 Age Units	) Gender		xport Filtered Clinic	al Da
Clinical Data (3) Show/Hide Cli	inical Columns 🗄 Excipient Name						Clear All Filters on Clinical Data E	xport Filtered Clinic	
Clinical Data (3) Show/Hide Cli Ref ID I	inical Columns 🗄 Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Clear All Filters on Clinical Data E Route of Exposure or Administration	xport Filtered Clinic	al Da
Clinical Data (3) Show/Hide Cli Ref ID Select	Excipient Name	Study TypeSelect Other study type - Lab/Drug de	Age Category	Age	Age Units	Gender	Clear All Filters on Clinical Data E Route of Exposure or Administration	xport Filtered Clinic Dose	al Da

Filter criteria is on 'Ref ID' with '171, 1016' Value.

Based on the filter criteria the corresponding values will be filtered in the Clinical Data table.

b. If user wants to apply the filter on any one of the other fields, say "Age" as shown below.

EUPF	I.				EP databa			United States	Pediatric Formulation Initiative
bodhanapu venkat	<mark>a reddy (Your lo</mark>	ogin session will expir	e after 30 minutes of	inactivity)	Search BY	Excipients   Se	arch FOR Excipients   Export	User Guide   Help	o   Log
earch Results	Back				Total References	: 15		F	Record 1
eneral Information								Excipien	it Naviga
xcipient Chemical AS Registry Numb		ium Chloride							
Excipient Category	/Function :								
Pharmacopoeial St	tatus:								
Regulatory Status:									
Synonyms:									
Acceptable Daily In	ntake:								
Revision Date.									
Clinical Data (3)	Non Clinical Data	(3) Invitro Data	(1) Regulatory a	and other informatio	n (5) Reviews (3	)	Different colors	indicates Unique Re	eference
how/Hide Clinic	al Columns 🗉						Clear All Filters on Clinical Data	Export Filtered Clini	cal Data
Ref ID 🜌	Excipient Name	Study Type	Age Category		Age Units	Gender	Route of Exposure or Administrati		Dos
Ref ID	Excipient Name	study Type	Age Category	Age 🗹	Age Units	Gender	Route of Exposure of Administrati	on Dose	Dos
Select 🗸	Select 🗸	Select 🗸	Select 🗸	Select 🗸	Select 🗸	Select 🗸	Select 🔽	Select 💌	Sel
1016 E	Benzalkonium	Unspecified	0 duile	18 to 61	Veen	Male	Tanial	0.5 (15)	% w/v
1010	Chloride	Unspecified	Adult	18 10 61	Years	male	Topical	0.5 (15)	Chamb

Filter criteria is on 'Ref ID' with '171, 1016' value and 'Age' with '18 to 61' value.

Based on the filter criteria the corresponding values get progressively filtered in the Clinical Data table.

If the user want to apply the filter on the already filter applied field(s), in the dropdown of the field will contain the distinct values of the visible rows from the data (i.e. Already filter applied value (121) in that respective field (Ref ID) will not be displayed).

User can able to Clear all filters which are applied on that particular tab will be cleared by using "Clear All Filters on Clinical Data" Button as shown below.

EUPF					Fety and toxicity of ex			United States	Pediatric Formulatio Initiative
bodhanapu venk	ata reddy (Your k	ogin session will expir	e after 30 minutes of i	inactivity)	Search BY	Excipients   Sea	arch FOR Excipients   Export	User Guide   Help	Lo
Search Result	ts <u>Back</u>				Total References	: 15		R	Record 1
EXCIPIENT Catego Excipient Catego Pharmacopoeial Regulatory Statu	ory/Function : Status:	ium Chloride							
	Intake:								
Acceptable Daily Revision Date:		(3) Invitro Data	(1) Regulatory a	and other information	n (5) Reviews (3	)	Different color	s indicates Unique Re	eference
Synonyms: Acceptable Daily Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Cliri		(3) Invitro Data	(1) Regulatory a	and other information	n (5) Reviews (3	)	Different color Clear All Filters on Clinical Data	s indicates Unique Re Export Filtered Clinic	
Acceptable Daily Revision Date: Clinical Data (3)	Non Clinical Data	(3) Invitro Data Study Type	(1) Regulatory a Age Category Select	Age	n (5) Reviews (3 Age Units Select	) Gender Select v		Export Filtered Clinic	
Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clin Ref ID	Non Clinical Data nical Columns 🕑 Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Clear All Filters on Clinical Data Route of Exposure or Administrati	Export Filtered Clinic	cal Data Do
Acceptable Daily Revision Date: Clinical Data (3) Show/Hide Clir Ref ID Select	Non Clinical Data nical Columns ® Excipient Name Select V Benzalkonium	Study Type	Age CategorySelect Adult	Age Select 💌	Age Units	Gender	Clear All Filters on Clinical Data Route of Exposure or Administrati	Export Filtered Clinic ion Dose	cal Data Do Se

This will be applicable for all the fields in the Clinical Data tabs where ever it is applicable.

The same filtering functionality will be applicable for Non Clinical Data and Invitro Data tabs in the "Search Results" page.

#### Note:

- 1. User can identify the filter(s) applied field(s) by observing the filter image(s) beside the field(s) name.
- Once the filter is applied on the particular filter then again user wants to apply the filter on the same field then the only values which are visible are available in the dropdown to filter the data. (I.e. if user wants to change the filtering criteria then user will clear the filters by clicking on Clear All Filters button on the particular tab/section wise.)

#### B. Vertical (Column wise) Filtering:

For example user is trying to apply the vertical (Show/Hide) filters on Clinical Data tab;

Proposed functionality is as below.

a. If User is trying to apply the vertical filter(s) on any one of the columns, say Ref ID as shown below.

•		r loain session will ex	pire after 30 minute:	s of inactivity)	Search BY	'Excipients I Se	arch FOR Excipient	s   Export	User Guide   Help	l Loo
Search Results	Back				Total References	: 15				Record 1
									Excipien	t Navigat
General Information	2									
Excipient Chemical		onium Chloride								
CAS Registry Numb	ber: 8001-54-5									
+ Evenient Cata	u/Eurotion :									
<ul> <li>Excipient Categor</li> <li>Pharmacopoeial S</li> </ul>										
<ul> <li>Regulatory Status</li> </ul>										
* Synonyms:										
	Intake:									
Acceptable Daily I     Revision Date:	Intake:									
Acceptable Daily I     Revision Date:								Difference		
Acceptable Daily I     Revision Date:     Clinical Data (3)	Non Clinical Da	ta (3) Invitro Da	ta (1) Regulato	ory and other informatio	n (5) Reviews (3	i)		Different colors	indicates Unique R	eference
Acceptable Daily I     Revision Date:     Clinical Data (3)	Non Clinical Da	ta (3) Invitro Da	ta (1) Regulato	ory and other informatio	n (5) Reviews (3	i)	Clear All Filters		indicates Unique R Export Filtered Clini	
Acceptable Daily I	Non Clinical Da	1	ta (1) Regulato	ory and other informatio	n (5) Reviews (3 Gender		Clear All Filters	on Clinical Data		
Acceptable Daily I     Acceptable Daily I     Revision Date:     Clinical Data (3)     Show/Hide Clini     Ref ID     Scipient Name	Non Clinical Da	1	Age	Age Units	Gender	Route of Exposu		on Clinical Data	Export Filtered Clini Dose Units	cal Data Durati
Acceptable Daily I     Acceptable Daily I     Acvision Date:     Clinical Data (3)     Show/Hide Clini     Ref ID     Excipient Name     Study Type	Non Clinical Da	1	Age					on Clinical Data	Export Filtered Clini Dose Units	cal Data
Acceptable Daily I     Acceptable Daily I     Acvision Date:     Clinical Data (3)     Show/Hide Clini     Ref ID     Excipient Name     Study Type     Ace Category	Non Clinical Da	1	Age Select	Age Units	Gender	Route of Exposur		n Clinical Data n Dose Select V	Export Filtered Clini Dose Units	cal Data Durati
Acceptable Daily I     Acceptable Date:     Acceptable Date:     Clinical Data (3)     Show/Hide Clini     Ref ID     Excipient Name     Study Type     Age Category     Age	Non Clinical Da	1	Age	Age Units	Gender	Route of Exposu		on Clinical Data	Export Filtered Clini Dose Units	cal Data Durati
Acceptable Daily I     Acceptable Date:     Ac	Non Clinical Da ical Columns		Age Select	Age Units	Gender	Route of Exposur		n Clinical Data n Dose Select V	Export Filtered Clini Dose Units	cal Data Durati
Acceptable Daily I     Acceptable Daily I     Acceptable Data (3)     Clinical Data (3)     Show/Hide Clini     Ref ID     Excipient Name     Study Type     Age Category     Age     Age Units	Non Clinical Da ical Columns		Age Select	Age Units	Gender	Route of Exposur		n Clinical Data n Dose Select V	Export Filtered Clini Dose Units	cal Data Durati
Acceptable Daily I     Acceptable Date:     Ac	Non Clinical Da ical Columns		Age Select 34 (Mean age	Age Units Select Years	Gender Select V Male	Route of Exposur		n Clinical Data Dose Select • 0.5; 1	Export Filtered Clini Dose Units Select V % aq	Cal Data Duration Sele 48
Deceptable Daily 1     Revision Date:     Clinical Data (3)     Show/Hide Clini     Ref ID     Excipient Name     Study Type     Age     Age Category     Age     Gender     Route of Expose	Non Clinical Da ical Columns		Age Select 34 (Mean age	Age Units Select Years	Gender Select V Male	Route of Exposur		n Clinical Data Dose Select • 0.5; 1	Export Filtered Clini Dose Units Select V % aq	Cal Data Duration Sele 48

Based on the filter criteria the corresponding Column & Values will be hidden on the Clinical Data table.

If user wants to apply the filters on any one of the other fields, say "Excipient Name" as shown below.

						L FOR F L L	1 m 1 m	0.11	
odhanapu venk	ata reddy (Your I	ogin session will expir	e after 30 minutes of i	nactivity)	Search BY Excipients   Se	arch FOR Excipients	Export Us	er Guide	Help   Lo
earch Result	s <u>Back</u>				Total References: 15				Record 1
								Exci	ipient Naviga
neral Informatio	<u>n</u>								
cipient Chemica	I Name: Benzalkor	ium Chloride							
S Registry Num	ber: 8001-54-5								
Excipient Catego	n/Eunction								
Excipient Catego Pharmacopoeial									
. marmacopoeiai									
Regulatory Statu	S:								
	S:								
Regulatory Statu Synonyms: Acceptable Daily									
Synonyms:									
Synonyms: Acceptable Daily Revision Date:	Intake:	(3) Invitro Data	(1) Regulatory a	and other information	n (5) Deviews (3)		Different colors in	dicates Uniqu	ue Reference
Synonyms: Acceptable Daily Revision Date: Clinical Data (3)	Intake: Non Clinical Data	(3) Invitro Data	(1) Regulatory a	nd other information	n (5) Reviews (3)		Different colors in		
Synonyms: Acceptable Daily Revision Date: Clinical Data (3)	Intake: Non Clinical Data ical Columns 🕀					Clear All Filters or	Clinical Data E	xport Filtered	Clinical Data
Synonyms: Acceptable Daily Revision Date: Clinical Data (3)	Intake: Non Clinical Data	(3) Invitro Data	(1) Regulatory a	nd other informatio	n (5) Reviews (3) Route of Exposure or Administratio	Clear All Filters or			Clinical Data
Synonyms: Acceptable Daily Revision Date: Alinical Data (3) how/Hide Clin Study Type	Intake: Non Clinical Data ical Columns 🕀					Clear All Filters or	Clinical Data E	xport Filtered	Clinical Data
Synonyms: Acceptable Daily Revision Date: Inical Data (3) Now/Hide Clin Study Type Select	Intake: Non Clinical Data ical Columns @ Age Category Select v	Age Select	Age Units	Gender	Route of Exposure or Administratio	Clear All Filters or Dose	Clinical Data E Dose Units	Duration of	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: Clinical Data (3) how/Hide Clin Study Type	Intake: Non Clinical Data ical Columns @ Age Category Select v	Age	Age Units	Gender	Route of Exposure or Administratio	Clear All Filters or Dose	Clinical Data E	port Filtered	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: linical Data (3) tow/Hide Clin Study Type Select	Intake: Non Clinical Data ical Columns @ Age Category Select v	Age Select	Age Units	Gender	Route of Exposure or Administratio	Clear All Filters or Dose	Clinical Data E Dose Units	Duration of	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: lifiical Data (3) atow/Hide Clin Study Type Select V ther study type ther study type ther study type	Intake: Non Clinical Data ical Columns @ Age Category Select v	Age Select	Age Units	Gender	Route of Exposure or Administratio	Clear All Filters or Dose	Clinical Data E Dose Units	Duration of	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: ilinical Data (3) <b>study Type</b> Select ther study type ther study type ther study type	Intake: Non Clinical Data tical Columns @ Age Category Select	Age Select 💌 34 (Mean age)	Age UnitsSelect	Gender Select 💌 Male	Route of Exposure or Administratio	Clear All Filters on Dose Select V 0.5; 1	Clinical Data E Dose Units Select V % aq	Duration of Select 48	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: Ilinical Data (3) now/Hide Clin Study Type Select Select  wither study type ther study type ther study type uther study type Viore)	Intake: Non Clinical Data tical Columns @ Age Category Select	Age Select 💌 34 (Mean age)	Age UnitsSelect	Gender Select 💌 Male	Route of Exposure or Administratio	Clear All Filters on Dose Select V 0.5; 1	Clinical Data     Example       Dose Units      Select       % aq	Apport Filtered Duration of Select 48 48	Clinical Data Treatment
Synonyms: Acceptable Daily Revision Date: Inical Data (3) Now/Hide Clin Study Type Select	Intake: Non Clinical Data tical Columns @ Age Category Select	Age Select 💌 34 (Mean age)	Age UnitsSelect	Gender Select 💌 Male	Route of Exposure or Administratio	Clear All Filters on Dose Select V 0.5; 1	Clinical Data E Dose Units Select V % aq	Duration of Select 48	Clinical Data Treatment

Search Results

This will be applicable for all the fields in the Clinical Data tab where ever it is applicable.

The same filtering functionality will be applicable for Non Clinical Data and Invitro Data tabs in the "Search Results" page.

### 8.8 Show/Hide Columns

User is also allowed to view or to hide the required columns using the "Show/Hide Columns" as shown below

Clinical Data (3)	Non Clinical Data	(3) Invitro Data	(1) Regulatory a	nd other informatior	(5) Reviews (3)	)			Different color	s indicates Unique Refer	rences
Show/Hide Cliı	nical Columns 🗄	]						Clear All Filters	on Clinical Data	Export Filtered Clinical D	ata
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Dur
Select 🔽	Select 💌	Select	Select	Select	Select	Select 🔽	Select	Select	Select 🔽	Select	Se
<u>121</u>	Benzalkonium Chloride	Other study type	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	Houn
<u>171</u>	Benzalkonium Chloride	Other study type - Lab/Drug de (More)	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48	Hour
<u>1016</u>	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	Hour
•											4

When user clicks "[+]" besides "Show/Hide Columns" then it displays all the columns in the page as shown below. By default all the columns appears in the checked state.

how/Hide C	linical Columns 🗉							Clear All Filters	on Clinical Data	Export Filtered Clinical D
🔽 Ref ID		_	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
Excipient N Study Type		Ξ	Select 💌	Select 💌	Select 💌	Select 🔽	Select	Select 💙	Select 💌	Select 🔽
☑ Age Catego ☑ Age ☑ Age Units	ry		Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48
Gender Route of Ex	posure or Administra	tion -	Adult	Unspecified	Unspecified	Male	Topical	0.5	%	48
.016	Benzalkonium Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48

User is allowed to customize the required columns to display the information using the check boxes as shown below

Clinical	Data (3)	Non Clinical Data	(3) Invitro Dat	a (1) Regulatory and other information	(5) Reviews (3)				Different colo	rs indicates Uniqu	e References
Show/	Hide Clin	ical Columns 🗆		_				Cl	ear All Filters on Clinical Data	Export Filtered Cli	nical Data
🗹 Ref			T	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	Duration Units	Frequency of Administration	System/Organ	Safety / Tol
🗹 Stud	ipient Nam dy Type	e	-	Select 💙	Select 💌	Select 💌	Select 💌	Select 💌	Select	Select 💌	
🗖 🗛 ge	Category Units			Topical	0.5; 1	% aq	48	Hours	Unspecified	Integumentary System	Irritant cont
and a second	ider ite of Expos	sure or Administrat	ion .	Topical	0.5	%	48	Hours	once	Integumentary System	Scaling or fi
<u>1016</u>		Unspecified	Years	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	Hours	Once	Integumentary System	Predominan (More)
<											

When user selects the required columns then the page gets refreshed and search results page only displays the selected columns as shown below

how/Hide Clinical Colu	nns		Clear All Filters on Clinical Data	Export Filter	d Clinical Data
Ref ID	Study Type	Age Units	Route of Exposure or Administration	Reference	Reference Yea
Select	Select 💌	Select	Select		
121	Other study type	Years	Topical	NA, Willis CM, Stephens JM, Wi <u>(More)</u>	1988
71	Other study type - Lab/Drug de(More)	Unspecified	Topical	NA, Willis CM, Stephens CJ, Wi (More)	1992
1016	Unspecified	Years	Topical	NA, Willis CM, Stephens CJ, Wi (More)	1989

## 8.9 Navigations in Search Results page

Whenever user selects more than one excipient as shown below

	Database of safety and toxicity of excipients for paediatrics		USSPER
Bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity)		Search BY Excipients   Search FOR Excipients	User Guide   Help   Logout
Excipient(s) Intermediate Page Back          Number of Excipients found: 3         Image: Constraint of Excipients found: 3			
	Contact Feedback Disclaimer		GOSTAR GOBIOM

Then clicks "Submit" button search results page appears displaying the corresponding information along with the navigation links to navigate in between the excipient selected as shown below

Served Information       Excipient Nave       Excipient Nave       Excipient Nave         Served Information       Chindre       Excipient Nave       I       Get First        Excipient Nave         Served Information       Chindre       Excipient Nave       I       Get First        F		11 050	r Guide								Versio	<b>n-</b> 2
Search Result Back Data Reference: 15		- *				Database o	f safety and toxicity of				United States	Pediatric Formulatio Initiative
Carcinet Information	oodhanapu venka	ata reddy (Your log	in session will expire	after 30 minutes of in	activity)			Search BY Exc	ipients   Search F	OR Excipients   E	xport   User Guide	Help
Restant Charming	Search Resul	lts <u>Back</u>					Total Reference	s: 15			F	Record 1
CAS Registy Number: 8011-54-5         *: Dicipient Category/Function :         *: Status	eneral Informati	<u>on</u>								1 Go		-
Pharmacopoeial Status:         Preprint         Pharmacopoeial Status:         Pharmacopoeial Status:     <			ium Chloride									
# Acceptable Daily Intere# existion Date:Invitre Data ()Invitre Data ()Regulatory and the information ()Reviews ()Different Coloma ()Different Coloma ()Different Coloma ()Export Filtered Cline ()Different Cline ()<	Pharmacopoeia	al Status:										
Clear All Filters on Clinical Data       Export Filtered Clinical Data       Dose       Dose       Dose       Duration of Treatment       D         Image: Select-I V       Image: Sele	Acceptable Dail	ly Intake:										
Ref D       Excipient Name       Study Type       Age Category       Age       Age Units       Gender       Route of Exposure or Administration       Dose       Dose Units       Duration of Treatment       D        Select      Select-	10 C			(1) Regulatory a	and other information	1 (5) Reviews (3	)				1	Referer
Select	snow/Hide Cli	nical Columns ±										
121     Chloride     Unter study type     Adult     34 (Hean age)     Tears     Male     Topical     0.5; 1     % ag     48     He       121     Benzalkonium Chloride     Other study type i.uk/brg de Chloride     Adult     Unspecified     Male     Topical     0.5     %     48     He       1016     Benzalkonium Chloride     Unspecified     Adult     18 to 61     Years     Male     Topical     0.5 (15)     % w/v (ul/Finn Chamber)     48     He	Ref ID	Excipient Name		Age Category	Age	Age Units	Gender	Route of Exposure or Administration				_
121     Deficial control     - Lab/Orug de (More)     Adult     Unspecified     Male     Topical     0.5     %     48     Ho       1016     Benzalkonium Chloride     Unspecified     Adult     18 to 61     Years     Male     Topical     0.5 (15)     % w/v (ul/Finn Chamber)     48     Ho			Study Type						Dose	Dose Units	Duration of Treatme	nt Du
Interview     Aduit     10 to 01     rears     Mole     ropical     0.5 (15)     Chamber)     46     no	Select 💌	Select 🗸	Study Type	Select 💌	Select 💌	Select 💌	Select 💌	Select	Dose	Dose Units	Duration of Treatmen	nt Du
	Select v	Select V Benzalkonium Chloride	Study Type	Select 💌	Select 💌 34 (Mean age)	Select 💌 Years	Select 💌 Male	Select V	Dose	Dose Units	Duration of Treatmen	nt Du
	Select 💌 121 171	Select     Benzalkonium     Chloride     Benzalkonium     Chloride	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Select 💌 Adult Adult	Select V 34 (Mean age) Unspecified	Select 💙 Years Unspecified	Select 💌 Male Male	Select V Topical Topical	Dose Select 0.5; 1 0.5	Dose UnitsSelect % aq %	Duration of Treatment Select 48 48	nt Dui S Hour Hou
	Select 💌 121 171	Select     Benzalkonium     Chloride     Benzalkonium     Chloride	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Select V Adult Adult Adult	Select V 34 (Mean age) Unspecified	Select 💙 Years Unspecified	Select 💌 Male Male	Select V Topical Topical	Dose Select 0.5; 1 0.5	Dose UnitsSelect % aq %	Duration of Treatment Select 48 48	nt Du S Hou Hou
Developed by GVK BIO Contact Feedback Disclaimer GOSTAR GOBI	Select 💌 121 171	Select     Benzalkonium     Chloride     Benzalkonium     Chloride	Study Type Select V Other study type Other study type - Lab/Drug de (More)	Select V Adult Adult Adult	Select V 34 (Mean age) Unspecified	Select 💙 Years Unspecified	Select 💌 Male Male	Select V Topical Topical	Dose Select 0.5; 1 0.5	Dose UnitsSelect % aq %	Duration of Treatment Select 48 48	_

When user selects multiple excipients then only these navigation links appears using which user can view the search results information of the related excipient.

Based on the selection initially "Benzalkonium chloride" information is displaying as shown below.

Here user is able to navigate among the excipients by using excipients navigation by using respective links (First, Previous, Next and Last) or Giving direct record number in the text field and then clicks on Go button.

Excipients navigation by using respective links like below,

#### Version- 1.0

	S Back				Total	References: 93				Record 2
										Excipient Naviga
neral Information	<u>n</u>							2	Go 4 First <	Previous >Next +
cipient Chemica	al Name: Benzyl Alc	ohol								
AS Registry Num										
- · · · • • •										
Excipient Catego Pharmacopoeial										
Regulatory Statu										
Synonyms:	J.									
Acceptable Daily	Intake:									
Revision Date:										
Clinical Data (10)	Non Clinical Dat		Regulatory and	other information (7)	) Reviews (2)					ates Unique Referen
now/Hide Clin	ical Columns 🗉						Clea	ar All Filters on Clin	ical Data Export	Filtered Clinical Data
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatn
	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	
										Duration of Treatn
Select 🔽	Select 💙	Select V	Select ¥	Select 💙	Select ¥	Select 💌	Select V	Select 💙	Select 💌	Duration of Treatm
Select 🔽										Duration of Treatn
Select	Select 💙	Select V	Select ¥	Select 💙	Select ¥	Select 💌	Select V	Select 💙	Select 💌	Duration of Treatm
Select 💌	Select 💟 Benzyl Alcohol	Select 💌 Case study	Select 💌 Adult Preterm	Select	Select	Select	Select V	Select 💌	Select 💌	Duration of Treatm
Select 💌	Select 💙	Select V	Select 💌	Select 💙	Select ¥	Select 💌	Select V	Select 💙	Select 💌	Duration of Treatm
Select 💌	Select 💟 Benzyl Alcohol	Select V Case study ADME/Pharmacokinetics	Select V Adult Preterm newborn infants	Select	Select	Select	Select V	Select 💌	Select 💌	Duration of Treatm
Select v	Select V Benzyl Alcohol Benzyl Alcohol	Select Case study ADME/Pharmacokinetics ADME/Pharmacokinetics	Select  Adult Preterm newborn infants (born (,More) Term newborn	Select V	Select V	Select V Male/Female Unspecified	Select V Topical Parenteral	Select V	Select V	Unspecified
Select 💌	Select 💙 Benzyl Alcohol	Select V Case study ADME/Pharmacokinetics studies	Select V Adult Preterm newborn infants (born (More)	Select	Select	Select	Select V	Select 💌	Select 💌	Duration of Treatm

Excipients navigation by giving record number and clicks on Go Button as like below,

earch Result	s <u>Back</u>				Total R	eferences: 316				Record 3
										Excipient Naviga
eneral Informatio	m							3	Go 4 First <	Previous >Next I
xcipient Chemica AS Registry Nun	al Name: Propylene nber: 57-55-6	Glycol								
Excipient Catego	ory/Function :									
Pharmacopoeial	Status:									
Regulatory Statu	IS:									
Synonyms:										
Acceptable Daily	Intake:									
Revision Date:										
how/Hide Clir Ref ID	nical Columns 🗉	0. I T							ical Data Export	Filtered Clinical Dat
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatn
Select 🔽	Select 🔽	Select 💌	Select 💌	Select 🔽	Select 💌	Select 💌	Select 🔽	Select 💌	Select 💌	Select 💌
<u>19</u>	Propylene Glycol	Randomized controlled clinical(More)	Adult	21-28	Years	Male/Female	Oral	1 : 8 (In water)	Ratio	3
21	Propylene Glycol	Other study type	Adult	34 (Mean age)	Years	Male	Topical	50; 100	% aq	48
22	Propylene Glycol	Randomized controlled clinical(More)	Unspecified	Unspecified	Unspecified	Unspecified	Parenteral	35	vol %	1
	Propylene Glycol	Unspecified	Unspecified	Unspecified	Unspecified	Unspecified	Topical	20	%	1
23										
123										

Note:

 If user clicks on Ref ID from any section (Clinical Data, Non Clinical Data, Invitro Data, Regulatory & other information and Reviews), it will display the details about that particular reference. Once if the user moved from one tab/section to another then that reference details will be disappear.

### 8.10 Filtered Data Export

This application will provide the "Option of exporting only the data that has been filtered by the user". Filtered data export feature is available for 3 sections (Clinical Data, Non Clinical Data and Invitro Data)

Here user can export the data that has been filtered either horizontally or vertically or combination of both filters. For this user can find the respective button(s) to export the filtered data in the search results page in 4 cases as given below.

EUPF	el estatua				eP databa			United States	Pediatric Formulation Initiative
oodhanapu venk	ata reddy (Your I	ogin session will expir	e after 30 minutes of i	inactivity)	Search BY	Excipients   Sea	arch FOR Excipients   Export   U	Jser Guide   Hel	p   Log
earch Result	ts <u>Back</u>				Total References	: 15			Record 1
								Excipier	nt Naviga
neral Informatio	<u>on</u>								
cipient Chemic	al Name: Benzalkon	ium Chloride							
	nber: 8001-54-5								
F									
Excipient Catego									
Pharmacopoeial Regulatory Statu									
Synonyms:	10.								
Acceptable Daily	/ Intake:								
Revision Date:									
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	nical Columns 🗉	(3) Invitio Data	(1) Regulatory a	and other information	II (5) Reviews (5	<mark>)</mark>			
								Export Filtered Clin	_
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	n Dose	Do
Select	Select 💌	Select 🔽	Select	Select	Select	Select 💌	Select	Select	Sel
Select 🔽	Select 💌 Benzalkonium Chloride	Select 💌		Select 💌	Select	Select	Select V	Select •	Sel % aq
	Benzalkonium								

#### Case: 1

Filtered Data export by applying Horizontal Filters:

Here user can able to export the filtered data by applying horizontal filters in search results page for clinical data.

EUPF	Å				EP databa			United States	Pediatrio Pormulation Initiative
bodhanapu venka	ta reddy (Your l	ogin session will expir	e after 30 minutes of i	inactivity)	Search BY	Excipients   Sea	arch FOR Excipients   Export   U	lser Guide   Help	Log
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eneral Information xcipient Chemica AS Registry Num	I Name: Benzalkon	ium Chloride							
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Regulatory Status									
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Revision Date.									
Clinical Data (3)	Non Clinical Data	(3) Invitro Data	(1) Regulatory a	ind other information	n (5) Reviews (3	)	Different colors i	ndicates Unique Re	ference
how/Hide Clin	ical Columns 🗉						Clear All Filters on Clinical Data	Export Filtered Clinic	al Data
Ref ID 🜌	Excipient Name	Study Type	Age Category	Age 🗹	Age Units	Gender	Route of Exposure or Administration	Dose	Dos
Select	Select 💌	Select 💌	Select	Select	Select	Select 💌	Select	Select 💌	Sele
	Benzalkonium								% w/v
1016	Chloride	Unspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	Chamb
									-

If user wants to export this filtered data, then click on "Export Filtered Clinical Data" button.

It will display one dialog box, which will contain all the fields available in that respective table like below.

EUPFI	Clinical Data		Data		×		United Btates	Pediatrie Promulation Initiative
🚨 bodhanapu venkata reddy 🛛 (Your logi		be .				a ch FOR Excipients   Export   U	ser Guide   Help	Logout
Search Results Back	Age Catego Age Age Units Gender							Record 1 of 1
General Information Excipient Chemical Name: Benzalkoniur CAS Registry Number: 8001-54-5 Excipient Category/Function : Pharmacopoeial Status: Regulatory Status: Synonyms: Acceptable Daily Intake: Revision Date:	Dose     Dose Unit     Dose Unit     Duration (     Duration (     System/O     Safety / T     Dosage Fc     Conclusion     Reference     Reference	of Treatment Units y of Administration Irgan Tolerability / Adver orm n / Comments 3 Type	ı				Excipien	t Navigation
Clinical Data (3) Non Clinical Data (3 Show/Hide Clinical Columns ®	Reference		rt to Excel Expo	t to PDF			ndicates Unique Re	
Ref ID 2 Excipient Name	Study Type	Age Category	Age 🖼	Age Units	Gender	Clear All Filters on Clinical Data Route of Exposure or Administration	xport Filtered Clini	Dos
	Select 💌	Select	Select	Select	Select 💌	Select	Select	Sele
1016 Benzalkonium U Chloride	inspecified	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v Chamb
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Search Results

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

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Filtered tit ⊻i	Results_Clini w <u>D</u> ocum	nicalData_H. Nent Iools	Lindow 1 /1 Cl Re Ex Stu Ag Ag Ge Ra Ag Bg Ge Co Do Do Do Do Do Do Do Do Do Do Do Do Co Co Re Eff	Help inical D cord No: f ID cipient Na Jdy Type e Categor e	ata: 1 mme ry Creatmen its of Adminis an rrability / m Comme	r nt istration Adverse	1010 Benz Unsp Adult 18 toto Year Mate Topic 0.5 ( % w/ 48 Hour Once Integ Pred exoc in the shru Vacu Pato The I NA, 1 and 4	ealkonium pecified t of 1 s s cal 15) v (µl/Finn s ominanti ytosis of s upper si hen pykk olation, lij h patch tes Wills CM	Chambe     System     mild in r     small nun     ratum sp notic nucl     pid accun     ts of benz     , Stephen     nicroscop	eactions v her of pr ionosum, e. disrupier, disrupier nulation w alkonium is CJ, Will is CJ, Will	edominai ultrastru ied organ ithin kera chloride kinson JL J Invest [	ntly mono ctuarally f helles and atinocytes on huma D. Epiden Dermatol.	nuclear the affect I membra s was rar n skin pr mal dama 1989 No	cells, occ ted kerat ane and c ely obser oduced p age indu- ov.93(5).(	asional fi nocytes v considera ved redomina red by im 395-9(uil.	oci of nec were char ble intrac antly mild itants in n	rotic dar racterize vtoplasn reactior	mage		100% (	_	

#### Case: 2:

Filtered Data export by applying Vertical Filters:

Here user can able to export the filtered data by applying vertical filters in search results page for clinical data.

bodhanapu venk				for paediatrics					
	ata reddy (Your I	ogin session will expir	e after 30 minutes of i	inactivity)	Search BY Excipients   Sear	rch FOR Excipients	Export   Us	er Guide   Help	Lo
earch Result	S <u>Back</u>				Total References: 15			Record	d 1
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xcipient Chemics	al Name: Benzalkor	ium Chloride							
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Revision Date:	intake.								
Clinical Data (3)	Non Clinical Data	(3) Invitro Data	(1) Regulatory a	and other information	n (5) Reviews (3)		Different colors in	dicates Unique Referer	ICE
how/Hide Clir	nical Columns 🗉					Clear All Filters o	n Clinical Data E	xport Filtered Clinical Da	ita
Study Type	Age Category	Age	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment	
Select 🔽	Select 💌	Select 💌	Select 💌	Select 💌	Select 💌	Select 💌	Select 💌	Select	
	Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	1
Other study type				Male	Topical	0.5	%	48	
Other study type Other study type Lab/Drug de (More)	Adult	Unspecified	Unspecified						

If user wants to export this filtered data, then click on "Export Filtered Clinical Data" button.

It will display one dialog box, which will contain all the fields available in that respective table and user can identify that the columns which are **hidden** in search results page are in uncheck mode like below.

		Export Filtere	ed Clinical Data	a	×			0
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bodhanapu venkata reddy (Your I	login session will ex	Study Type			2 ents	Export   Us	ser Guide   Help	Log
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AS Registry Number: 8001-54-5		Duration Unit	s					
		Frequency of	Administration					
Excipient Category/Function :		System/Orga						
Pharmacopoeial Status:			ability / Adverse E	ffects				
Regulatory Status:		Dosage Form						
Synonyms:		Conclusion /	Comments					
Acceptable Daily Intake: Revision Date:		Reference Reference Ty						
Revision Date.		Reference Ty						
Clinical Data (3) Non Clinical Data	i (3) Invitro Da					Different colors in	ndicates Unique Refe	erences
how/Hide Clinical Columns 🖲			Export to	Excel Export to PDF	ters o	n Clinical Data E	xport Filtered Clinical	l Data
Study Type Age Category	Age	Age Units	Genaer	KOUTE OF EXPOSURE OF Administratio	n vose	Dose Units	Duration of Treatm	nent
Select 🔽	Select 💌	Select 💌	Select 💌	Select	Select 💌	Select	Select 💌	
Other study type Adult	34 (Mean age)	Years	Male	Topical	0.5; 1	% aq	48	F
Other study type Lab/Drug de Adult ( <u>More)</u>	Unspecified	Unspecified	Male	Topical	0.5	%	48	F
		Years	Male	Topical	0.5 (15)	% w/v (µl/Finn	48	

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

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Search Results

Page | 101

Record No: 1	
Study Type	Other study type
Age Category	Adult
Age	34 (Mean age)
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5; 1
Dose Units	% aq
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Unspecified
System/Organ	Integumentary System
Safety / Tolerability / Adverse	Irritant contact dermatitis
Effects	
Dosage Form	Patch
Conclusion / Comments	The optimum concentration of benzalkonium chloride to induce mild to moderate skin reactions is estimated to be 0.5% using patch tests
Reference	NA, Willis CM, Stephens JM, Wilkinson JD. Experimentally-induced irritant contact dermatitis. Determination of optimum irritant concentrations. Contact Dermatitis. 1988 Jan;18(1):20-4, NA, 1988, NA(NA), NA-NA
Reference Type	J
Reference Year	1988
Record No: 2	
Study Type	Other study type - Lab/Drug development studies
Age Category	Adult
Age	Unspecified
Age Units	Unspecified
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5
Dose Units	%
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	once
System/Organ	Integumentary System
Safety / Tolerability / Adverse Effects	Scaling or faint, patchy erythema, erythema with mild edema, erythema with moderate edema, marked erythema with vesiculation, keratinocyte proliferation
Dosage Form Conclusion / Comments	Patch The study in healthy non atopic male subjects indicates that the cellular changes like proliferation i keratinocytes were related to chemical nature of irritants like benzalkonium chloride and its specific biochemical interactions on the skin rather than being the consequence of a generalized inflammatory response
Reference	NA, Willis CM, Stephens CJ, Wilkinson JD. Differential effects of structurally unrelated chemical irritants on the density of proliferating keratinocytes in 48 h patch test reactions. J Invest Dermatol 1992 Oct;99(4):449-53, NA, 1992, NA(NA), NA-NA
Reference Lype	
Reference Year	1992
Record No: 3	
Study Type	Unspecified
Age Category	Adult
Age	18 to 61
Age Units	Years
Cender	Male
Route of Exposure or Administration	
Dose	0.5 (15)
Dose Units	% w/v (µl/Finn Chamber)
Duration of Treatment	18 
Duration Units	Hours
Frequency of Administration	Once
System/Organ	Integumentary System
Satety / Lolerability / Adverse Effects	Predominantly mild in reactions with three negative reactions, mild and patchy spongiosis with exocytosis of small number of predominantly mononuclear cells, occasional foci of necrotic damag in the upper stratum spionosum, ultrastructuarally the affected keratinocytes were characterized by shrunken pyknotic nuclei, disrupted organelles and membrane and considerable intracytoplasmic vacuolation, lipid accumulation within keratinocytes was rarely observed
Dosage Form	Patch
Conclusion / Comments	The patch tests of benzalkonium chloride on human skin produced predominantly mild reactions
Reference	NA, Willis CM, Stephens CJ, Wilkinson JD. Epidermal damage induced by irritants in man: a light and electron microscopic study. J Invest Dermatol. 1909 Nov;93(5):695-9(url: http://www.ncbi.nlm.nih.gov/pubmed/2/94552), NA, 1989, NA(NA), NA-NA
	http://www.ncbi.nlm.nih.gov/pubmed/2794552), NA, 1989, NA(NA), NA-NA
Reference Type	J

Search Results

Page | 102

#### Case: 3:

Here user can export the data by applying both (Horizontal & Vertical) filters the search results page will looks like below.

				for paediatrics	fety and toxicity of excipients				Initiative
bodhanapu ven	kata reddy (Your	login session will expir	e after 30 minutes of	inactivity)	Search BY Excipients   Sear	ch FOR Excipients	Export   U	lser Guide   Help	Log
earch Resul	ts <u>Back</u>				Total References: 15			Re	ecord 1
								Excipient	Naviga
eneral Informati	on								
cipient Chemic	al Name: Benzalkor	nium Chloride							
	mber: 8001-54-5								
E 11 10 1									
Excipient Categ Pharmacopoeia									
Regulatory Stat									
Synonyms:	us.								
Acceptable Dail	v Intake:								
Revision Date:	y make.								
Clinical Data (3)	Non Clinical Data		(1) Regulatory a	and other information	n (5) Reviews (3)		Different colors	adoutoo Omquo Hoi	
how/Hide Cli	nical Columns 🗉					Clear All Filters of	n Clinical Data	Export Filtered Clinica	al Data
Study Type	Age Category	Age 🜌	Age Units	Gender	Route of Exposure or Administration	Dose	Dose Units	Duration of Treatr	nent
Select 🗸 🗸	Select	Select	Select	Select	Select	Select	Select	Select	
	Adult	18 to 61	Years	Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	
Inspecified							Chamber)		
nspecified									-
nspecified									
nspecified			1						
nspecified									
Inspecified									

If user wants to export this filtered data, then click on "Export Filtered Clinical Data" button.

It will display one dialog box, which will contain all the fields available in that respective table and user can identify that the columns which are **hidden** in search results page are in uncheck mode like below.

EuPFi	Clinical Data Fie	ed Clinical Dat	a	×			Us	spfi		
bodhanapu venkata reddy (Your login session will er	Ref ID Excipient Nar				ients	Export   U	United Sta	ten Permulation Initiative		
earch Results <u>Back</u>	Age Category Age Age Units Gender	Age Units					Record 1 of 1			
ieneral Information		osure or Administra	ation				Excip	ient Navigatio		
Excipient Chemical Name: Benzalkonium Chloride CAS Registry Number: 8001-54-5	Duration of T Duration Unit	s								
Excipient Category/Function :	System/Orga									
Pharmacopoeial Status:	Safety / Tole	rability / Adverse E	ffects							
Regulatory Status:	✓ Dosage Form									
E Synonyms:	Conclusion /	Comments								
Acceptable Daily Intake:	Reference									
Revision Date:	Reference Ty									
Clinical Data (3) Non Clinical Data (3) Invitro Da	Reference Ye	аг				Different colors i	ndicates Unique	e References		
Show/Hide Clinical Columns 🗉		Export to	Excel Export to PDF			Clinical Data		-		
Study Type Age Category Age 🖾	Age Units	Gender	Route of Exposure or Administration	Dose		Dose Units	Duration of T	reatment		
Select 💟Select 💟	Select 💌	Select	Select	Select	<b>~</b>	Select	Select			
Unspecified Adult 18 to 61	Years	Male	Topical	0.5 (15)		% w/v (µl/Finn Chamber)	48	F		

Here user can again filter the columns based on his/her need. And then click on Export to Excel/Export to PDF.

Based on the given export, the filtered data will be exported like below.

Home Insert Page Layout	Formulas Data	Review	View /	ASAP Oblibe											<b>e</b> –
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ther study type	Adult 34 (Me	an aYears	Male	Topical	0.5, 1	% ao 48	Hours		fe Integument	Initant con	Patch		NA, Willis J	1988	rear
ther study type - Lab/Drug developmen		ilie Unspecilie 1 Years		Topical	0.5	% 48 % w/v (µl/F48	Hours	Once	Integumen Integumen	Scaling or	Patch		NA, Willis J	1992 1989	
nspecified	Adult 18 to 6	i years	Male	Topical	0.5 (15)	% W/V (µl/F 48	Hours	Unce	Integumen	i 'redomina	ratch	The patch	NA, Willis J	1989	
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					-	1									
🕨 🗉 Clinical Data , 🐄				1	1			14							

The Same data will be export in PDF format also.

Search Results

Page | 104

#### Case: 4:

In addition to that, there is a provision to add/delete the columns to export the filtered data. And then click on Export to Excel/Export to PDF.

	Export Filtered Clinical Da	ta	×			0
	Clinical Data Fields				United States Pad	Austria mulation Elative
🚨 bodhanapu venkata reddy 🛛 (Your login session will e	Excipient Name     Study Type		ie	ents   Export   Us	er Guide   Help	Logout
	Age Category					
Search Results Back	✓ Age ✓ Age Units ✓ Gender				Rec	ord 1 of 1
General Information Excipient Chemical Name: Benzalkonium Chloride	<ul> <li>Route of Exposure or Administr</li> <li>Dose</li> <li>Dose Units</li> </ul>	ation			Excipient Na	avigation
CAS Registry Number: 8001-54-5	Duration of Treatment Duration Units					
Excipient Category/Function :	✓ Frequency of Administration ✓ System/Organ					
Pharmacopoeial Status:	Safety / Tolerability / Adverse	Effects				
Regulatory Status:	Dosage Form					
Synonyms:	Conclusion / Comments					
Acceptable Daily Intake:	Reference					
Revision Date:	Reference Type					
Clinical Data (3) Non Clinical Data (3) Invitro Da	Reference Year			Different colors in	dicates Unique Refer	ences
Show/Hide Clinical Columns 🗄	Export to	Export to PDF		rs on Clinical Data	port Filtered Clinical	Data
Study Type 🛛 Age Category 🔰 Age 🗹	Age Units Gender	Route of Exposure or Administration		Dose Units	Duration of Treatme	
Select 💟Select 💟Select	Select 🗸Select 🗸	Select	Select	Select 💌	Select 💌	
Unspecified Adult 18 to 61	Years Male	Topical	0.5 (15)	% w/v (µl/Finn Chamber)	48	F
L						
<						>

Based on the given export, the filtered data will be exported like below.

Liom		Pagels	word to	nemicilas	Data Remeior	Viet	w 650	Filtines												-	
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	ny mat Painter	<b>U</b> 2	u][ <u>===</u>	34 - A		5 <b>=</b> ( <b>=</b> )	i Mera	e & Center -	5 - 1/0	* * ***	98 Condit	ional Forma Linu 1 as Table	at Good	8	Neutral		Insert	Delete Format	(a) Finite (2) Clear 1	Sort 6 Filler	A File
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'ears	Male	Topical	0.5 (15)	% w/v (µl/	48 Hou	rs (	Once	Integument	Prodomina	Patch	The patch	NA, Willis	J	1989							
						_															

The Same data will be export in PDF format also.

User can also identify the same criteria as specified for the Clinical Data, is available with Non Clinical Data and Invitro Data tabs/sections.

#### Search Results

#### Note:

- Filtered data export is applicable for Clinical Data, Non Clinical Data and Invitro Data.
- The file names are
- 1. Excel "EupfiFilteredResults\_<Section Name>"
- 2. PDF "EupfiFilteredResults\_<Section Name>"

The Section Names for Clinical Data, Non Clinical Data and Invitro Data will be ClinicalData, NonClinicalData and InvitroData respectively.

## 8.11 No records found

If there is no data available for the given search criteria, then the below failure (No Records Found) page will appears.

	STEP database Database of safety and toxicity of excipients for paediatrics	Lined Grave
🕹 bodhanapu venkata reddy 👘 (Your login session will expire after 30 minutes of inactivity)		Search BY Excipients   Search FOR Excipients   User Guide   Help   Logout
Search Results Back	No Records Found	
	Contact Feedback Disclaimer	GÖSTAR GOBIOM

## 8.12 Back Link Functionality

In the application "Back" link is provided to navigate to the previous page, when user clicks "Back" link from any page then application navigates to the previous page.

**Example:** If user clicks "Back" from the "Search Results" page as shown below.

#### Version-1.0

Search Results Back		Total References: 292	Record 1 of 1
			Excipient Navigation
General Information			
Excipient Chemical Name:	Aspartame		
CAS Registry Number:	22839-47-0		
Excipient Category/Function :			
Excipient Category/Function     Emplement Category/Function     Emplement Category/Function			
Regulatory Status:			
I Synonyms.			
Acceptable Daily Intake:			
El Revision Date:			
N/A			

Then application navigates to the previous page (Excipient(s) Intermediate Page) as shown below.

Excipient(s) Intermediate Page	Back
– Number of Excipient found: 3	
Acesulfame K	
Aspartame	
Benzalkonium Chloride	
Submit	

#### Note:

- Back link functionality will be available for Excipients Intermediate Page, Search Results Page and Export Pages.
- If user clicks Back link in Export page then application will redirect to Search Results page by default and will not consider any filters (if applied).
- If user clicks Back link in Search Results page then application will redirect to Search BY Excipients or Search FOR Excipients or Excipients Intermediate page by default (if more than on excipient is found for the given search criteria).
- If user clicks Back link in Excipients Intermediate page then application will redirect to either Search BY Excipients or Search FOR Excipients page depends up on the Search criteria.
- Where ever the "Source URL" field is available in the Search Results page, there will be 2 conditions in displaying of data.
  - 1. If Source URL value starts with 'http://' then that will be displayed as direct **hyperlink** and if user clicks on that link that will redirect to that particular link.
  - 2. If Source URL value does not starts with 'http://' then that content will be displayed as it is in that particular cell(if that content is less than 30 characters)
  - 3. If Source URL value does not starts with 'http://' and the value is more than 30 characters then 'More' and 'Less' functionality will be applicable with that particular record.

For the above both the cases the whole content will be displayed as title for that particular cell for all the sections of Search Results page.

 Color coding is applicable for Clinical Data, Non Clinical Data and Invitro Data sections in the results page.

Search Results

Page | 107

• On each field name mouse hover, the respective field description will be displayed.

# 9 Export

STEP is also accommodating users to export the required information using the "Export" link from the main menu bar from the "Search Results" page as shown below.



When user clicks "Export" link from the main menu bar "Select to Export" page appears. By default "General Information fields" appears in expanded mode, remaining fields in collapsed mode as shown below.

General Information				
	Excipient ID	CAS Registry Number	C Excipient Name	
Excipient Category/Function	Pharmacopoeial Status	Synonyms	Revision Date	
Regulatory Status				
	Agency	Description	Permitted Functionality	
Use limits	Source URL	Reference		
General Acceptable Daily Intake				
	Source	Limit	Year	
Reference	Source URL			
Acceptable Daily Intake for Pediatrics				
	Source	Limit	Year	
Reference	Source URL			
Clinical Data				
Non Clinical Data				
Invitro Data				
Regulatory and other information				
Reviews				
Reference				

Click "[+]" symbol besides the name to expand the fields and select the required fields using check boxes and click "Export to Excel / Export to PDF" as shown below.

Eu – US PFI User Guide Version-1.0 EUPFI STEP database 🚨 bodhanapu venkata reddy 💫 (Your login session will expire after 30 minutes of inactivity) Search BY Excipients | Search FOR Excipients | User Guide | Help | Logo Select to Export Back General Information Excipient ID CAS Registry Numbe Excipient Name Revision Date Excipient Category/Function Pharmacopoeial Status Synonyms Regulatory Status Agency Description
Reference Permitted Functionality Use limits General Acceptable Daily Intake 🗹 All Source 🗹 Limit Vear Reference Source URL Acceptable Daily Intake for Pediatrics Source Source URL 🗖 Limit 🗆 Year Reference Clinical Data 🔽 All Ref ID C Excipient Name Study Type Age Category
 Route of Exposure or Administration 🗹 Age Age Units Gender Dose **Dose Units** Duration of Treatment Duration Units Frequency of Administration System/Organ Safety / Tolerability /Adverse Effects Dosage Form Conclusion / Comments Reference Reference Type Reference Yea Non Clinical Data Ref ID Excipient Name Study Type Species Age Category 🗹 Age Age Units Gender Dose / Concentration Dose Units Route of Exposure or Administration Duration of Treatment Duration Units System/Organ E Frequency of Administration Adverse Effect Dosage Form Conclusion / Comments Reference Reference Yea Reference Type 🗆 Invitro Data Ref ID Excipient Name Study Type Species Dose Dose Units Route of Exposure or Administration Duration of Treatment Duration Units System/Organ Safety / Tolerability / Adverse Effects Conclusion / Comments Reference Reference Type Dosage Form Reference Year Regulatory and other information 🗸 All Ref ID Z Excipient Name Reference Source Source URL Reference Year Reviews All Ref ID Excipient Name Reference Sour Source URI Reference Yea Reference Reference Export to Excel Export to PDF ancel Export GOSTAR GOBIOM Developed by GVK BIO Contact Feedback Disclaimer

Note: Excipient name appears in selected mode by default and in disable mode as shown below.

EuPFi	for	STEP database asse of safety and toxicity of excipients paediatrics	Litited States Print
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elect to Export Back			
General Information			
All	Excipient ID	CAS Registry Number	Excipient Name
Excipient Category/Function	Pharmacopoeial Status	Synonyms	Revision Date
egulatory Status			
All	Agency	Description	Permitted Functionality
Use limits	Source URL	Reference	
eneral Acceptable Daily Intake			
All	Source	🔲 Limit	Tear Year
Reference	Source URL		
ceptable Daily Intake for Pediatrics			
All	Source	Limit	Tear Year
Reference	Source URL		
Clinical Data			
	Ref ID	Excipient Name	Study Type
Age Category	Age	Age Units	Gender
Route of Exposure or Administration	Dose	Dose Units	Duration of Treatment
Duration Units	Frequency of Administration	System/Organ	Safety / Tolerability /Adverse Effects
Dosage Form	Conclusion / Comments	Reference	Reference Type
Reference Year			
Non Clinical Data			
	Ref ID	Excipient Name	Study Type
Species	Age Category	Age	Age Units
Gender	Dose / Concentration	Dose Units	Route of Exposure or Administration
Duration of Treatment	Duration Units	E Frequency of Administration	System/Organ
Adverse Effect	Dosage Form	Conclusion / Comments	Reference
Reference Type	Reference Year		
Invitro Data			
All	Ref ID	Z Excipient Name	Study Type
Species	Dose	Dose Units	Route of Exposure or Administration
Duration of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects
Dosage Form	Conclusion / Comments	Reference	Reference Type
Reference Year			
Regulatory and other information			
All	Ref ID	Excipient Name	Reference
Source	Source URL	Reference Year	
Reviews			
All	Ref ID	C Excipient Name	Reference
Source	Source URL	Reference Year	
Reference			
Reference			
	Export to	Excel Export to PDF Cancel Export	

## 9.1 Export to Excel

Click "Export to Excel" from the "Select to Export" page, then the "File Download" window appears as shown below.

Do you want to open or save EupfiExportResults.xls from localhost?	Open	Save	•	Cancel	x

Click "Open" to open the excel file or save it using "Save". Otherwise cancel the download using "Cancel" on the file download window. First page "Search Inputs" provides the information about the search criteria given by the user.

Export

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Then the excel file appears with the selected data and based on the categorization data in the excel sheets appears in separate sheets as shown below.

Hon	ne Insert	Page L	ayout Fo	ormulas D	ata Re	view Vi	ew Dev	eloper A	dd-Ins						🥶 –	•
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COT	40 mg/kg	1992	COT (199)													
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**Note**: Click "Source URL" from the excel, as shown below corresponding website appears in a new window as shown in the below figures respectively.

Export

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## 9.2 Export to PDF

Click "Export to PDF" from the "Select to Export" page, then the "File download" window appears as shown below.

Do you want to open or save EupfiExportResults.pdf from localhost? Open Save 💌 Cancel 🗴
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Click "Open" to open the PDF file or save it using "Save". Otherwise cancel the download using "Cancel" on the file download window.

Then the PDF appears with First page as "Search Inputs" with the information about the search criteria given by the user as shown below.



Based on the categorization data in the PDF appears in separate pages as shown below.

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General Information: Record No: 1		
Excipient Name	Benzalkonium Chloride	
Excipient ID	2	
CAS Registry Number	8001-54-5	
Excipient Category/Function	Antimicrobial preservative Disinfectant Wetting agent Solubilizing agent Antiseptic	
Pharmacopoeial Status	JP XV,PhEur 6 8,USP33–NF28 S1	
Synonyms	Alkyl Dimethyl Denzyl Ammonium Chloride, Alkyl Dimethylbenzyl Ammonium Chloride, Alkyldimethyl (Phenylmethyl) Quaternary Ammonium Chlorides, Ammonyz, Arqua, Benzalkonium Chloride Solution, Quaternary Ammonium Compounds, Benzylcoco Alkyldimethyl, Chlorides	
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In PDF export format, user can find the header with application logs. And if user clicks on those header images, the respective/appropriate link will be displayed like below

Eu – US PFI User Guide Version- 1.0 EupfiExportResults.pdf - Adobe Reader : 🕞 🍪 • | 🍪 : 🔶 🜩 1 / 12 : 💌 💌 149% • : 🔜 🔯 : Find e uspfi EUPFi TEP database Search Inputs Excipient Name Benzalkonium Chloride Security Warning The document is trying to connect to http://www.cupfl.org/ If you trust the site, choose Allow. If you do nber this action for this site for all PDF do E Re Help Allow Elock Cancel

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#### Note:

• Only the selected sections with selected fields will be exported (i.e. If none of the fields are selected in any section then that particular section will not be exported and will not create any separate sheet or page with those details).

Export

- Only PDF export will have the logos (as a header for all pages) and if user clicks on any logo, that respective link will display on the browser.
- The export file names will be like below
  - 1. Excel "EupfiExportResults.xls".
  - 2. PDF "EupfiExportResults.pdf.
- Source URL in both the exported formats (excel & PDF) will be displayed as **hyperlink**. On click of that particular link, the respective page will be opened by default.
- Due to MS-Office excel limitation (I.e. Sheet name can't exceed 31 characters); Sheet name will be displayed as "ADI for Pediatrics" instead of 'Acceptable Daily Intake for Pediatrics' only in Excel export. Whereas all the other places where ever 'Acceptable Daily Intake for Pediatrics' name occurs, the same name will be displayed.

## 9.3 Cancel Export

User can cancel the "Export" page using "Cancel Export" link as shown below

Eu – US PFI User Guide Version-1.0 STEP database EUPFi A bodhanapu venkata reddy (Your login session will expire after 30 minutes of inactivity) Search BY Excipients | Search FOR Excipients | User Guide | Help | Logou Select to Export Back General Information Excinient ID CAS Registry Number V Excinient Name Excipient Category/Function Revision Date Pharmacopoeial Status Synonyms Regulatory Status Agency Description Permitted Functionality Use limits Reference Source URL General Acceptable Daily Intake Source Limit V Year Source URL Reference Acceptable Daily Intake for Pediatrics Source I imit Year Reference Source URL Clinical Data 🔽 All Ref ID Excipient Name Study Type Age Category 🗹 Age Age Units Gender Route of Exposure or Administration Dose Dose Units Duration of Treatment **Duration Units** Frequency of Administration System/Organ Safety / Tolerability /Adverse Effects Dosage Form Conclusion / Comments Reference Reference Type Reference Year Non Clinical Data Ref ID Excipient Name Study Type ✓ Age Species Age Category Age Units Route of Exposure or Administration Gender Dose / Concentration Dose Units Duration of Treatment Duration Units Frequency of Administration System/Organ Conclusion / Comments Adverse Effect Dosage Form Reference Reference Type Reference Year Invitro Data Ref ID Excipient Name Study Type Species Dose Dose Units Route of Exposure or Administration Duration of Treatment System/Organ Safety / Tolerability / Adverse Effects Duration Units Dosage Form Conclusion / Comments Reference Reference Type Reference Year Regulatory and other information 🗹 All Ref ID Reference Excipient Name Source Source URL Reference Year Reviews Ref ID Excipient Name Reference Source Source URI Reference Year Reference Reference Export to Excel Export to PDF Cancel Export GOSTAR GOBIOM Developed by GVK BIO Contact Feedback Disclaimer

Then the export page gets cancelled and the application navigates to the "Search Results" page.

Note:

• If user clicks on the "Cancel Export" link in Export page, by default it will displays the Search Results page (without considering any filter criteria, if any applied).

## 10 Help

Help link from the main menu bar facilitates the help information about the application to the user. When user clicks "Help" from any page in the application, then the current page information appears in new window.

**Example:** When user clicks "Help" from "Export" page as shown below.

Help

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Select to Export B	elp.pdf - Adobe Reader View Document Tools Window Help ) • • • • • 1 / 7 • • • • 1 Export STEP is also accommodating users to the main menu bar from the "Search I • • • • • • • • • • • • • • • • • • •	Export export the required information to tesults" page as shown below.	ind • sing the "Export" link from		Excipient Name Revision Date Permitted Functionality Year Year
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### Note:

Help link is available for over all application. (I.e. Search BY Excipients, Search FOR Excipients, and Excipients Intermediate, Search Results and Export pages)

## **11 Glossary**

Attribute: In data modeling, specific items of data that can be collected for a class.

**Availability** - The degree to which a system (or system component) is operational and accessible when required for use.

**Capacity** - A measure of the amount of input a system could process and/or amount of work a system can perform; for example, number of users, number of reports to be generated.

**Document** - Written and/or graphical information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, reviews, or results.

**End user**: The ultimate consumer of a product, especially the one for whom the product has been designed. End-users for STEP database application include Pharmaceutical Scientists, Regulators, Toxicologists, physicians, nurses, epidemiologists, health care providers etc.

Entity - Represents data attributes about which data are collected and maintained.

**Functional Requirement:** A description of what a system should be able to do-a function it should perform.

**Life Cycle**: All the steps or phases a project passes through during its system life; from concept development to disposition.

**Methodology:** A set of methods, procedures, and standards that define the approach for completing a system development or maintenance project.

**Non-functional Requirements:** Software design requirements related to the efficiency, reliability, portability, and usability of the system. Also known as supplementary requirement.

**Process:** A set of activities that produces products and services for customers.

**Process Flow:** The set of steps or working states in a documented standard process.

**Requirement:** A requirement describes a condition or capability to which a system must conform; either derived directly from user needs, or stated in a contract, standard, specification, or other formally imposed document. A requirement is a desired feature, property, or function to be met by the application.

**Scope** - The established boundary (or extent) of what must be accomplished; during planning, This defines what the project will consist of (and just as important, what the project will not Consists of.

Page | 118

**Software Requirements Specifications (SRS):** A project artifact that defines the complete system requirements through use cases and supplementary specifications.

**Web-based**: A set of interconnected web pages, usually including a homepage, generally located on the same server, and prepared and maintained as a collection of information by a person, group, or organization. Web-based applications are usually accessed with a web browser (e.g., Microsoft Internet Explorer, Netscape).

**User interface**: The programming that controls a display for the user (usually on a computer monitor) and that allows the end user to interact with the system with commands and mechanisms to control system operation and input data.

**User Manual** - A formal document that contains all essential information for the user to make Full use of the new or upgraded system.