European Paediatric Formulation Initiative

Eu – US PFI

Safety and Toxicity of Excipients for Paediatric [STEP]

User Guide

European Paediatric Formulation Initiative (EuPFI)

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CONTENTS

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.

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.

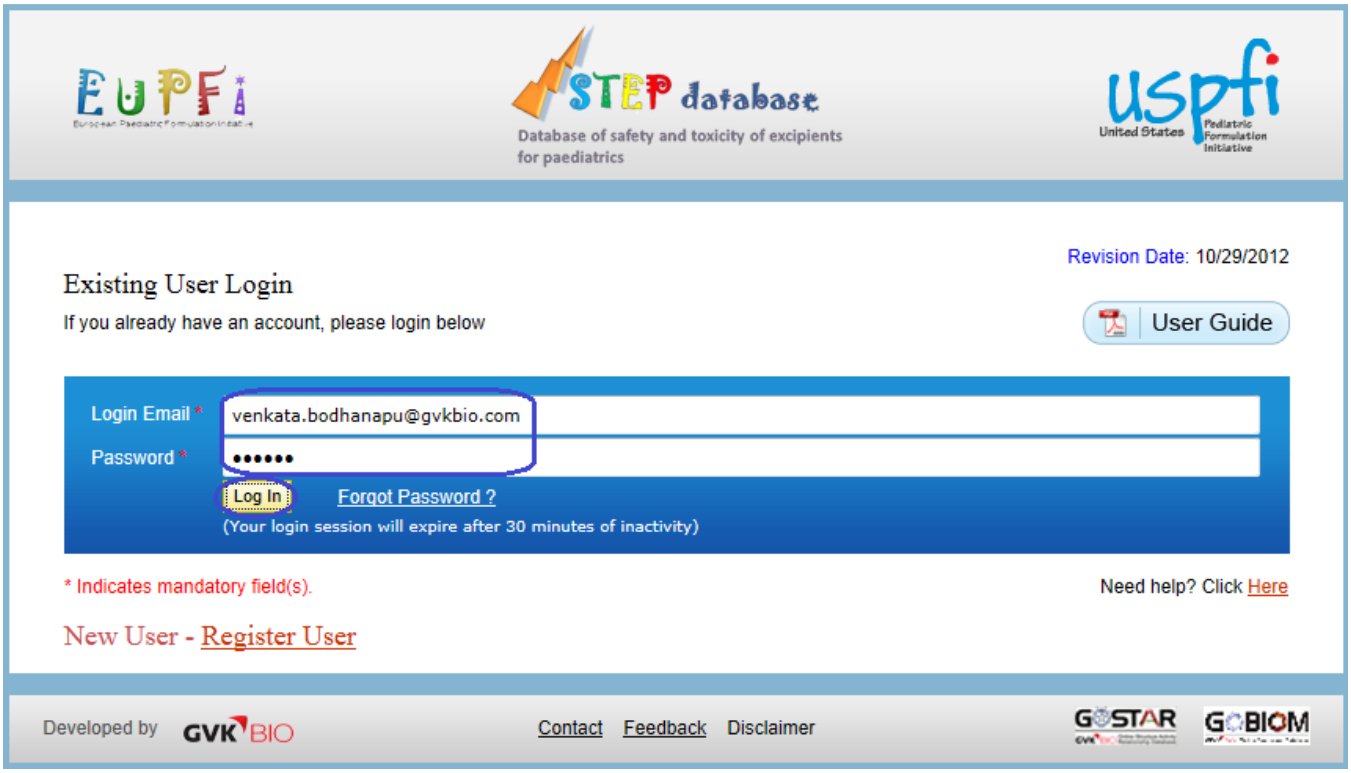
2 Getting started

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.

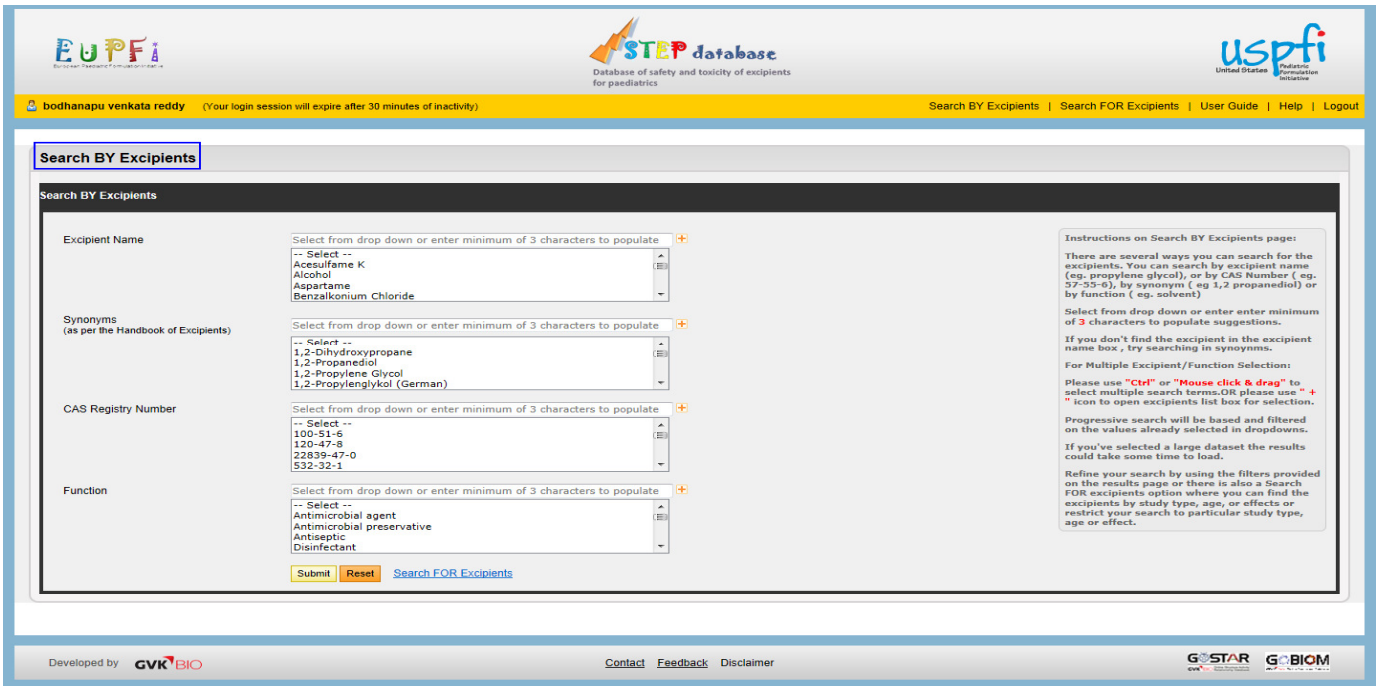
In order to address this need, the European (Eu) and United States (US) Paediatric Formulation Initiatives (PFIs) are working together to create and maintain a database of Safety and Toxicity of Excipients for Paediatrics (STEP).

2.1 Log in

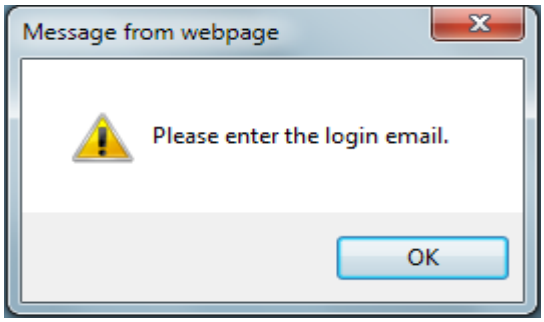
Enter the user credentials in the login page and click “Login” as shown below.



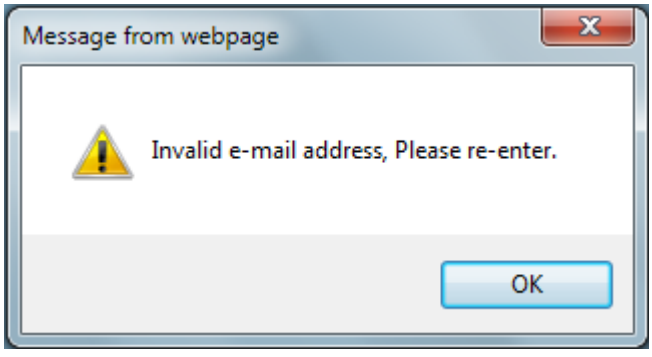
“Search BY Excipients” page appears as shown below.



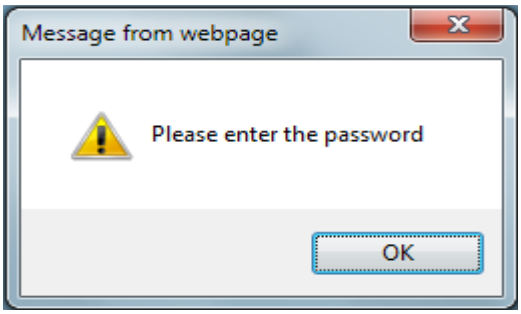
When user clicks “Log in” without entering the email id then the below alert message appears.



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

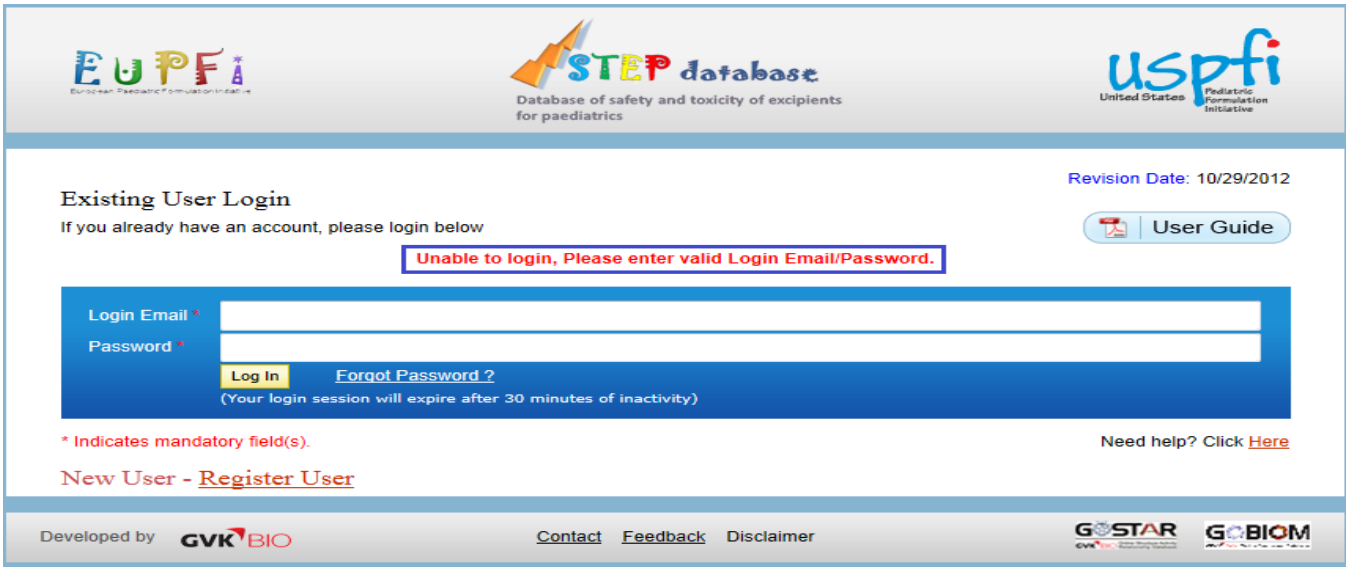


When user clicks “Log in” without entering password, the below alert message appears

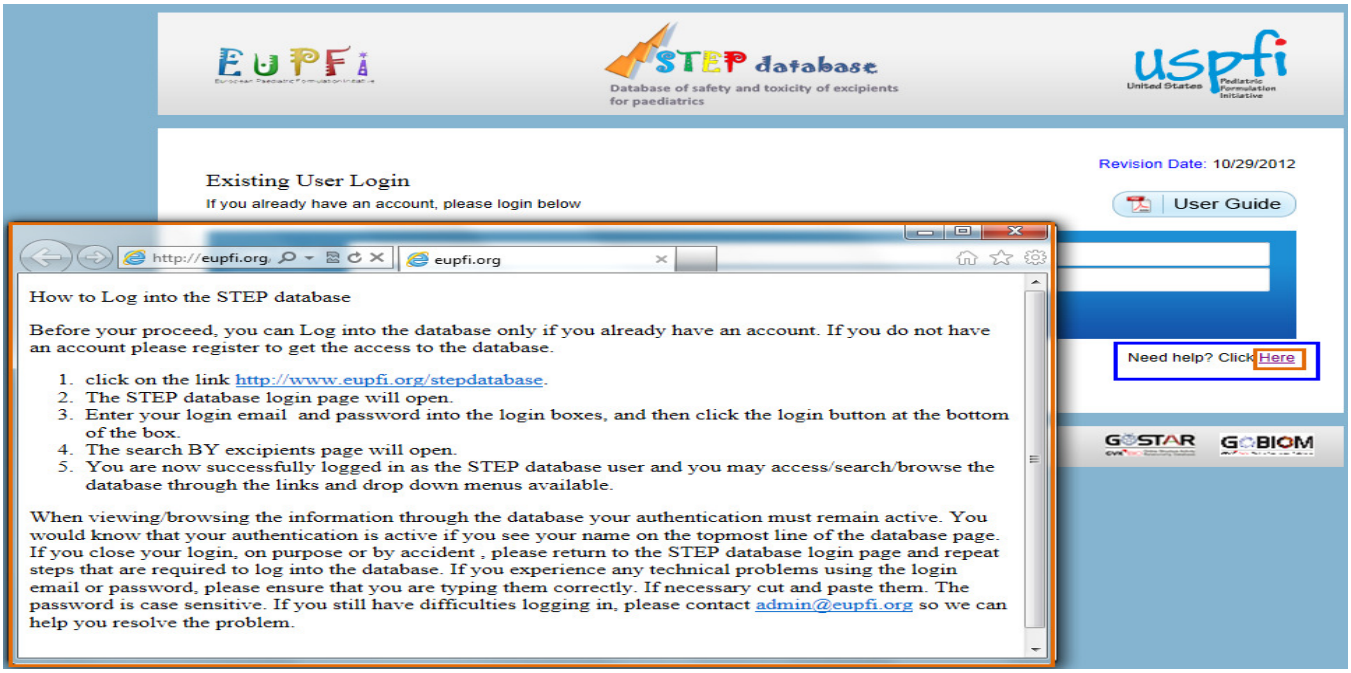


If user logins with unregistered Login Email then the message appears as shown below.

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



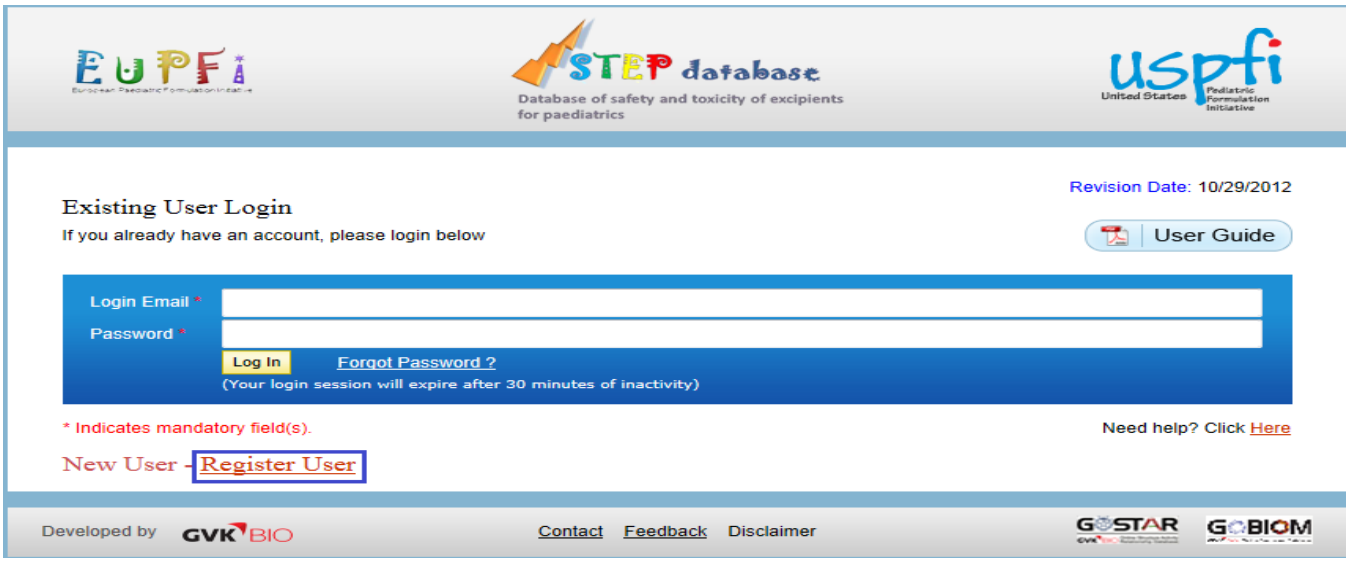
If user needs any help in STEP Database login process then, clicks on Need help? Click Here (Link), it will displays one window with the details,



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

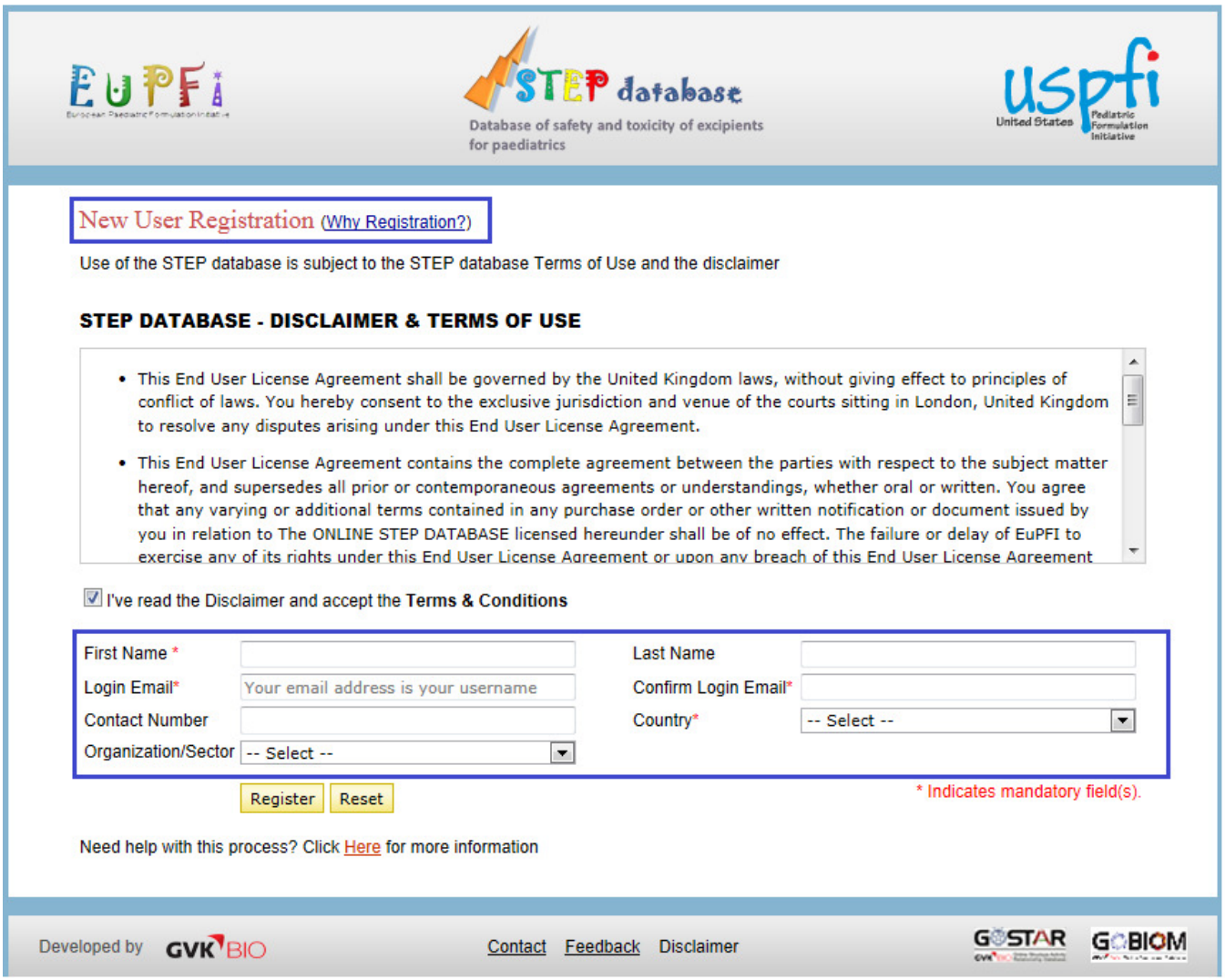
2.2 New user registration

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.

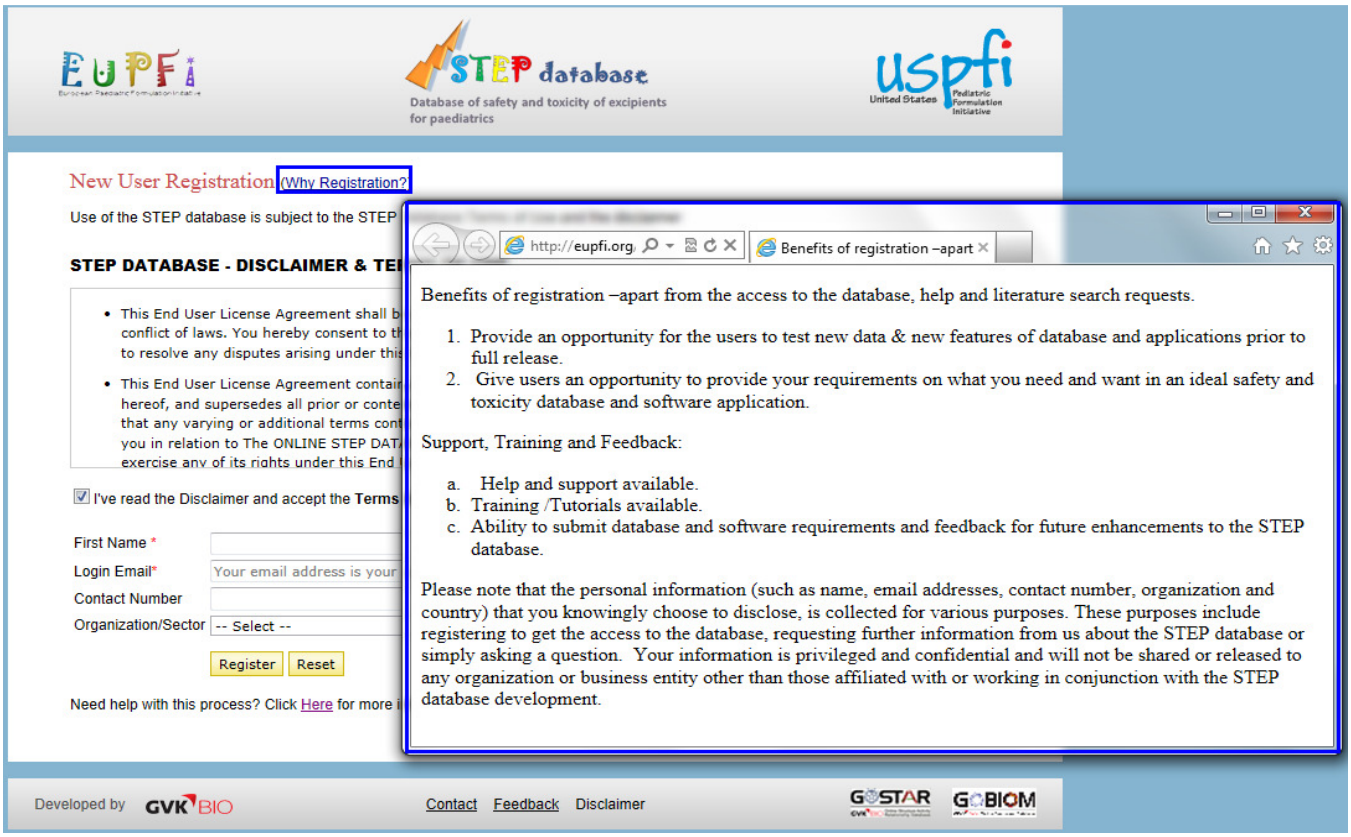


Note: **"**New User - Register User" page appears, here "I've read the Disclaimer and accepted the Terms & Conditions" checkbox appears in selected mode by default and cursor is at first name field by default.

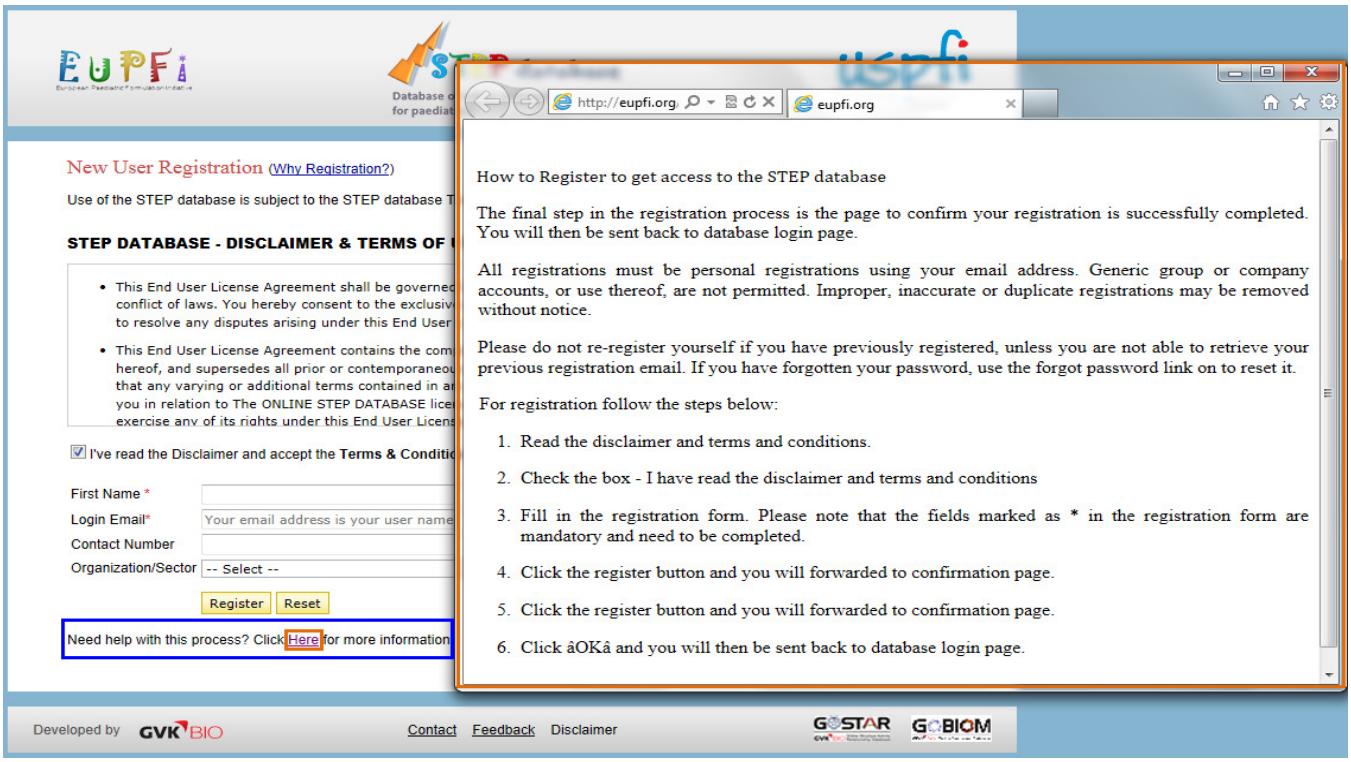
Click "Why Registration?" link then the benefits for registration information appears as shown below.



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



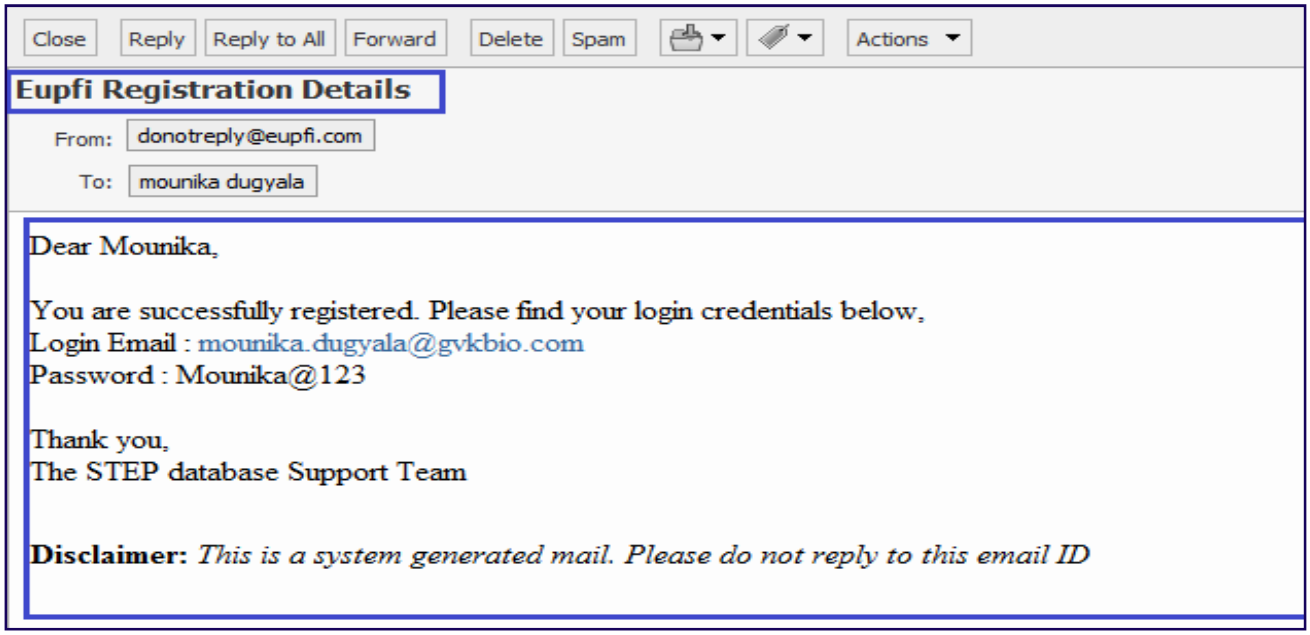
To get help on user creation click on link “Here”. Help page is displayed as shown below.



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

After successful creation, below page appears containing user information.

An email is sent to user containing registration details.

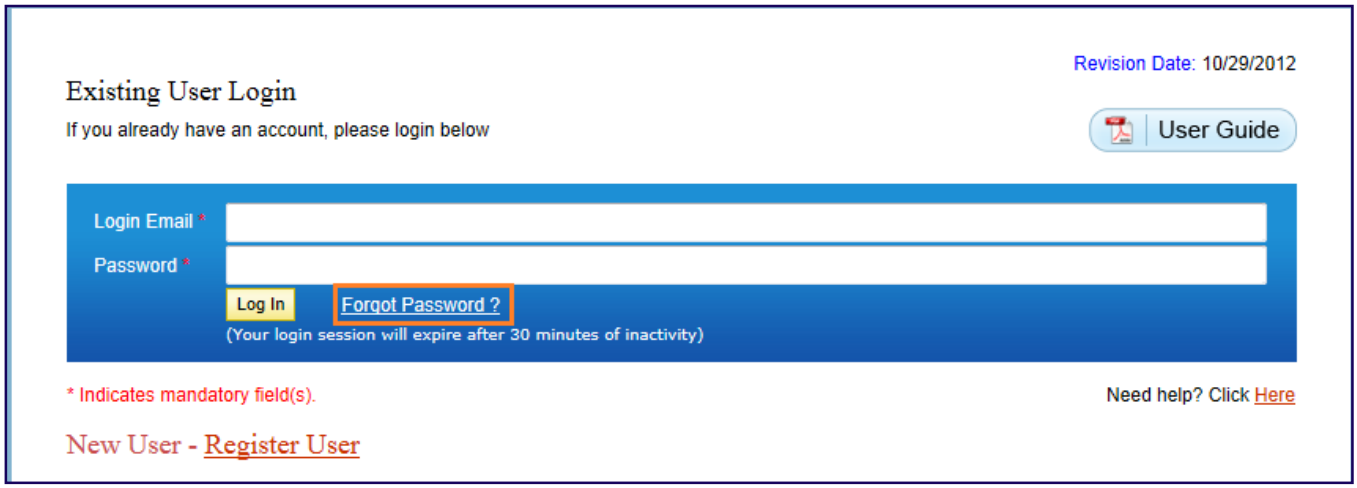


2.3 Existing User

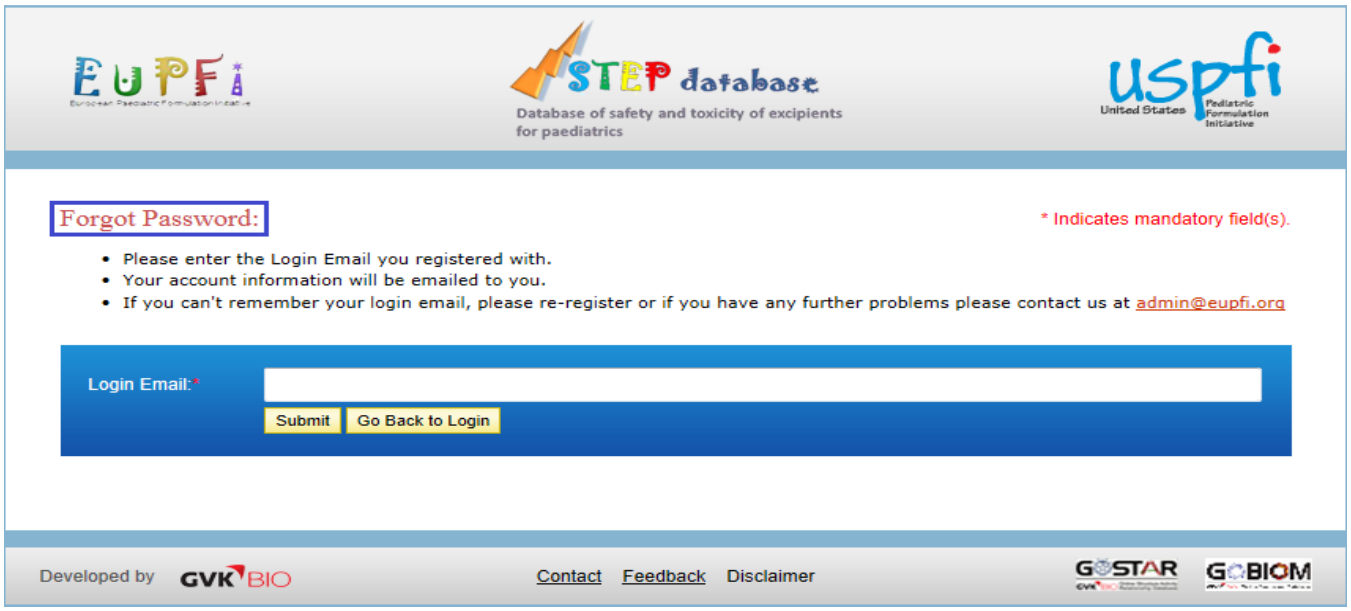
When user tries to register with already registered email ID, then an error message displayed as show below.

2.4 Forgot Password

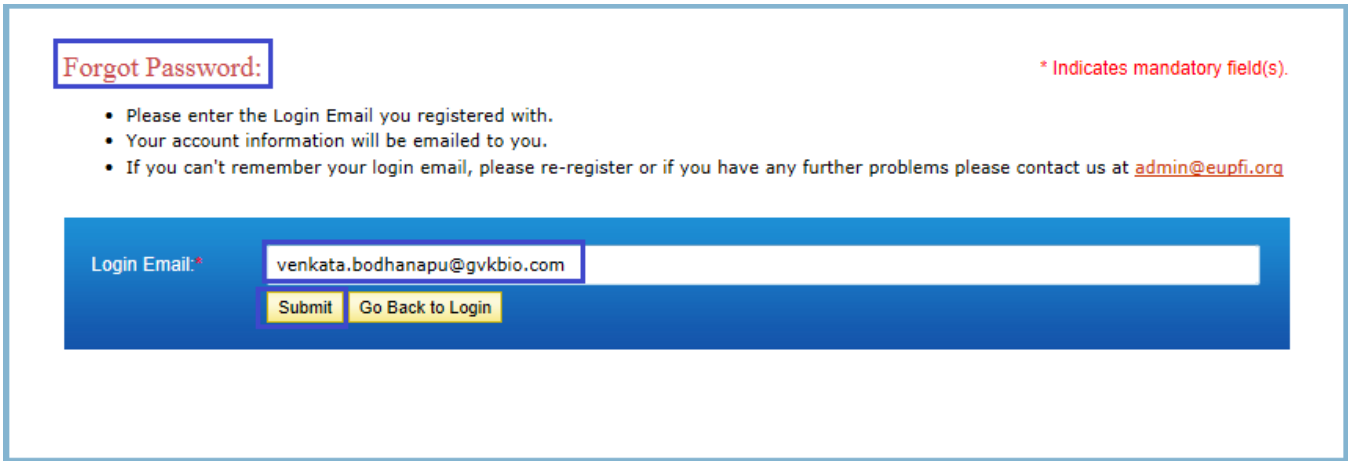
User can retrieve the password using “Forgot Password” in the “Login” page by clicking on “Forgot Password” link as shown below



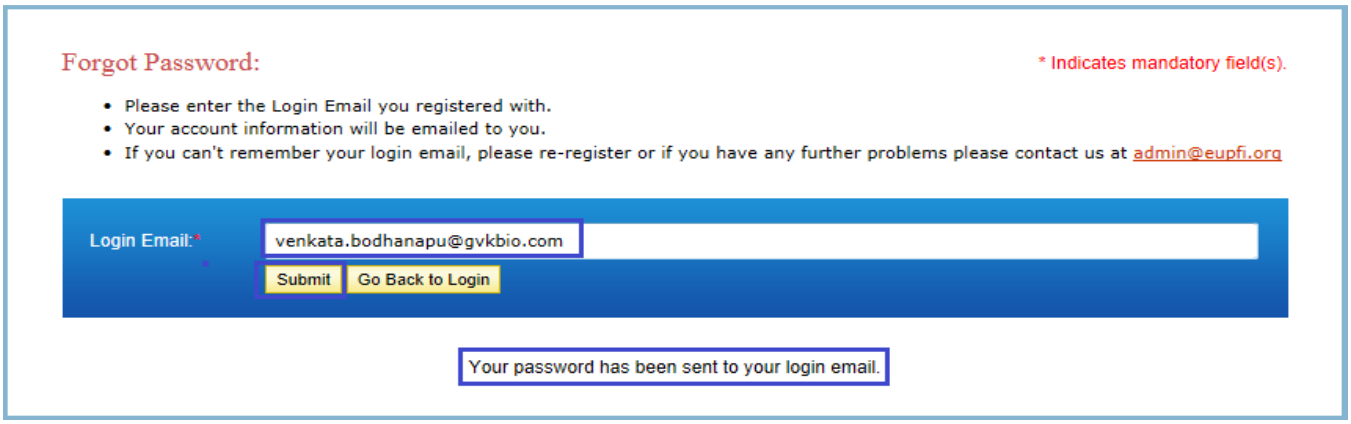
“Forgot Password” page appears as shown below.



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

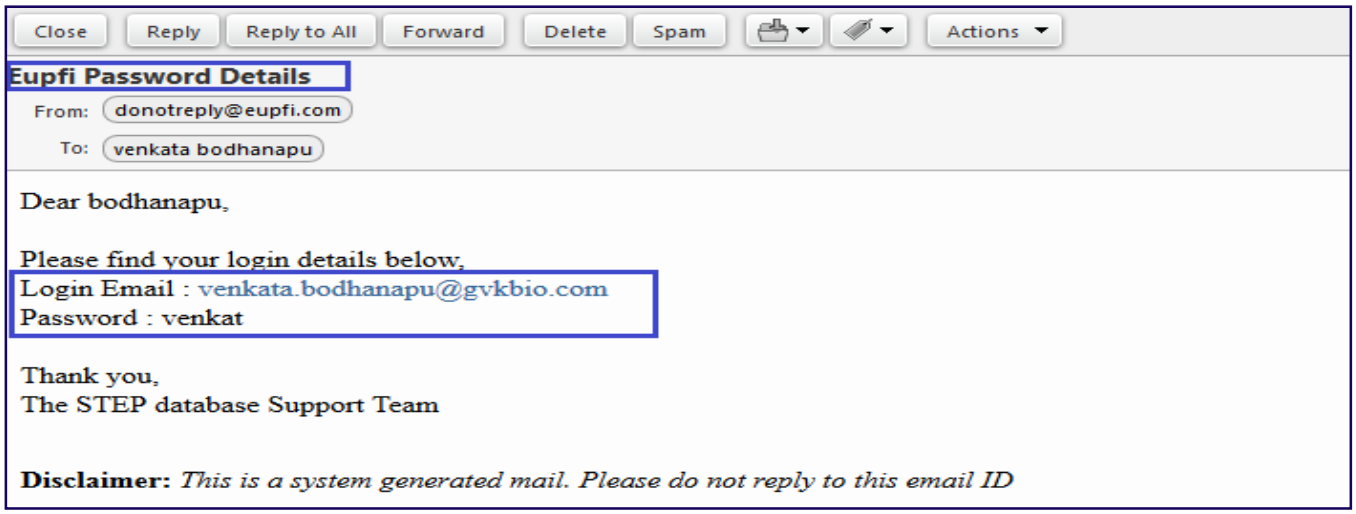


Then a message appears indicating the password has been sent to your login email as shown below.

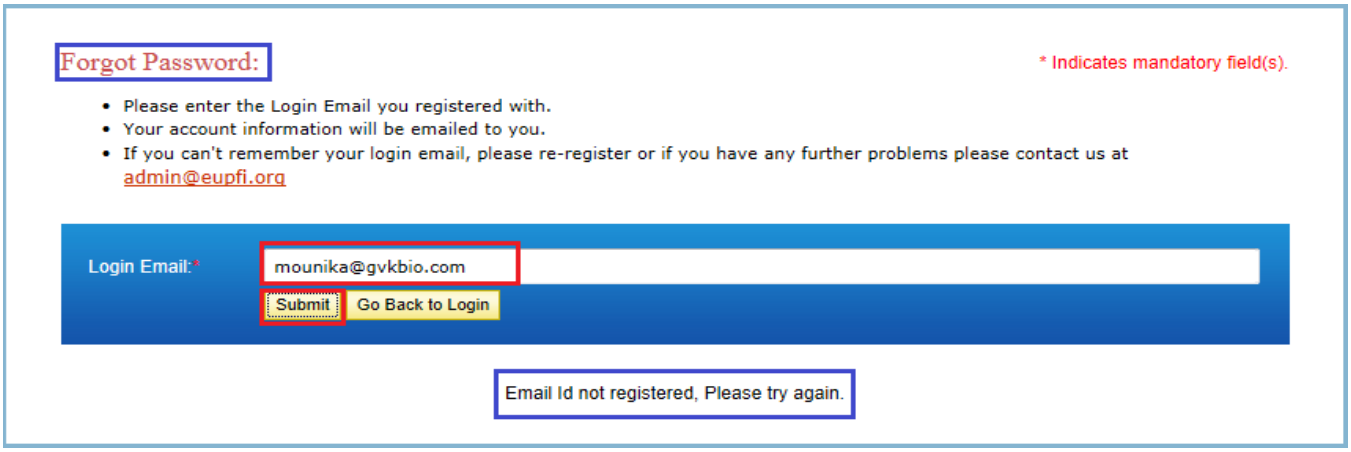


Use the received password to login into the STEP Database application.

Example mail content:



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



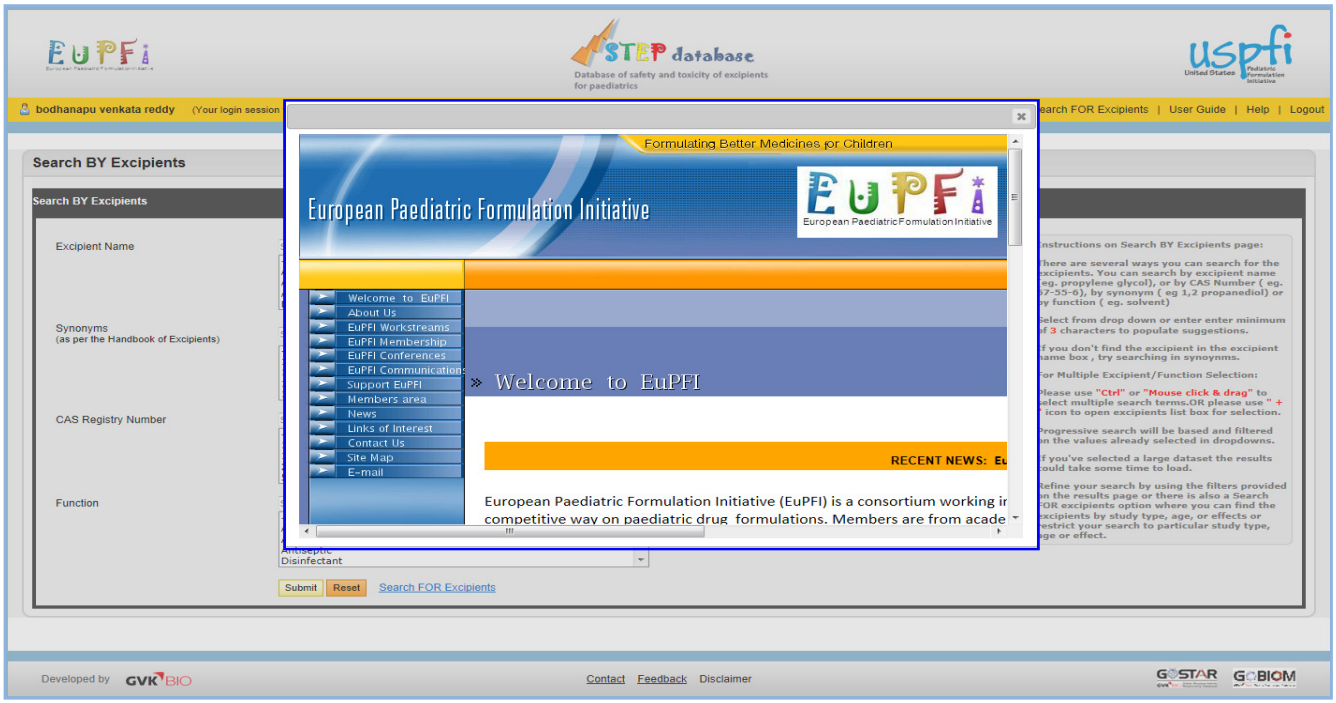
Note:

- 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

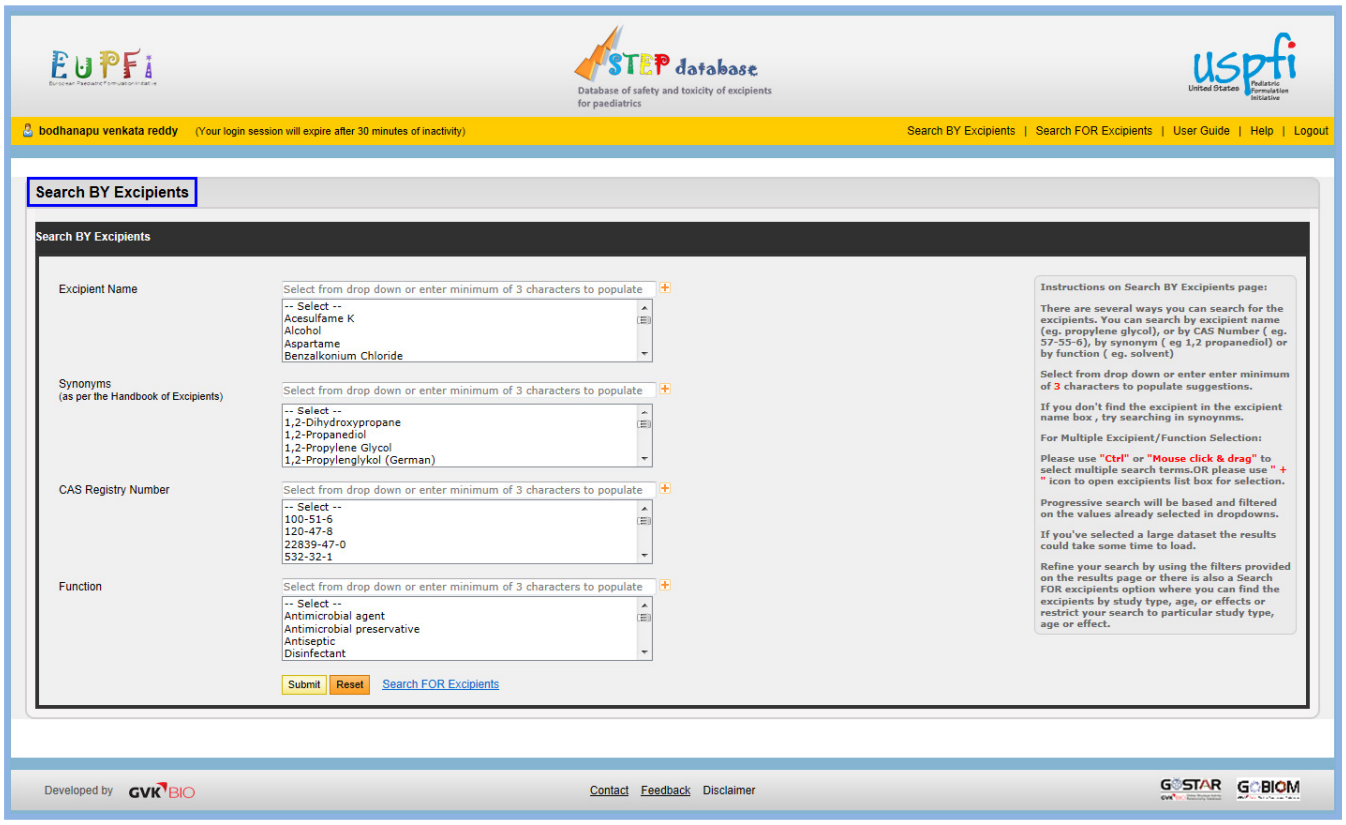
STEP provides a new option for the regular user who ever are visited more than 10 times can provide Feedback on the application using feedback form

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 10th time.

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

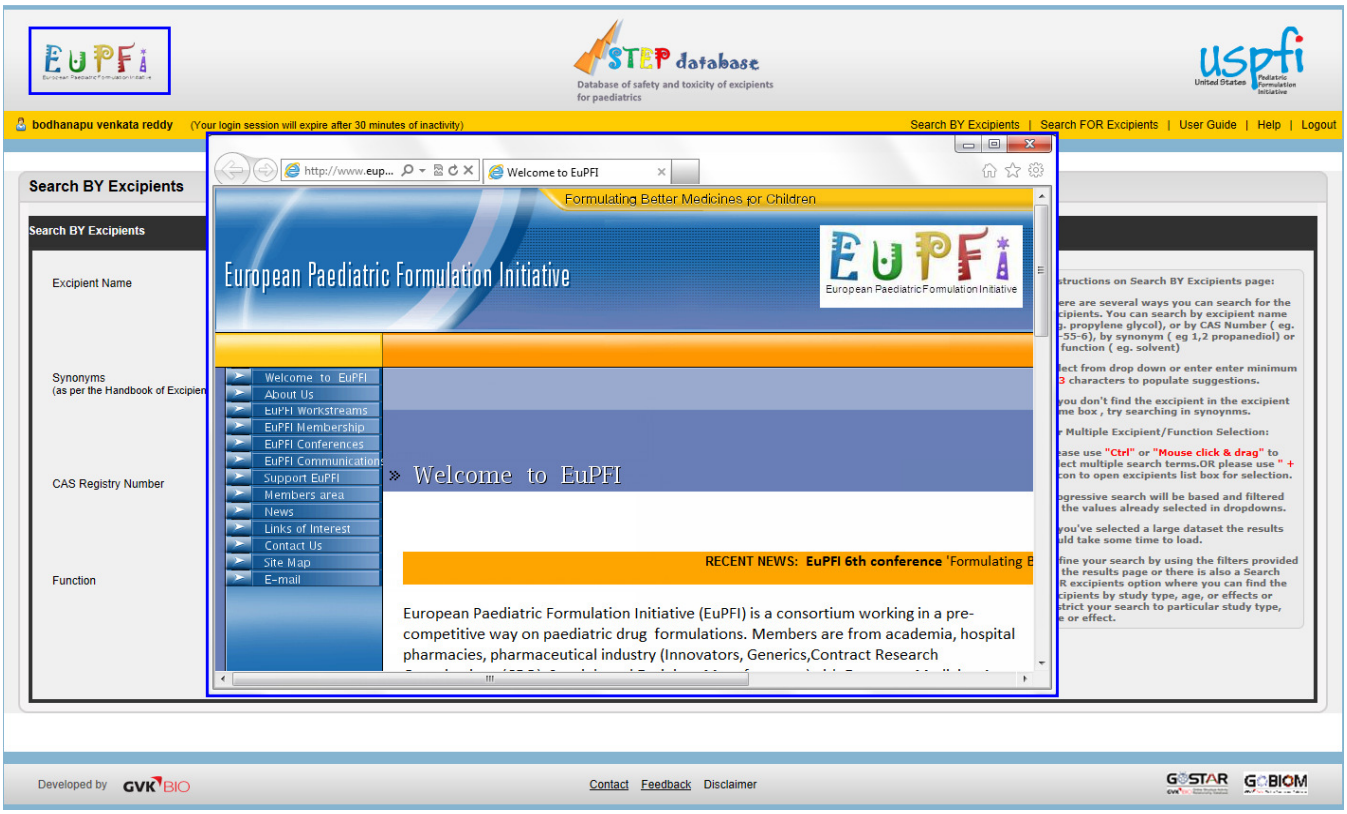


Note:

- 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 10th login.

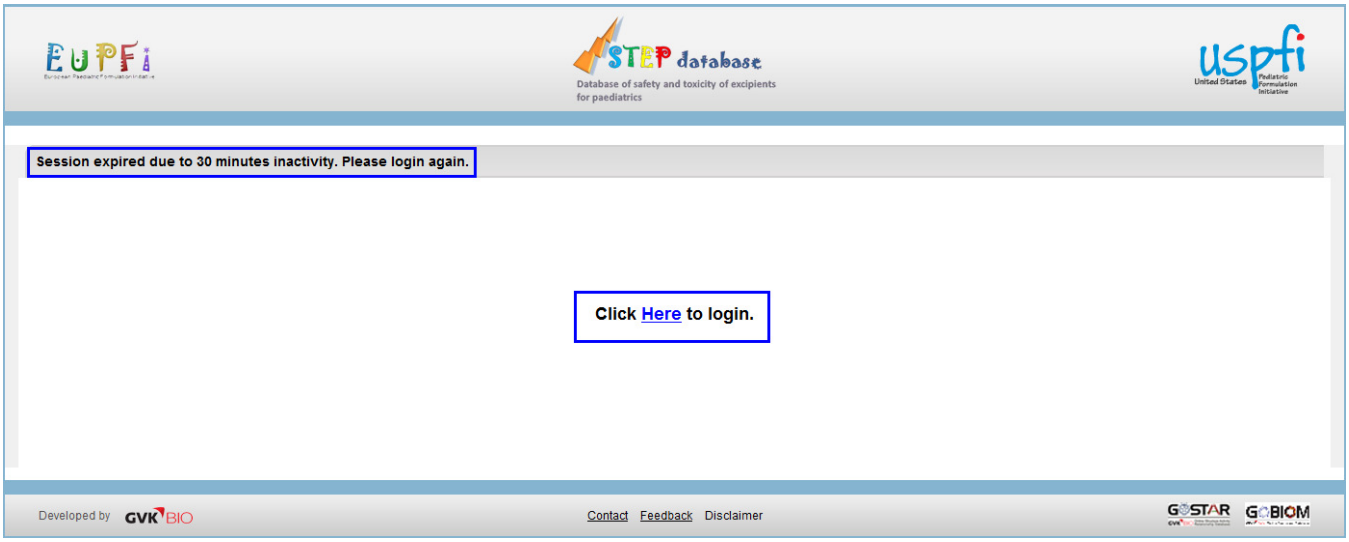
2.6 Website links

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

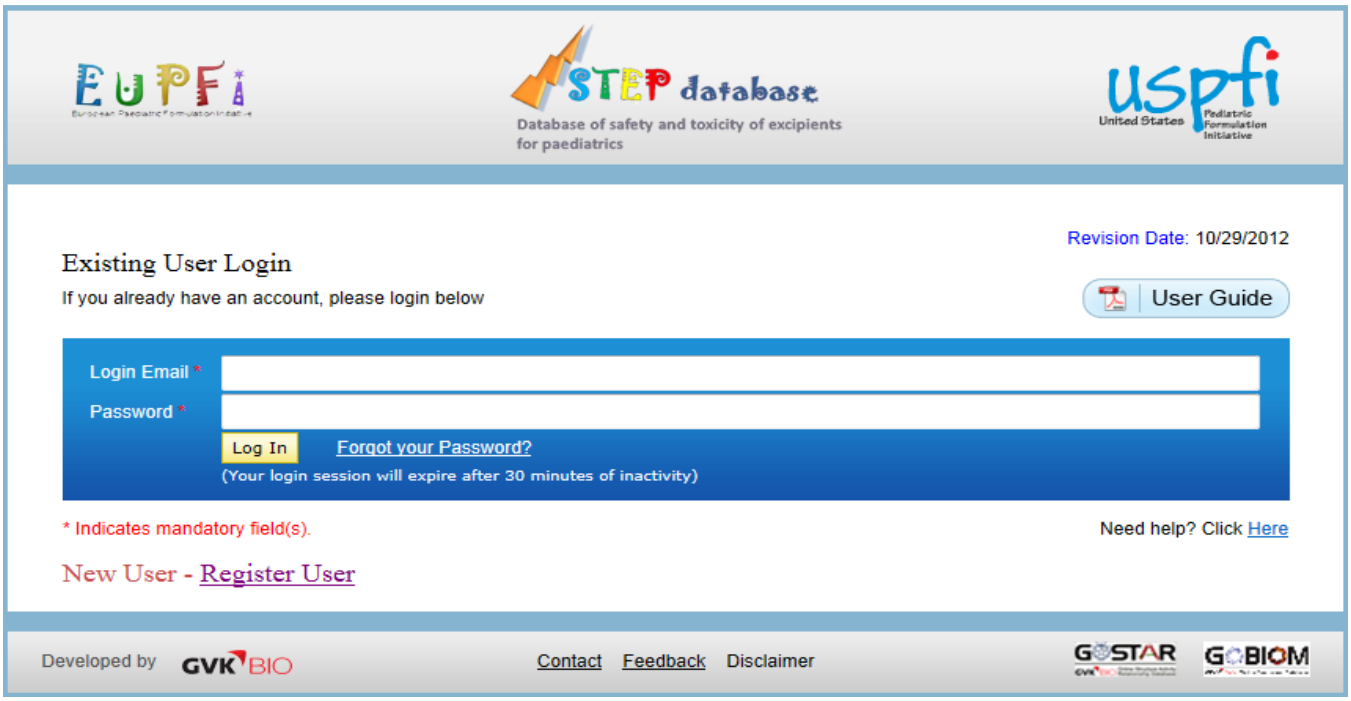


3 Session expiration

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.



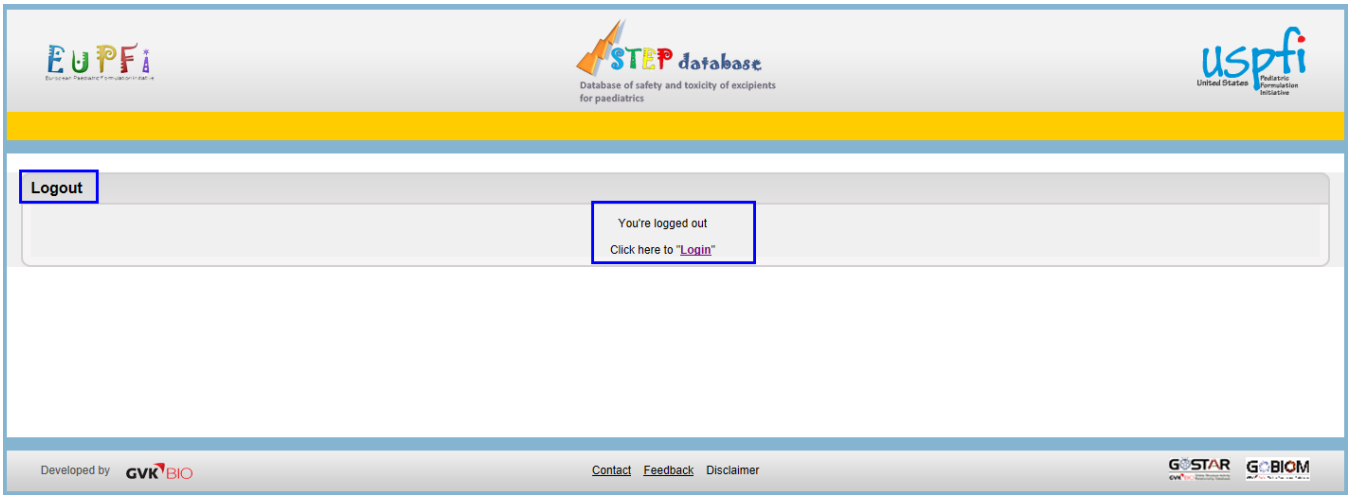
To login to the application click “Here” link which automatically opens the application’s login page.



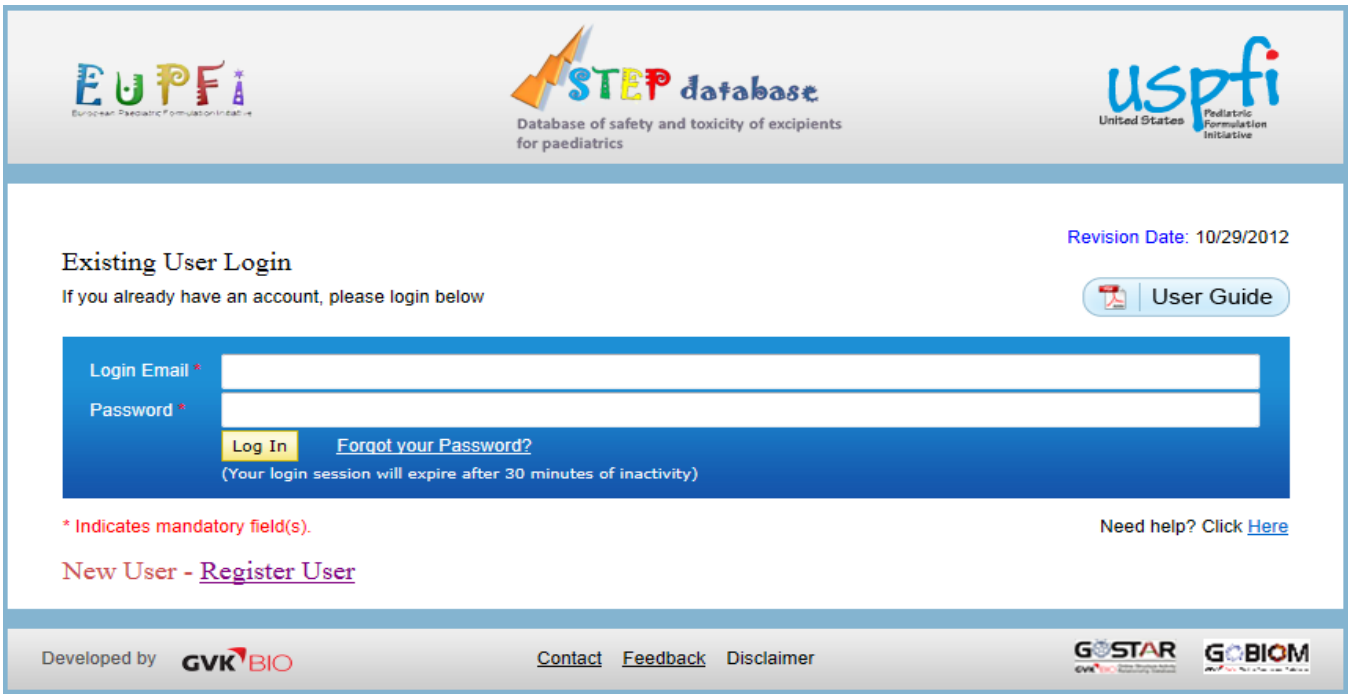
4 Logout

Click Logout link as shown below

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

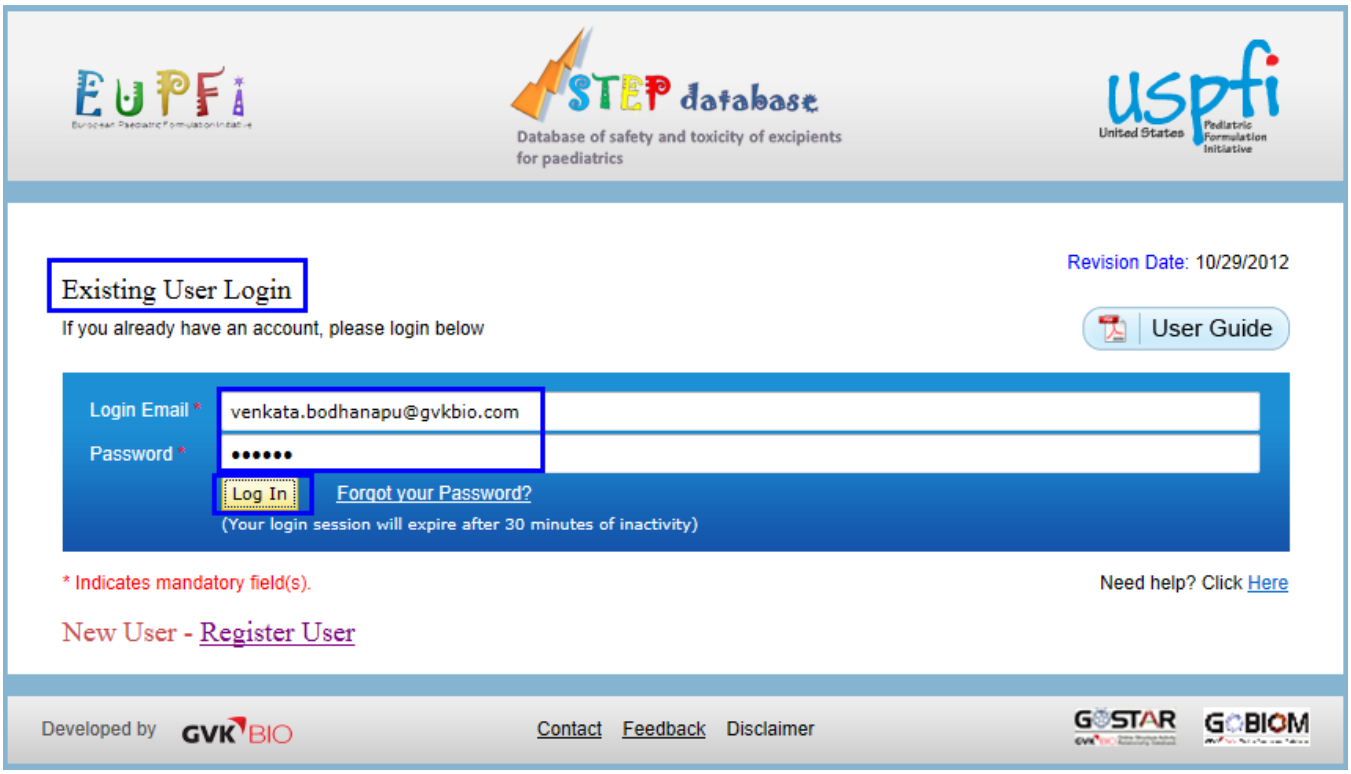


Then the application's login page appears as shown below

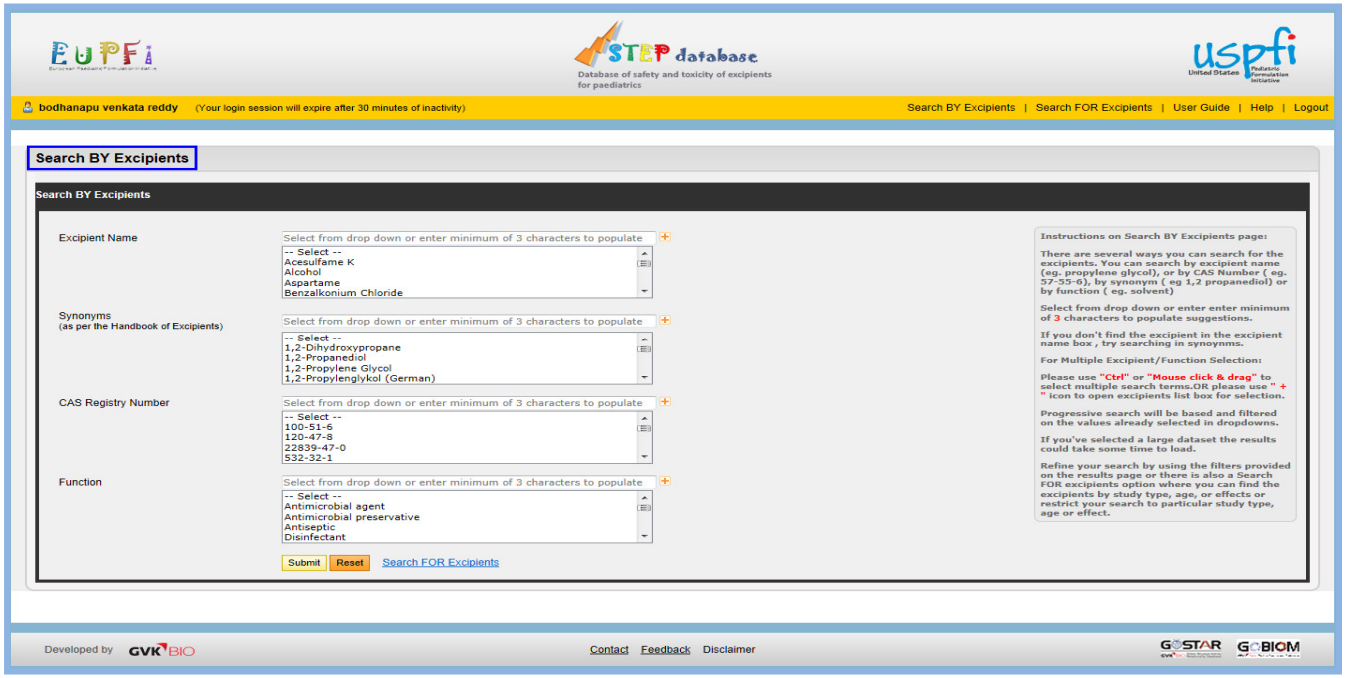


5 Search BY Excipients

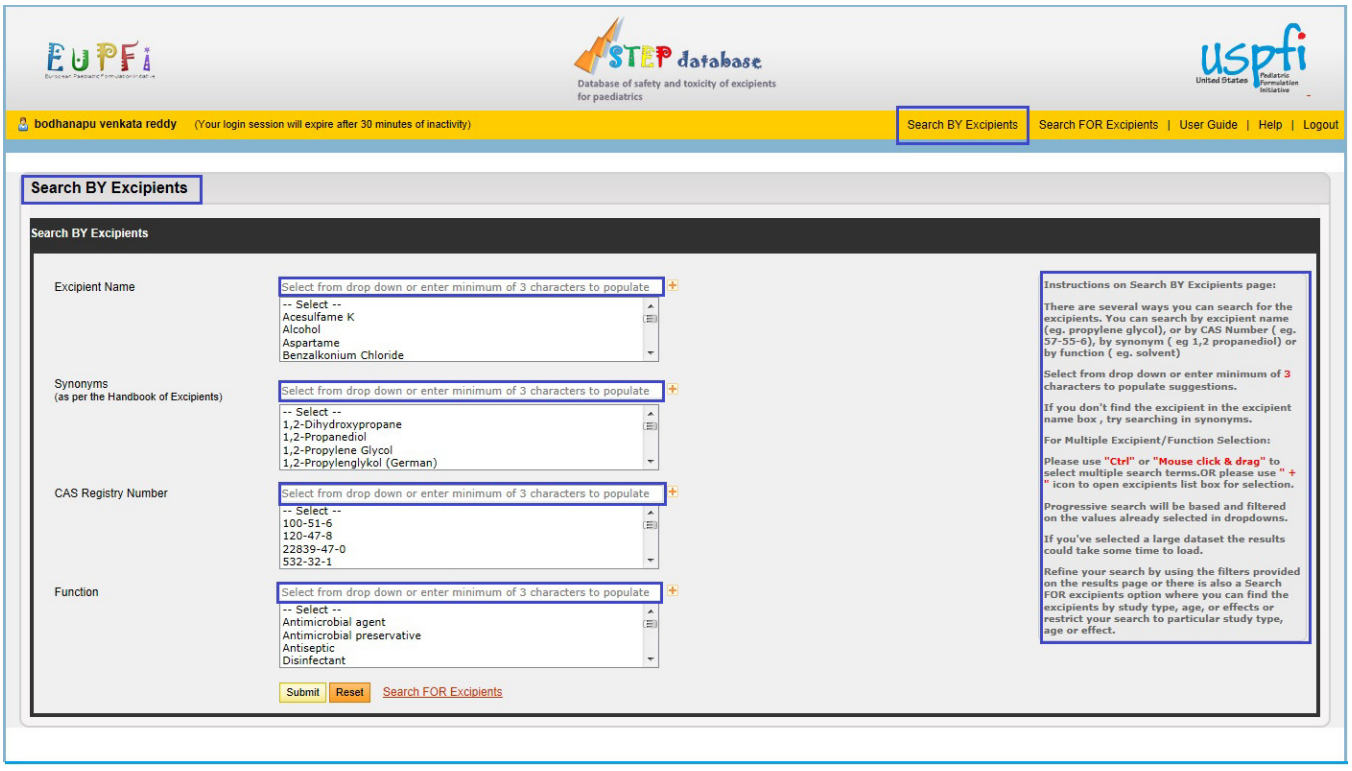
Enter the valid user credentials in the "Login" page and click "Login" as shown below.



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



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.”



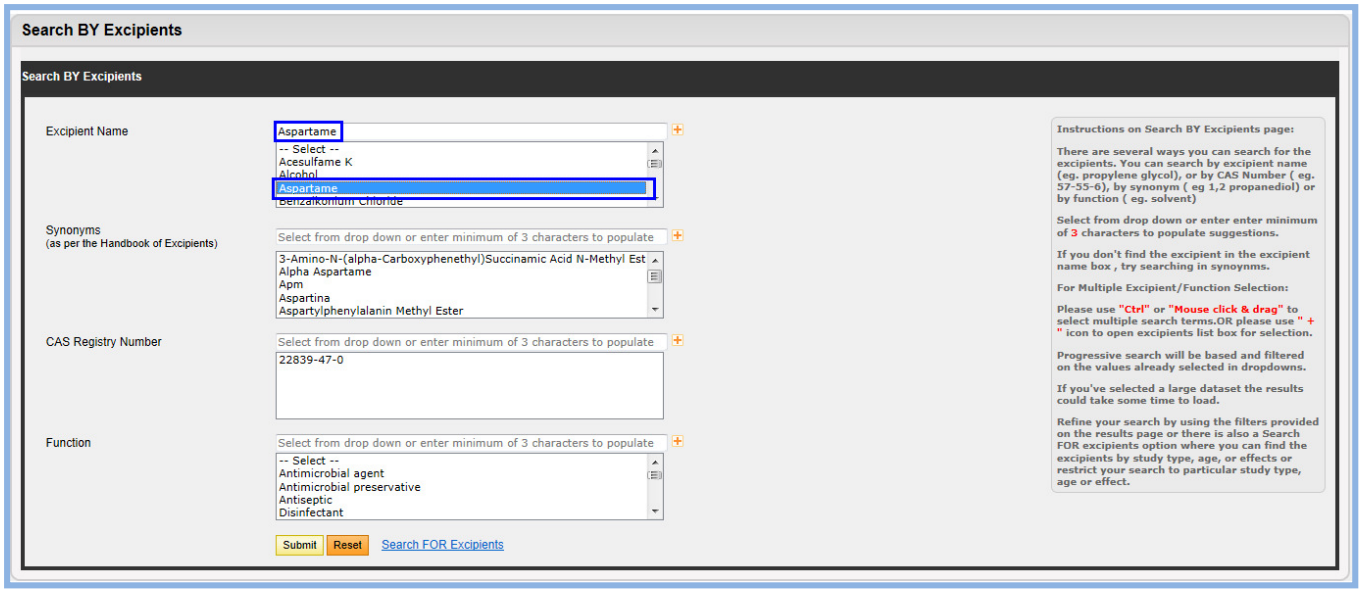
5.1 Search BY Excipients

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.

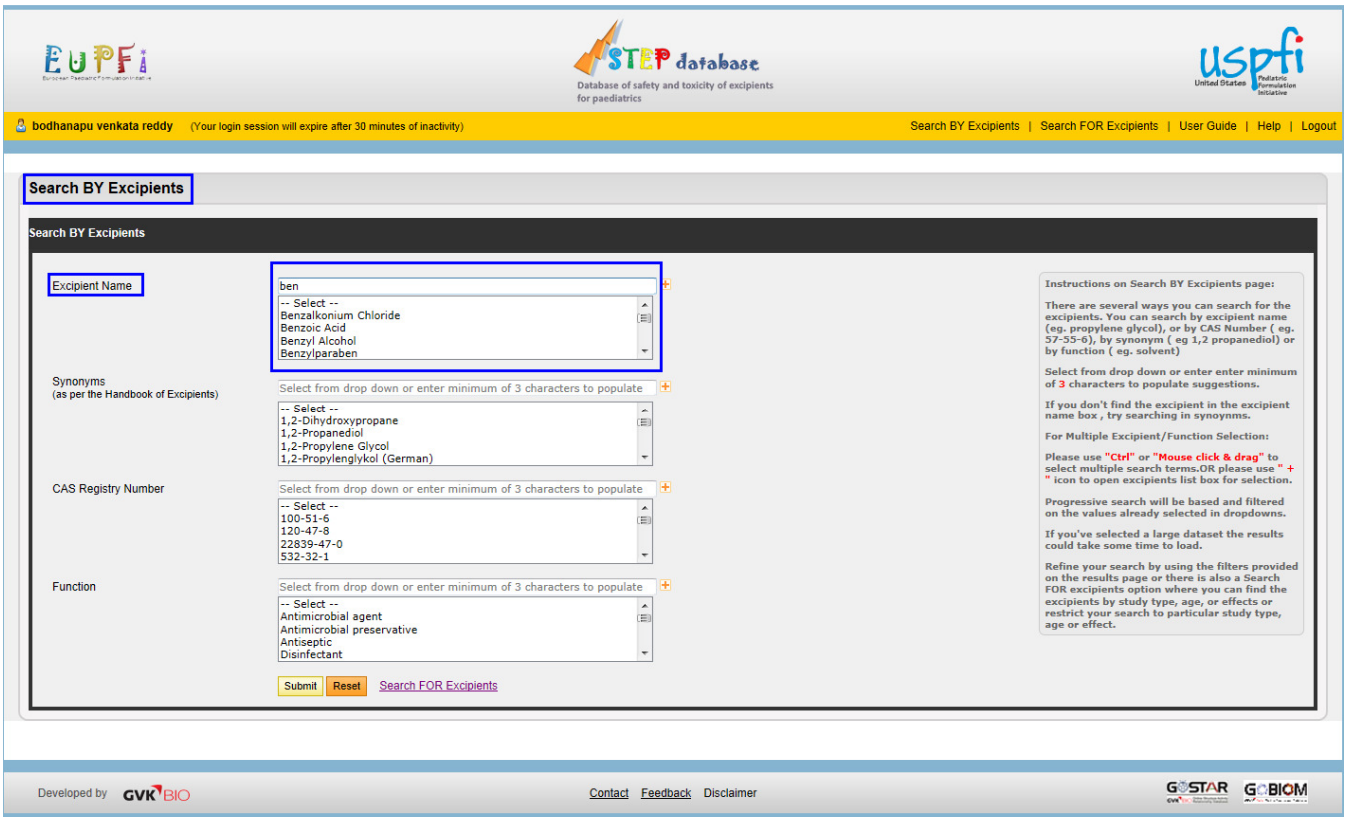
5.1.1 Excipient Name

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.

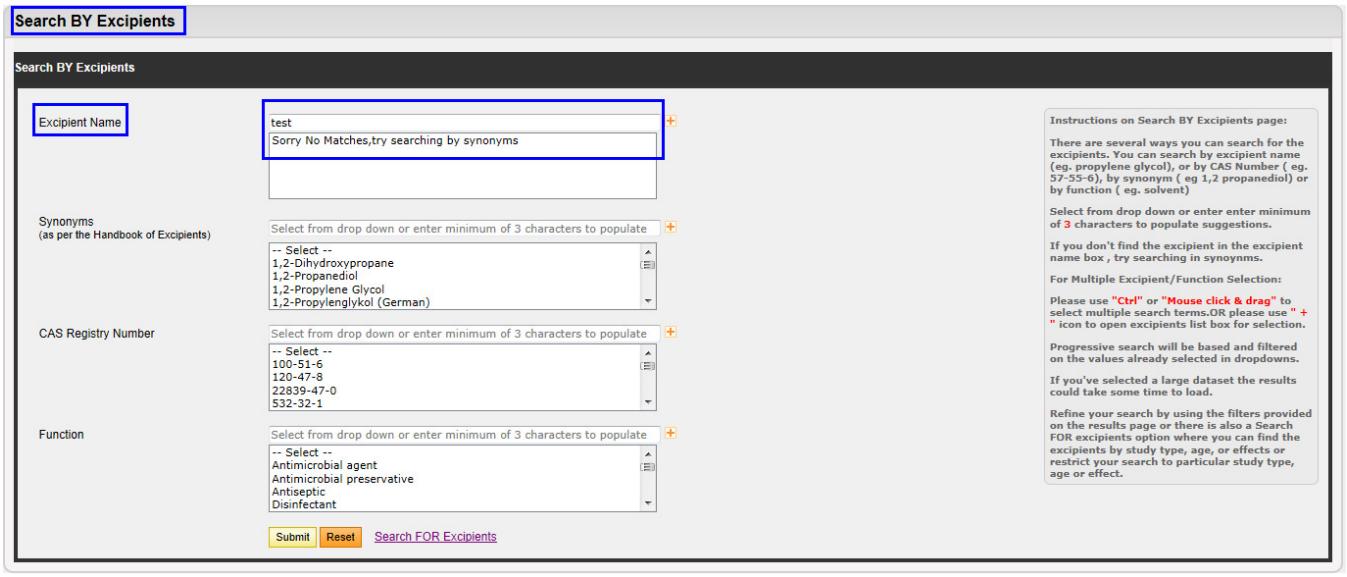


User can get the suggestions after entering minimum of 3 characters in Excipient Name text box. If the data is available then it will display like below,



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

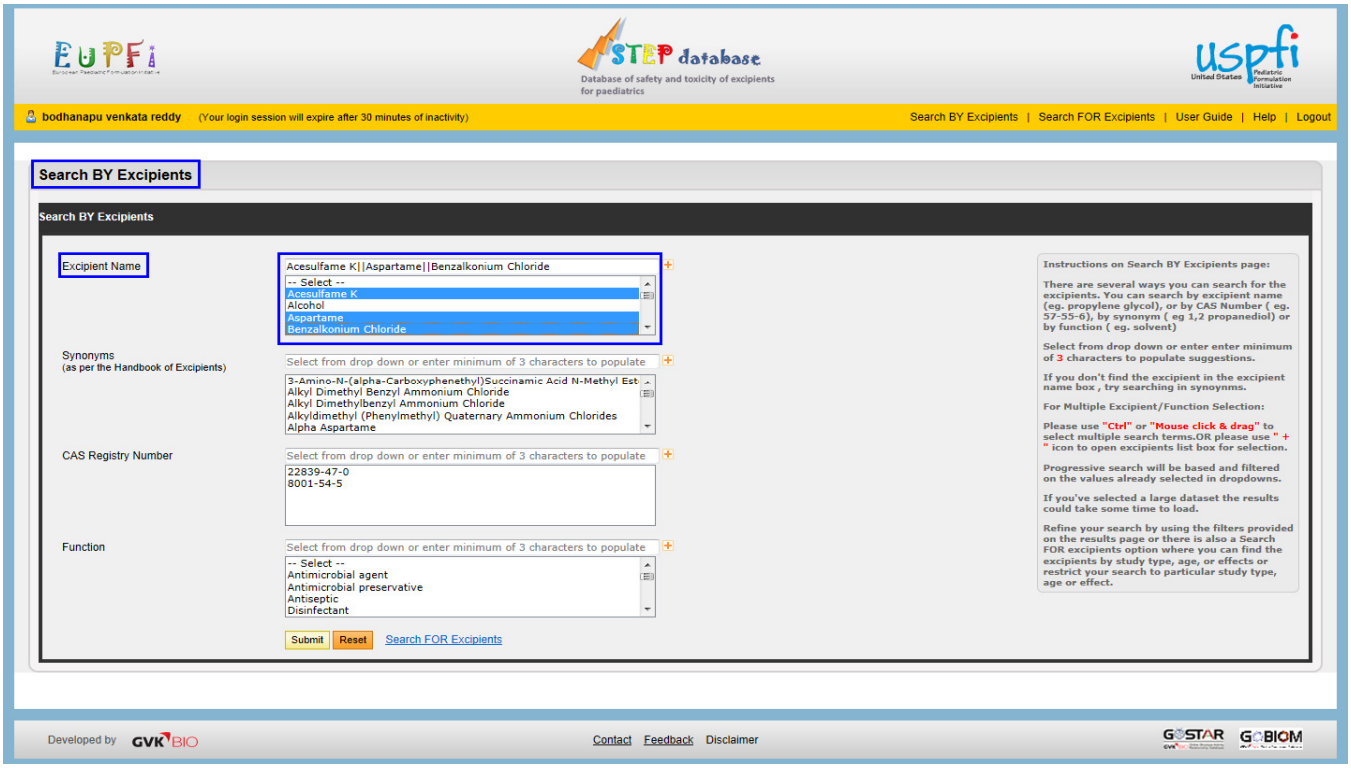
If data is not available for the given 3 characters then it will display the message like below.



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

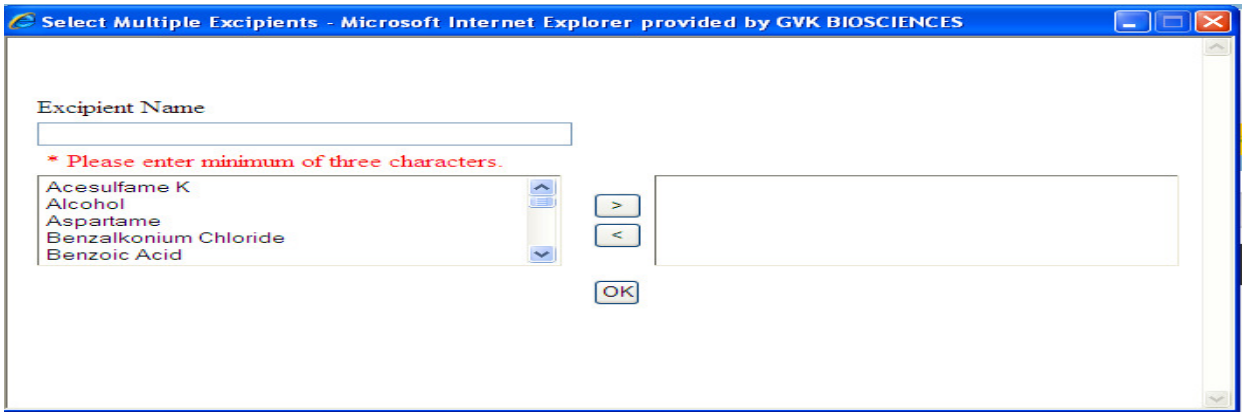
5.1.1.1 Multiple Excipient selection

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

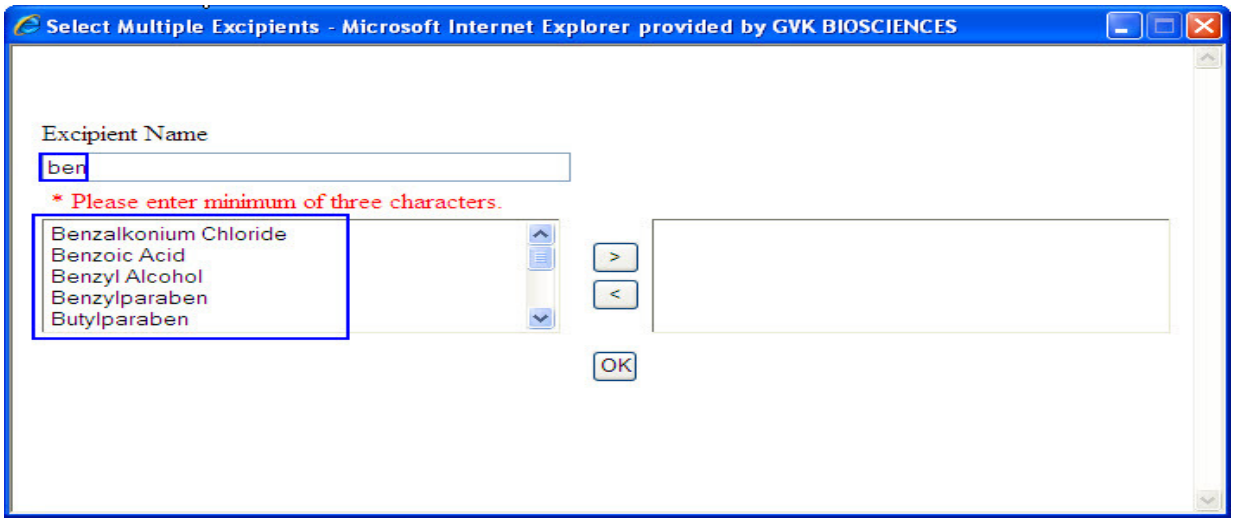


5.1.1.2 Excipient selection based on the category

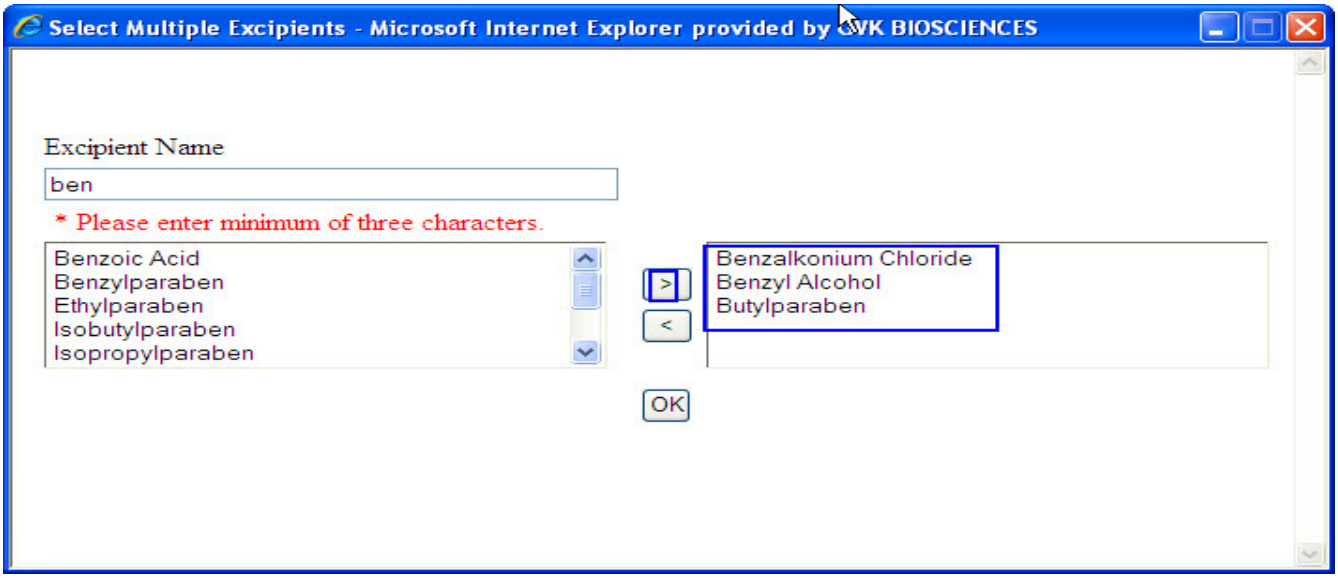
In the basic search page user only has the privilege of selecting "Excipients" of one category at a time but there is an another option of selecting multiple category related excipients at a time using "+" symbol. When user clicks "+" symbol besides the "Excipient Name" text box then the below pop up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



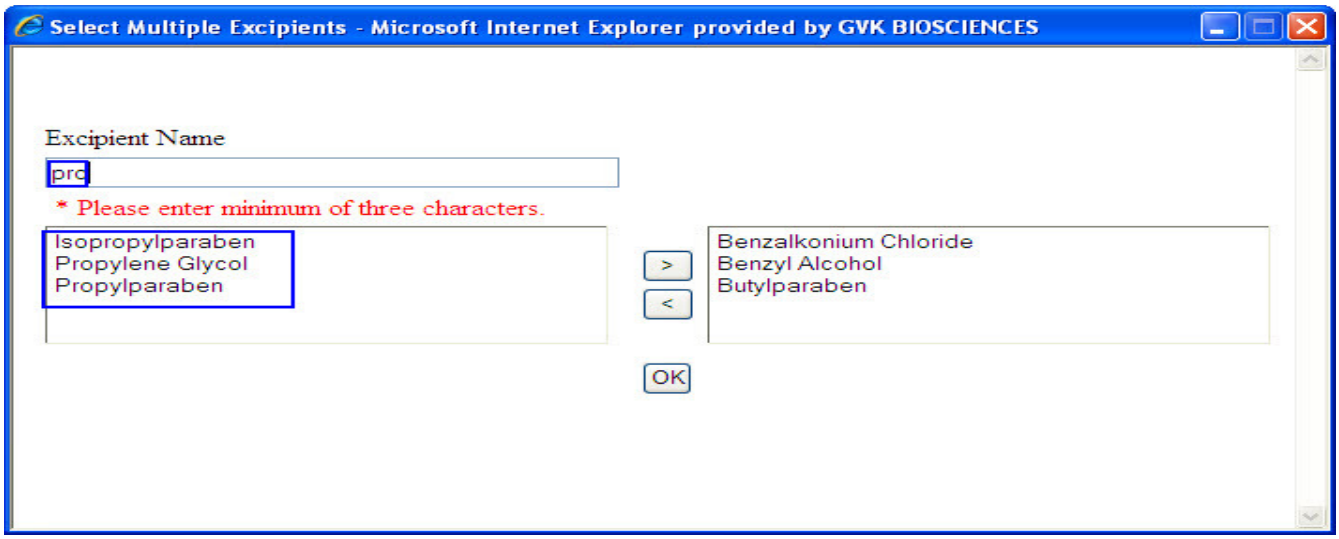
Auto search is available in the pop-up window, when user specifies 3 or more characters in the excipient name then the relevant excipient names appears as shown below.



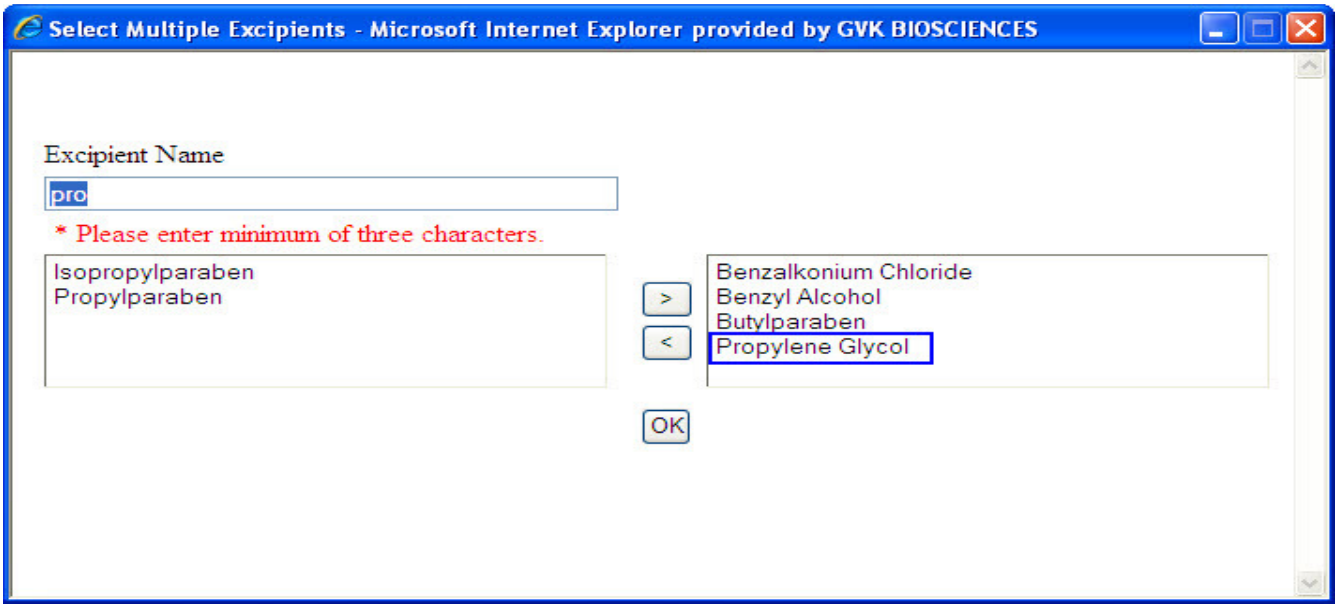
Then user is allowed to select the required excipients from the list and can click **">"** button then the selected excipient name appears in the empty text box as shown below to



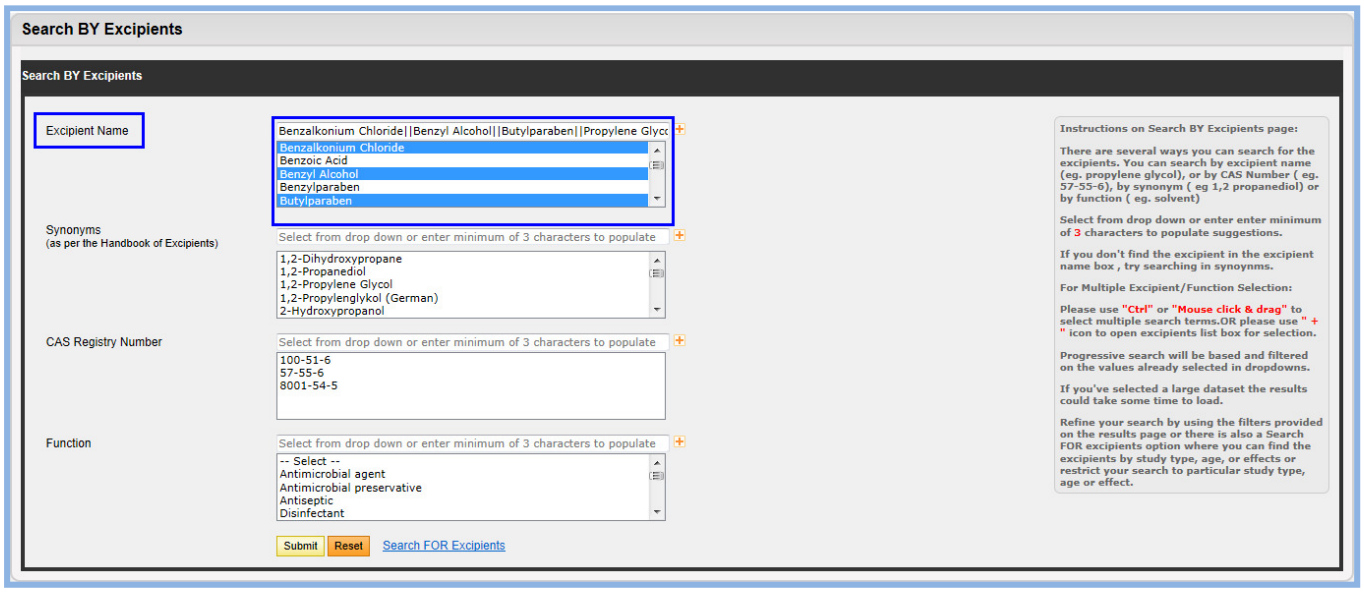
If user needs to select any other excipient from another category can again enter the excipient name then the relevant excipients list appears as shown below



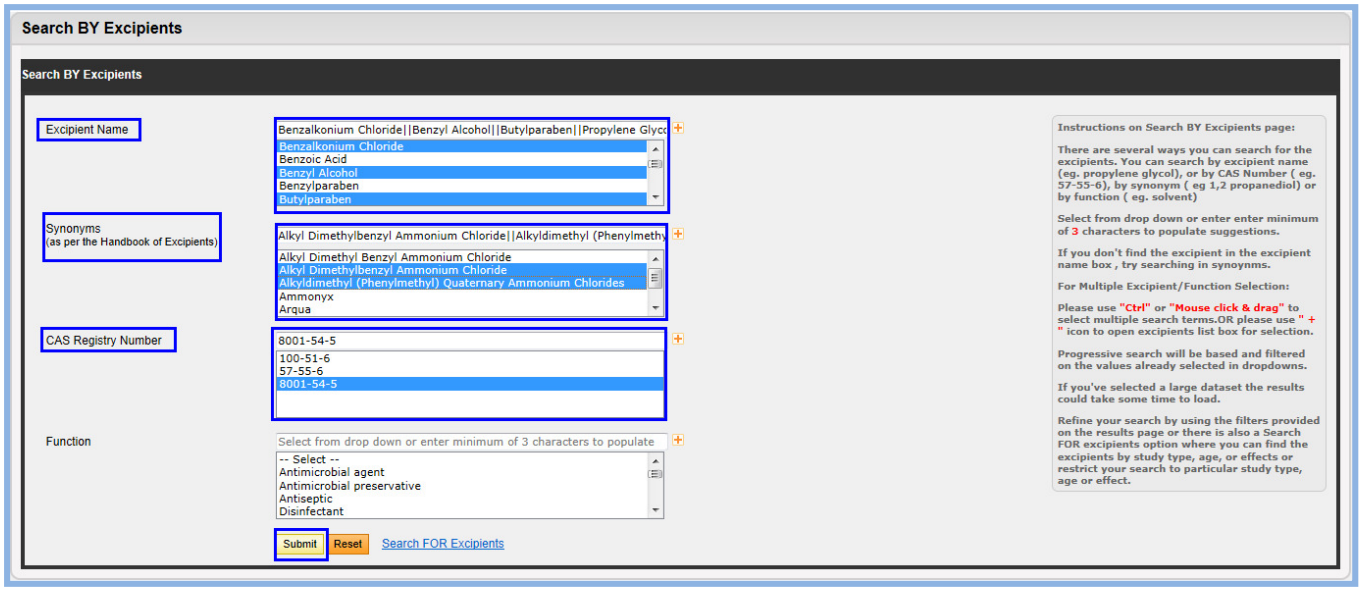
Then user can select the required excipient from the list and click "**>**" button to add it then it appears along with the earlier selected excipient as shown below



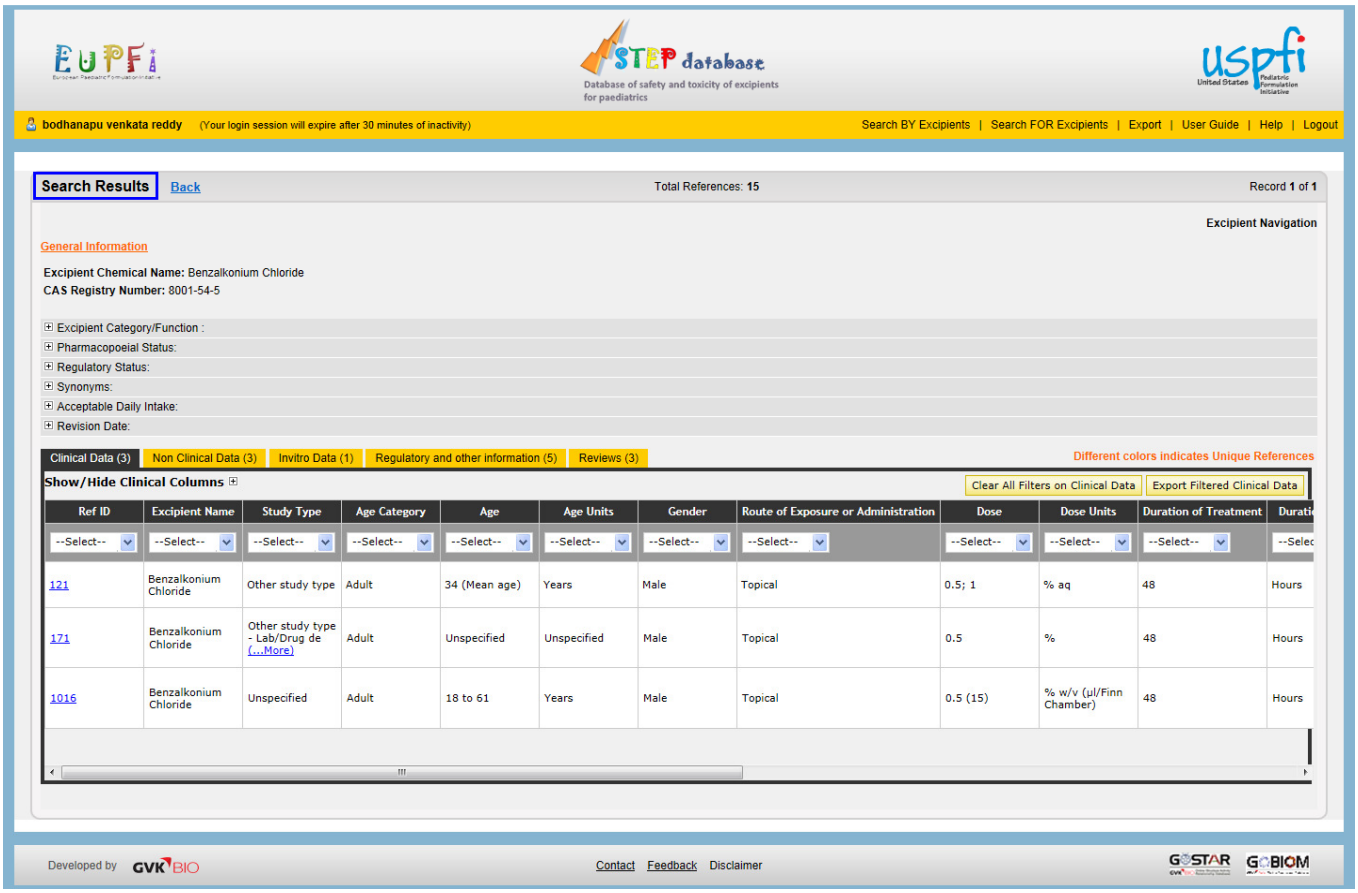
Click "Ok" button then the selected search criteria appears in the "Search BY Excipients" page as shown below



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

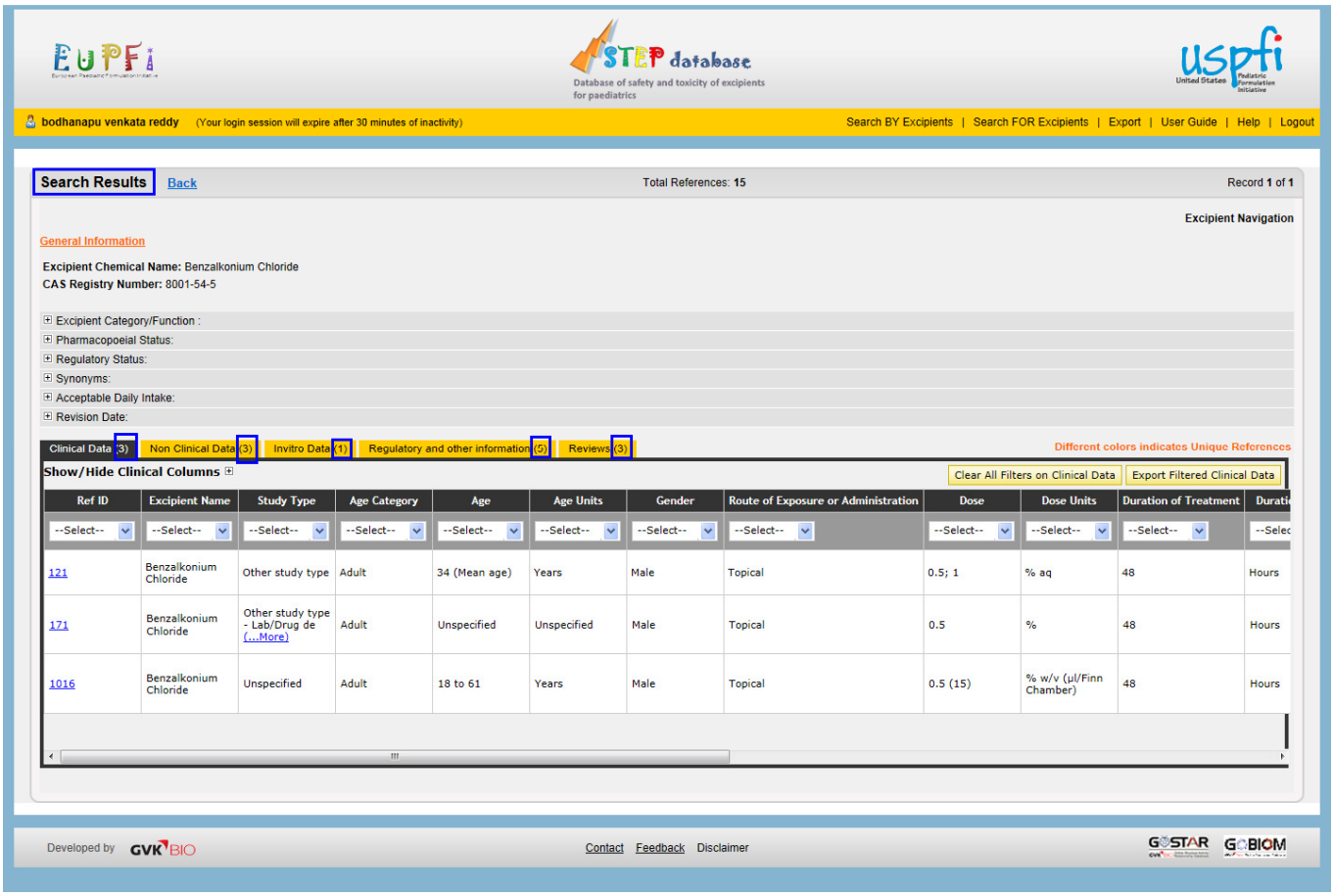


Then click “Submit” button to retrieve the search results considering the search criteria.



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.



Note:

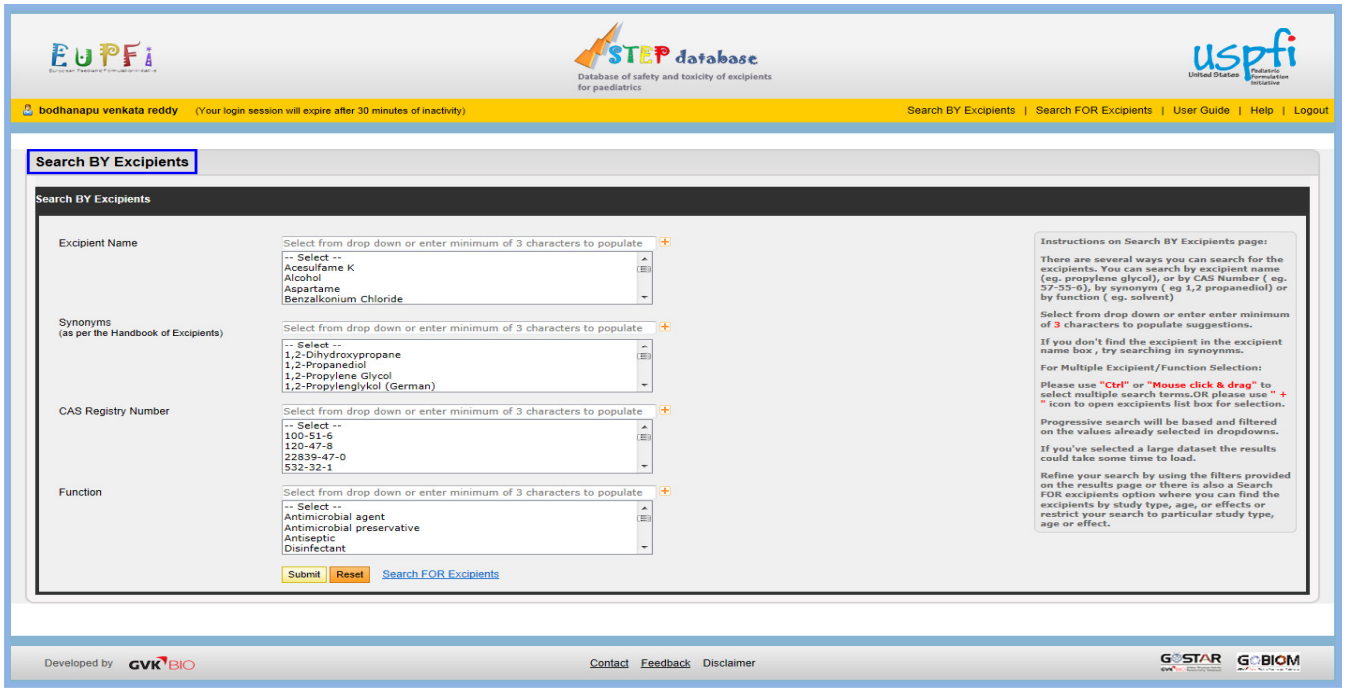
- Based on the selected “Excipient Name” remaining data in the “CAS Registry Number”, “Synonyms” appears.
- When user selects “Excipient Name” and “CAS Registry Number” then based on both those values data in the “Synonyms” appears.
- The progressive filtering will populate the data by ‘Contains’ search, 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

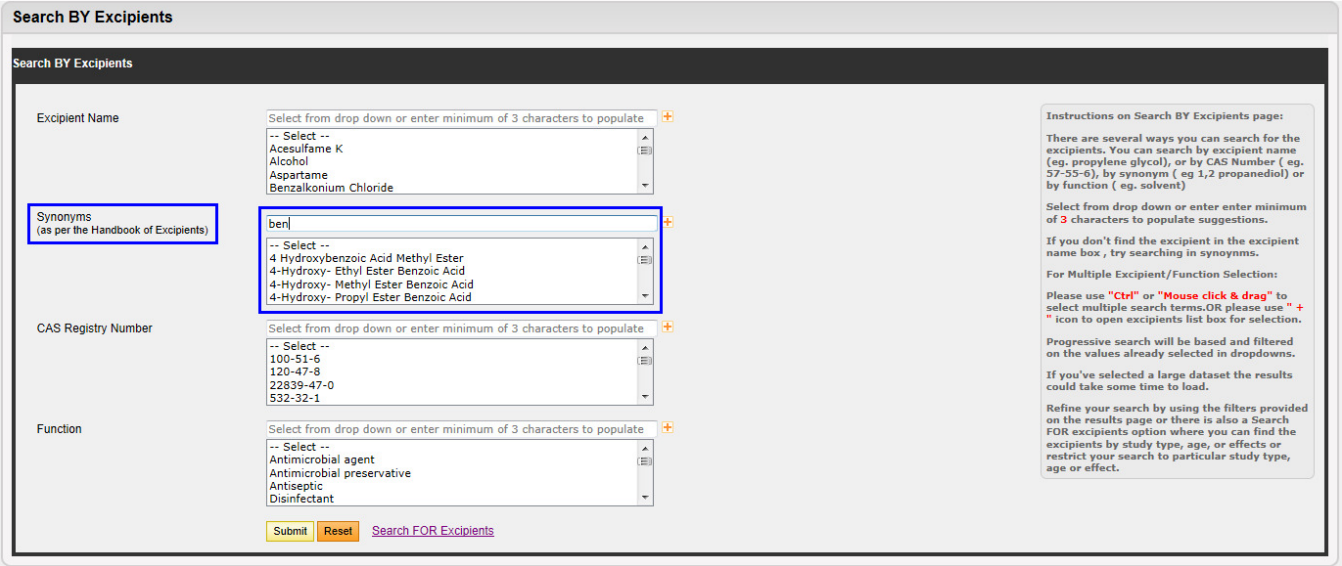
Example: The privilege of selecting the required synonyms using the Synonyms is also facilitated. When user selects synonyms using "Synonyms" then based on that selected synonyms remaining data in the "Excipient Name, CAS Registry Number" appears as shown below

Search BY Excipients page before selecting the Synonyms



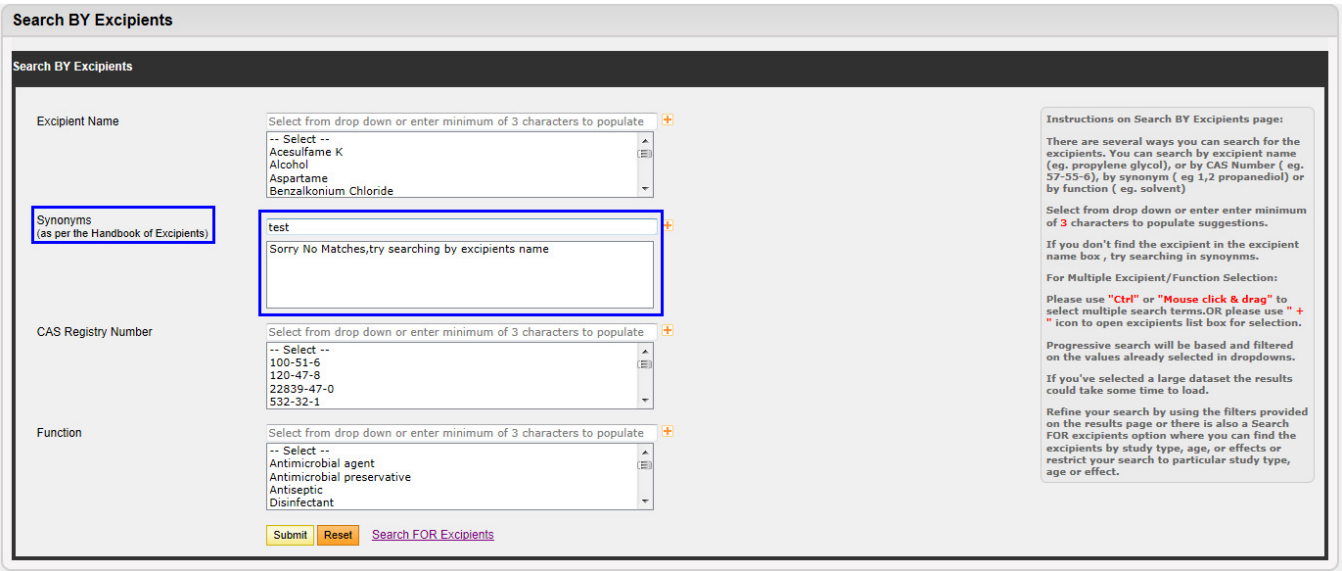
Search BY Excipients page after selecting the Synonyms

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,

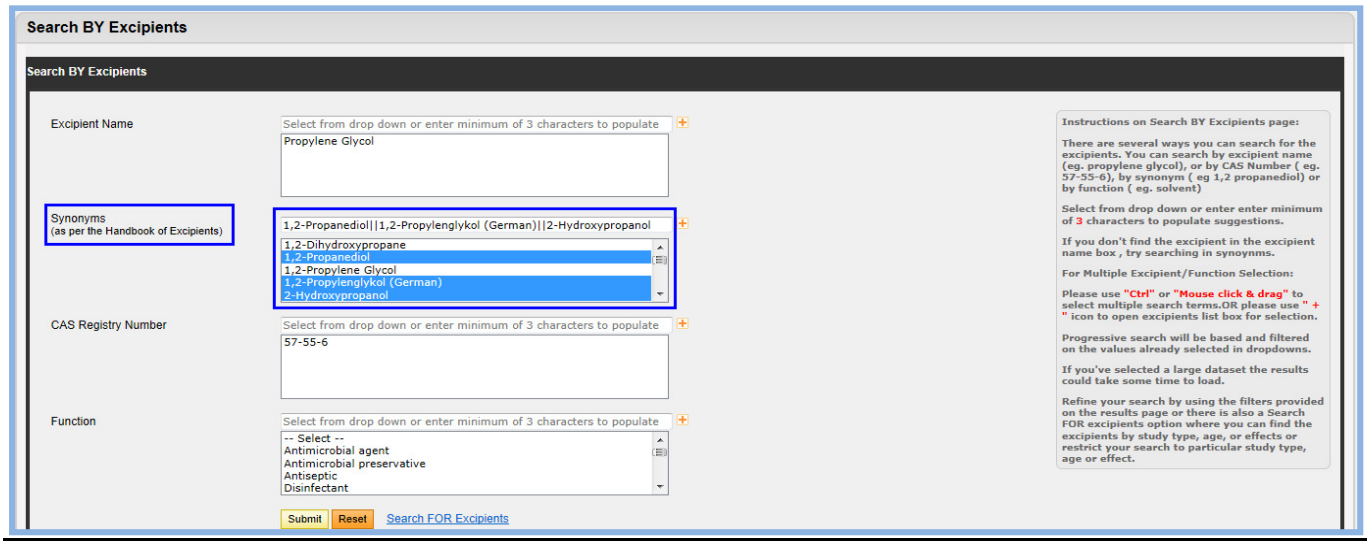


Among the available data user can select and then clicks on Submit button to get the Search Results page.

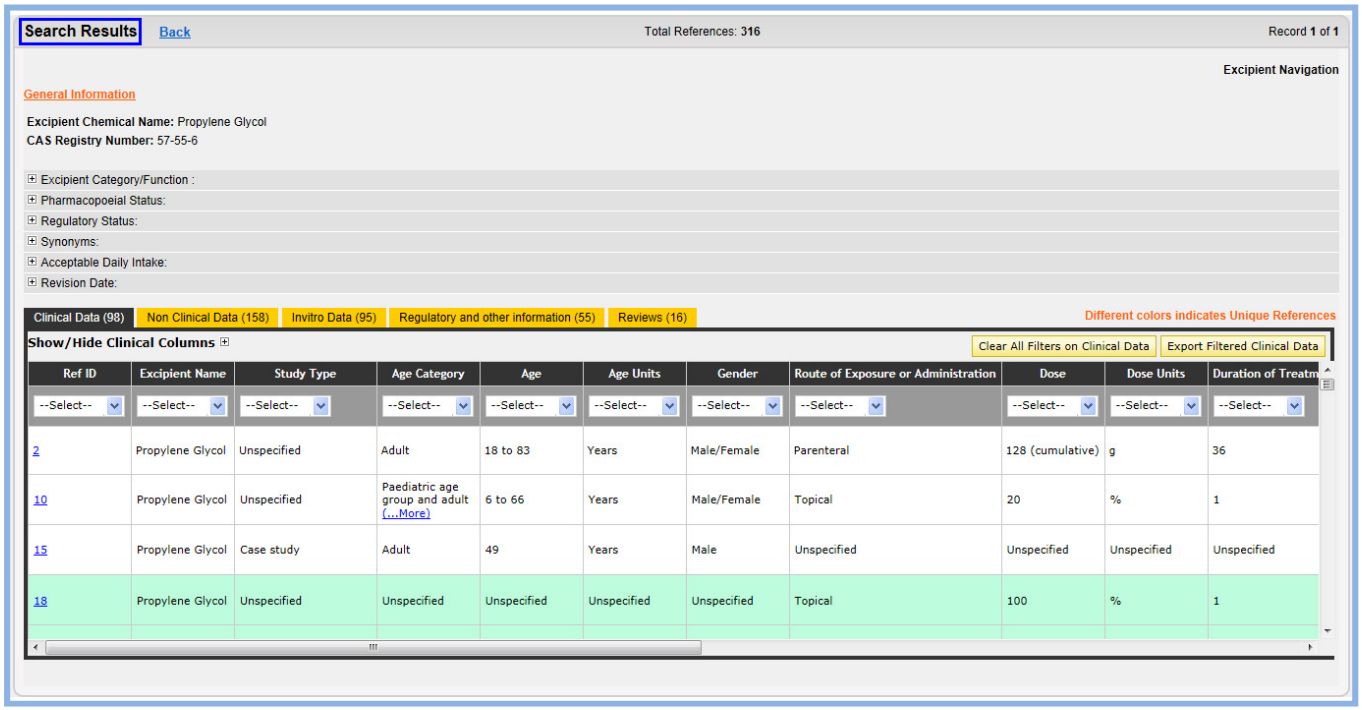
If data is not available for the given 3 characters then it will display the message like below.



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



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



5.1.3 CAS Registry Number

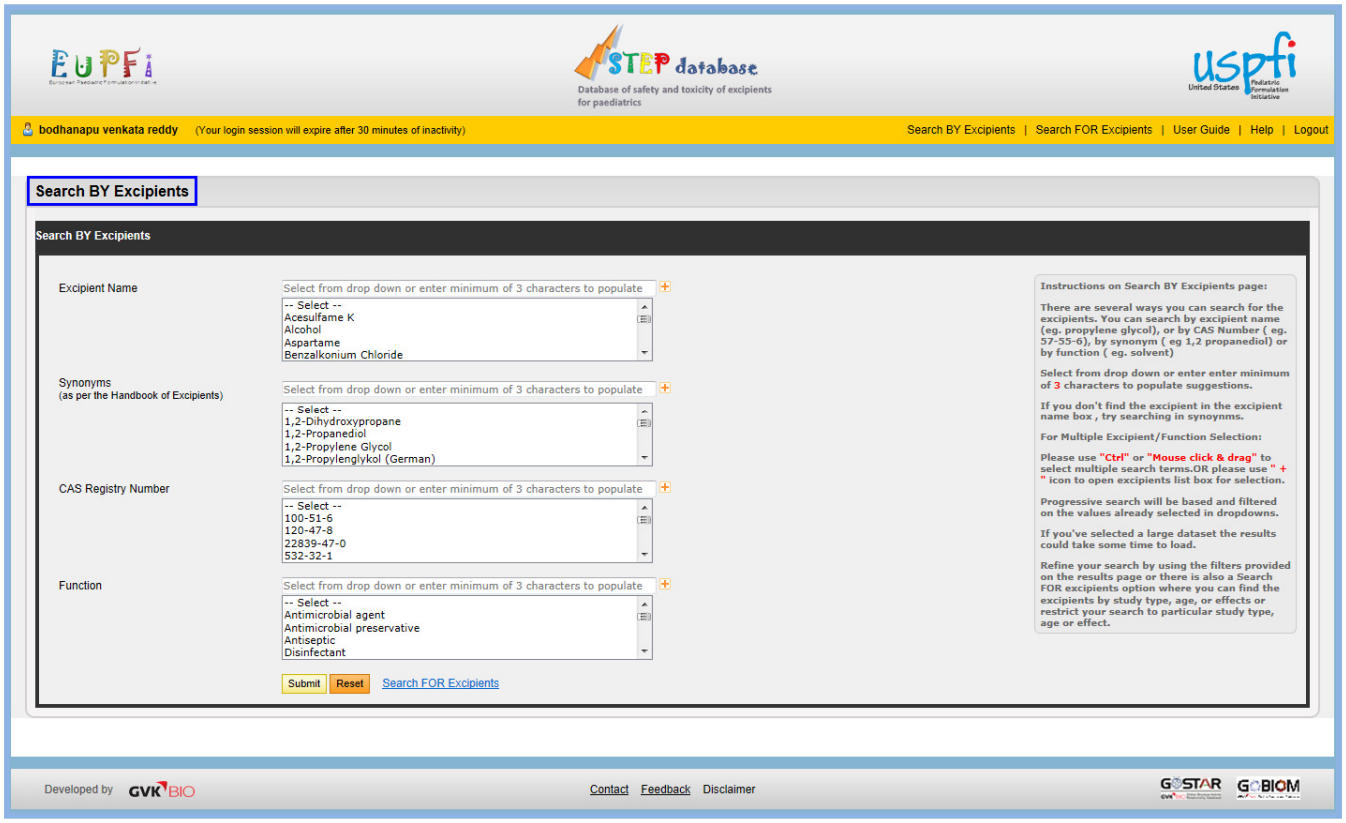
CAS Registry Number is a numeric designation assigned by the “Chemical Abstracts Service” of the American Chemical Society that uniquely identifies a specific chemical compound, regardless of the name or nomenclature system used.

Example:

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

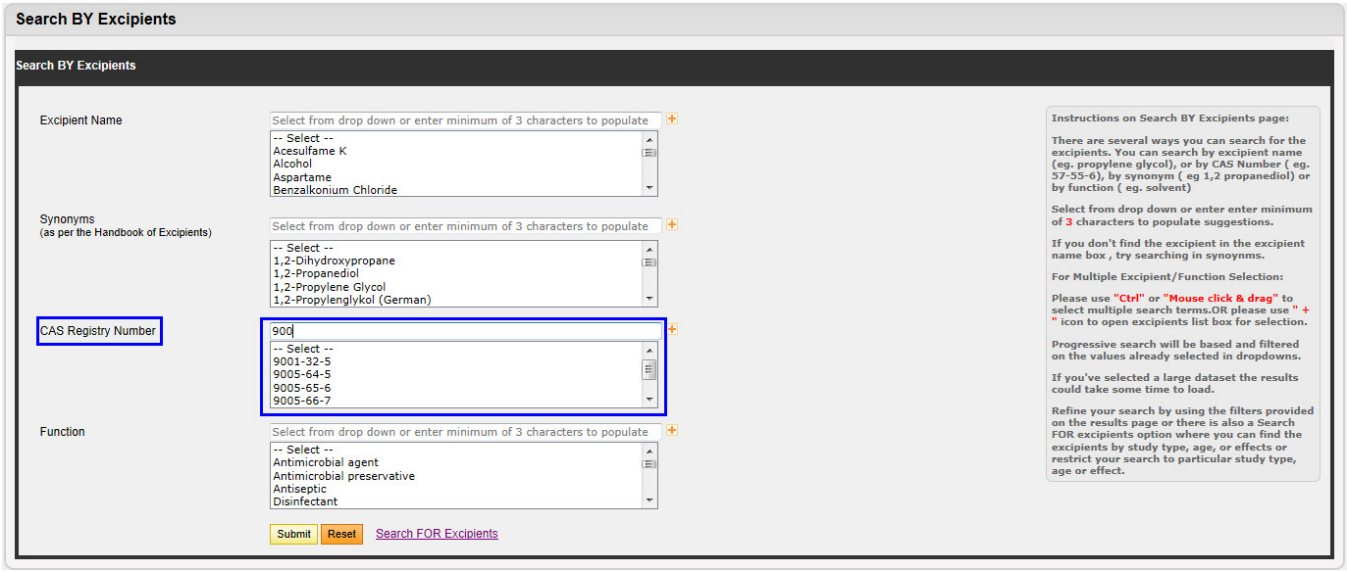
The privilege of selecting the required CAS numbers using the CAS Registry number is also facilitated. When user selects CAS registry number using “CAS Registry Number” then based on that selected CAS Registry Number remaining data in the “Excipient Name, Synonyms” appears as shown below

Search BY Excipients before selecting the CAS Registry Number



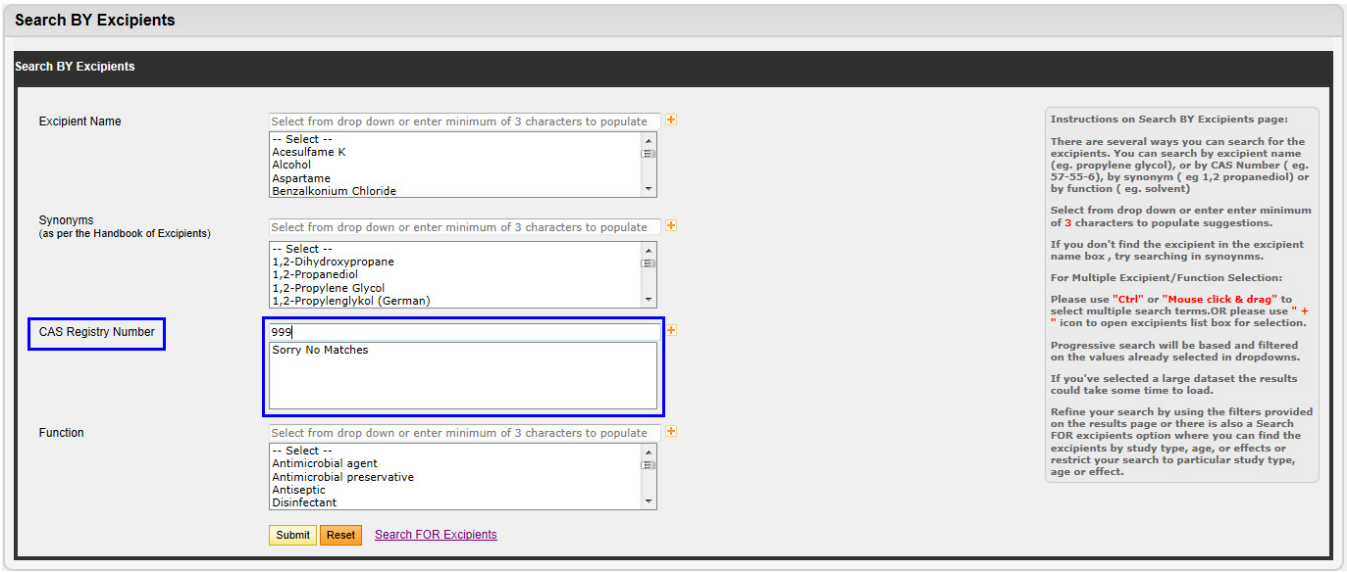
Search BY Excipients after selecting the CAS Registry Number

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,

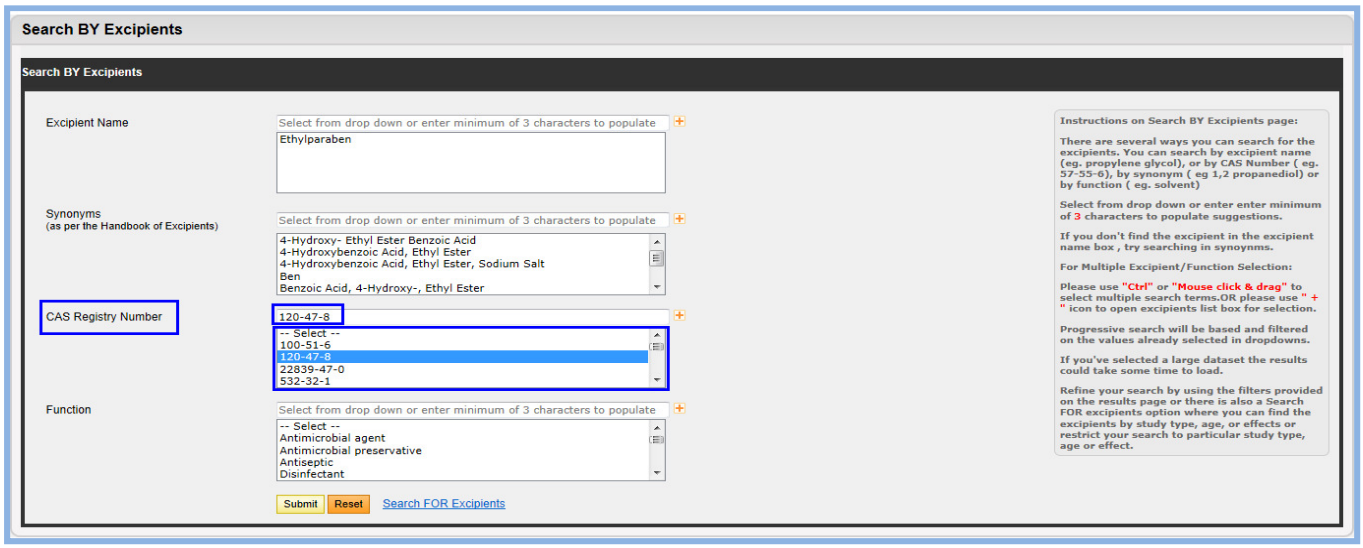


Among the available data user can select and then clicks on Submit button to get the Search Results page.

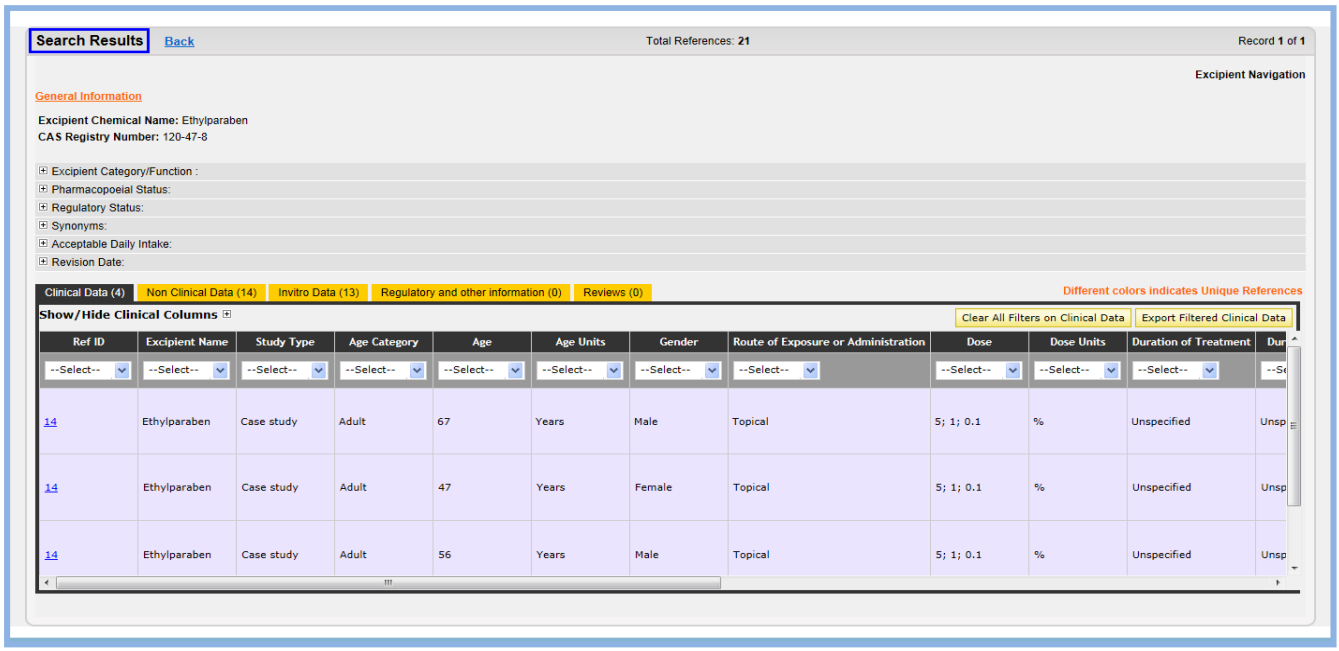
If data is not available for the given 3 characters then it will display the message like below.



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



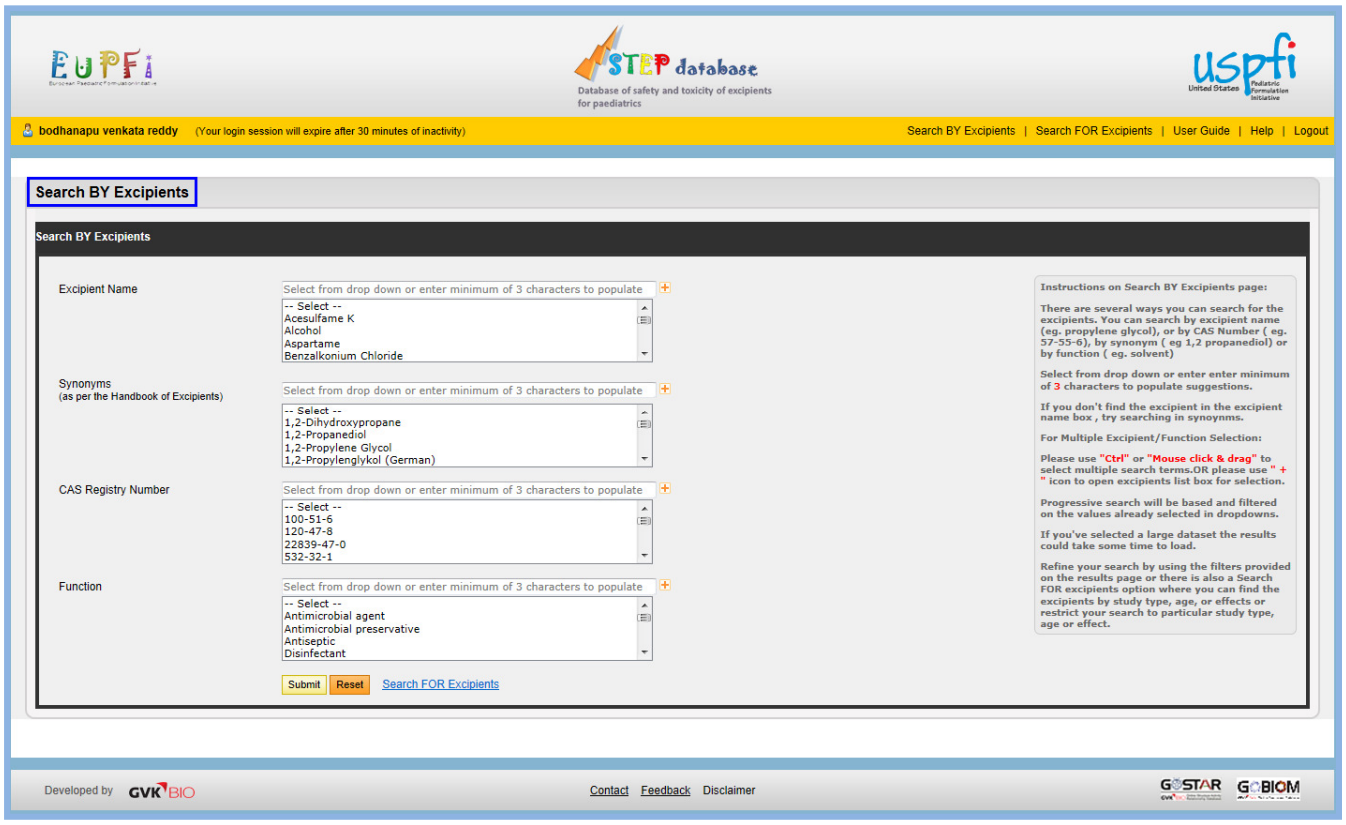
Click “Submit” then the search results appears as shown below.



5.1.4 Function

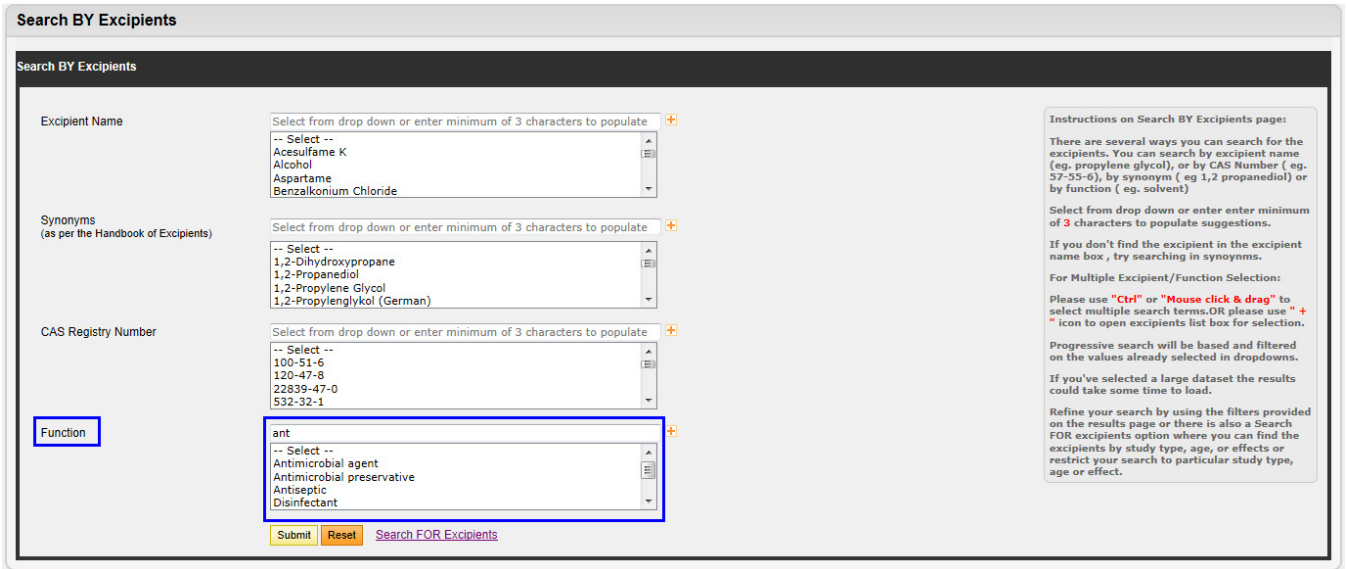
Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below

Search BY Excipients before selecting the Function



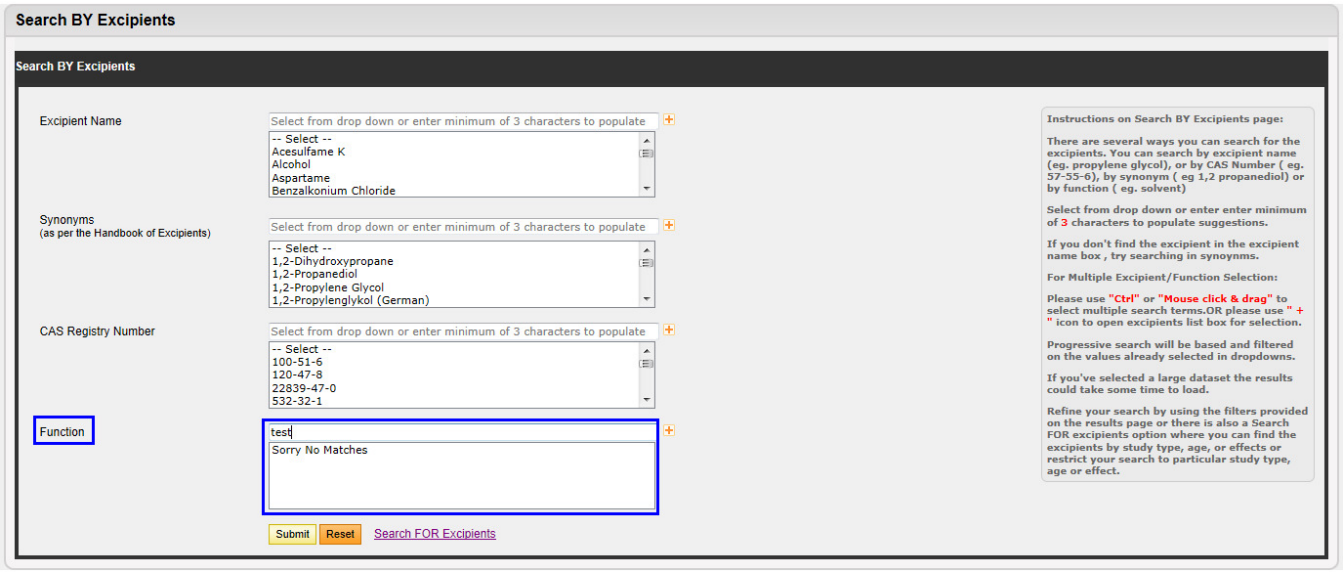
Search BY Excipients after selecting the Function

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,

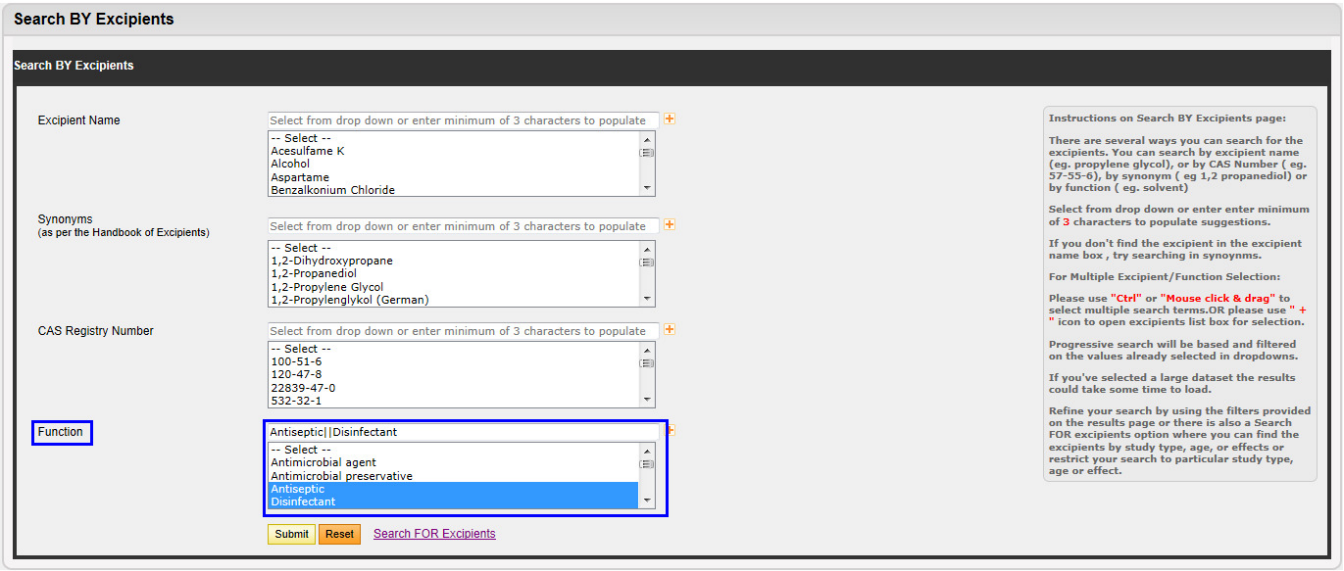


Among the available data user can select and then clicks on Submit button to get the Search Results page.

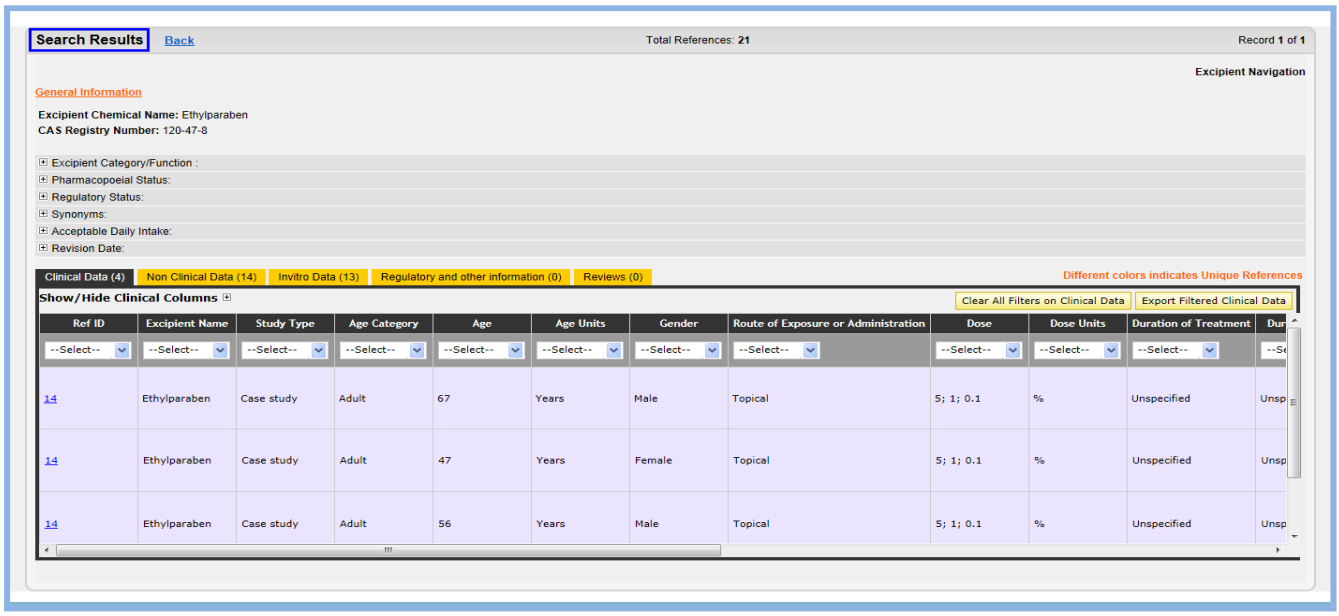
If data is not available for the given 3 characters then it will display the message like below.



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



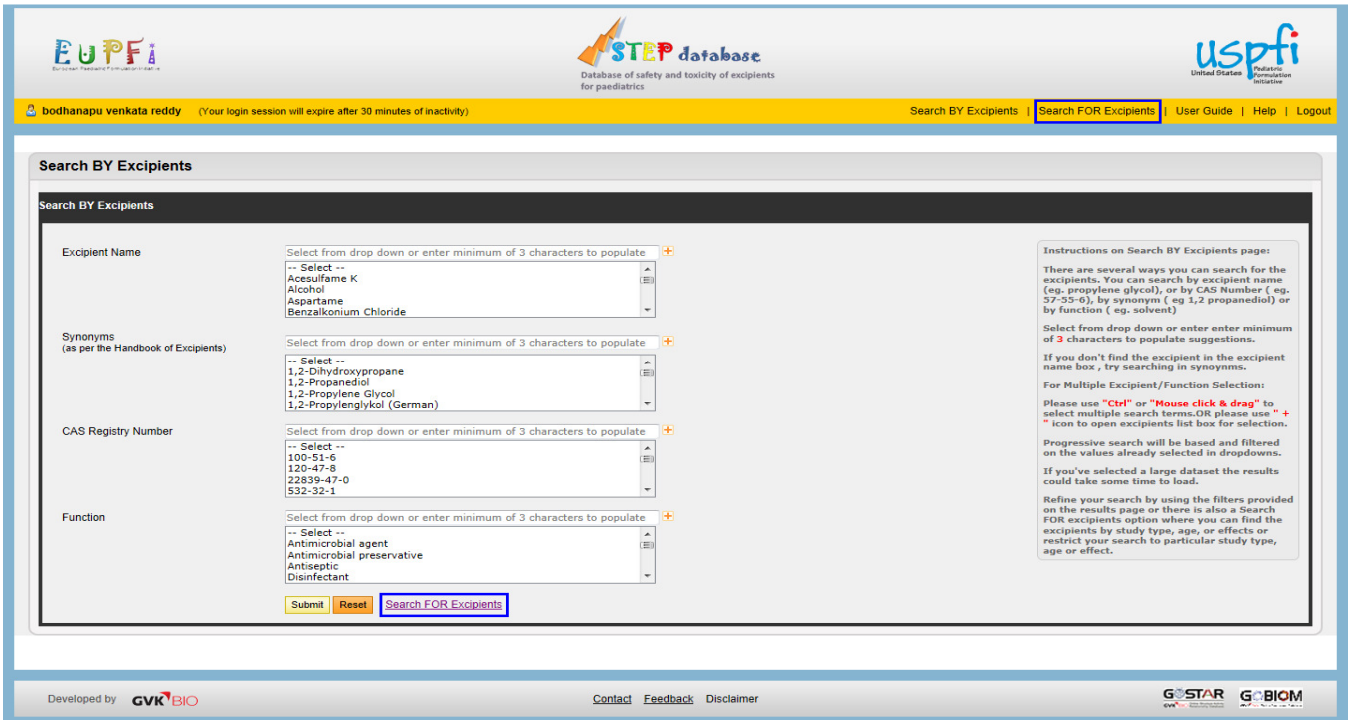
Click “Submit” then the search results appears as shown below.



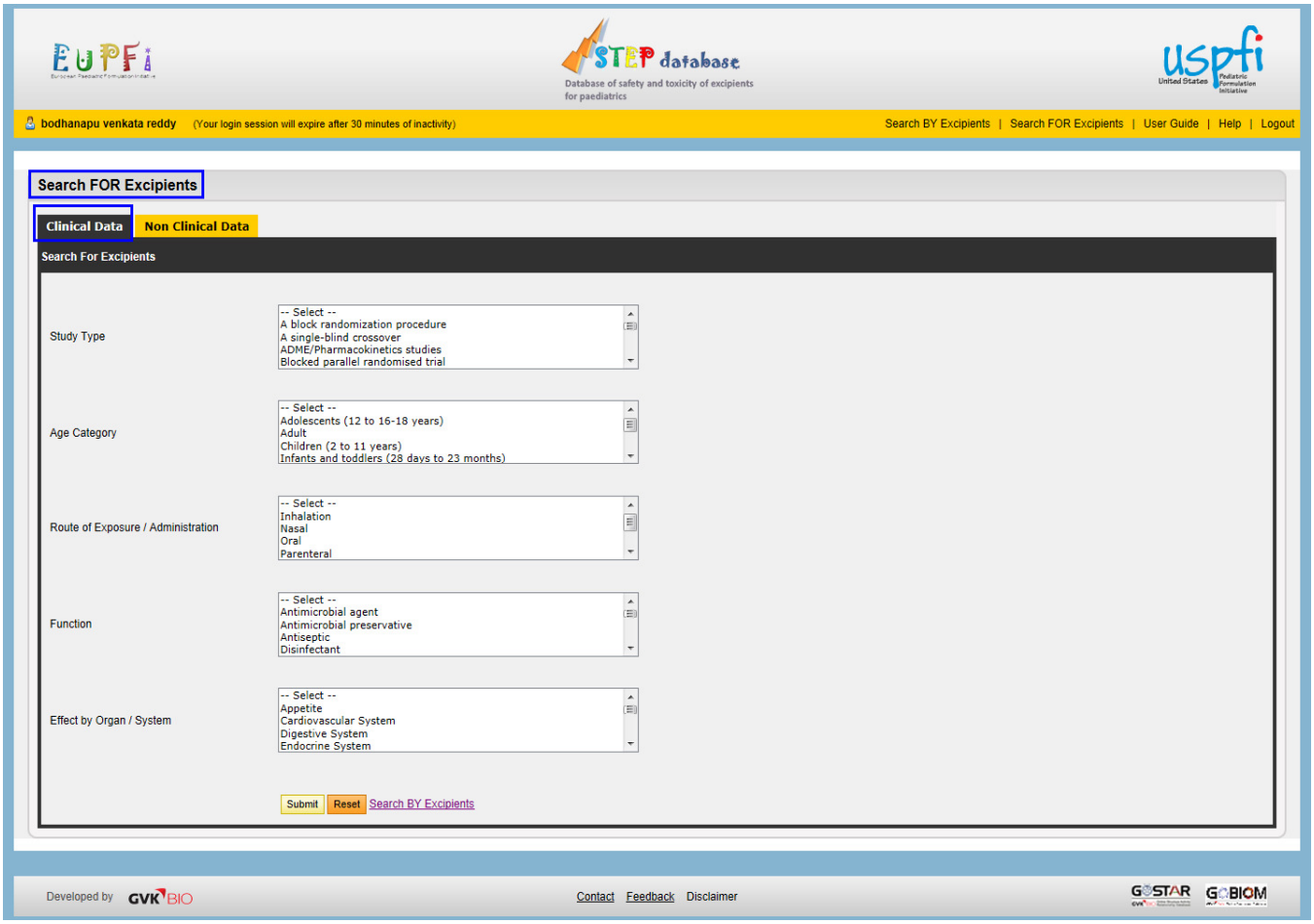
Note: Progressive filtering functionality is available for Excipient Name, CAS Registry Number and Synonyms fields. And Function field is an individual field.

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.



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.



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

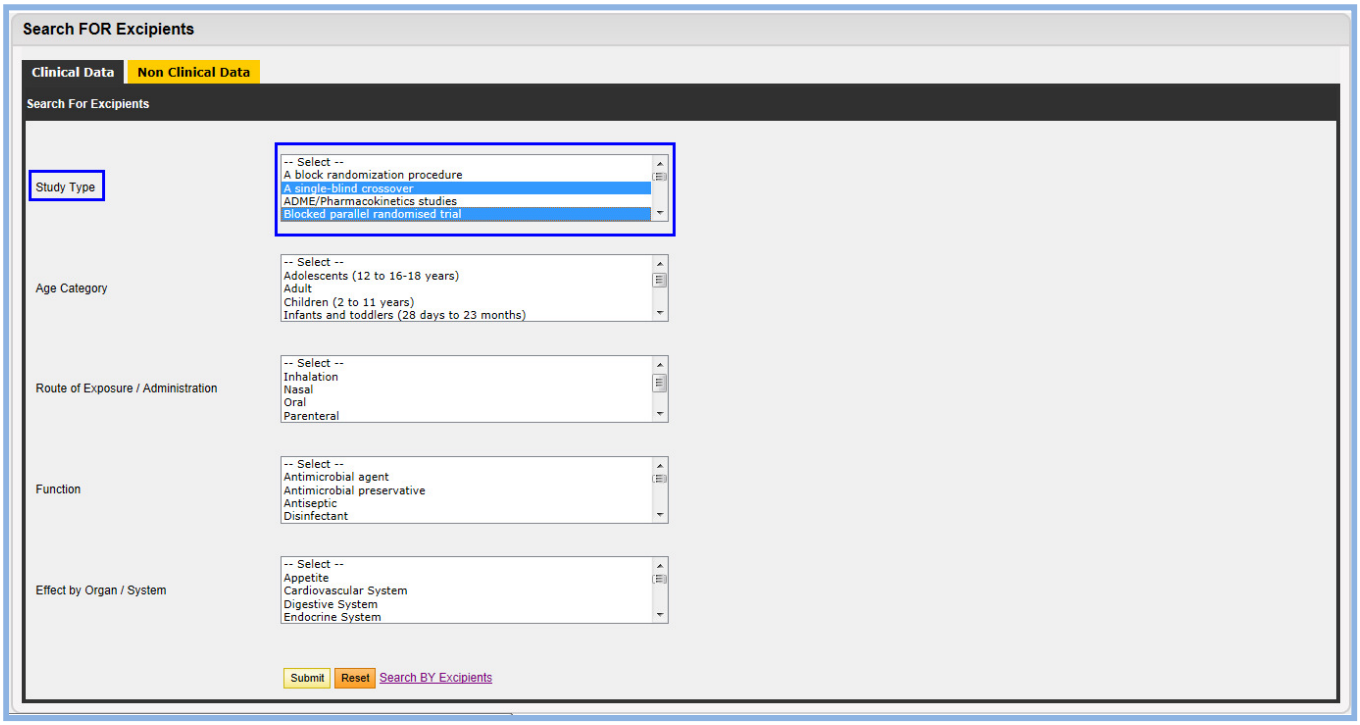
- ✓ Study Type
- ✓ Age Category
- ✓ Route of Exposure / Administration
- ✓ Function
- ✓ Effect by Organ / System

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.

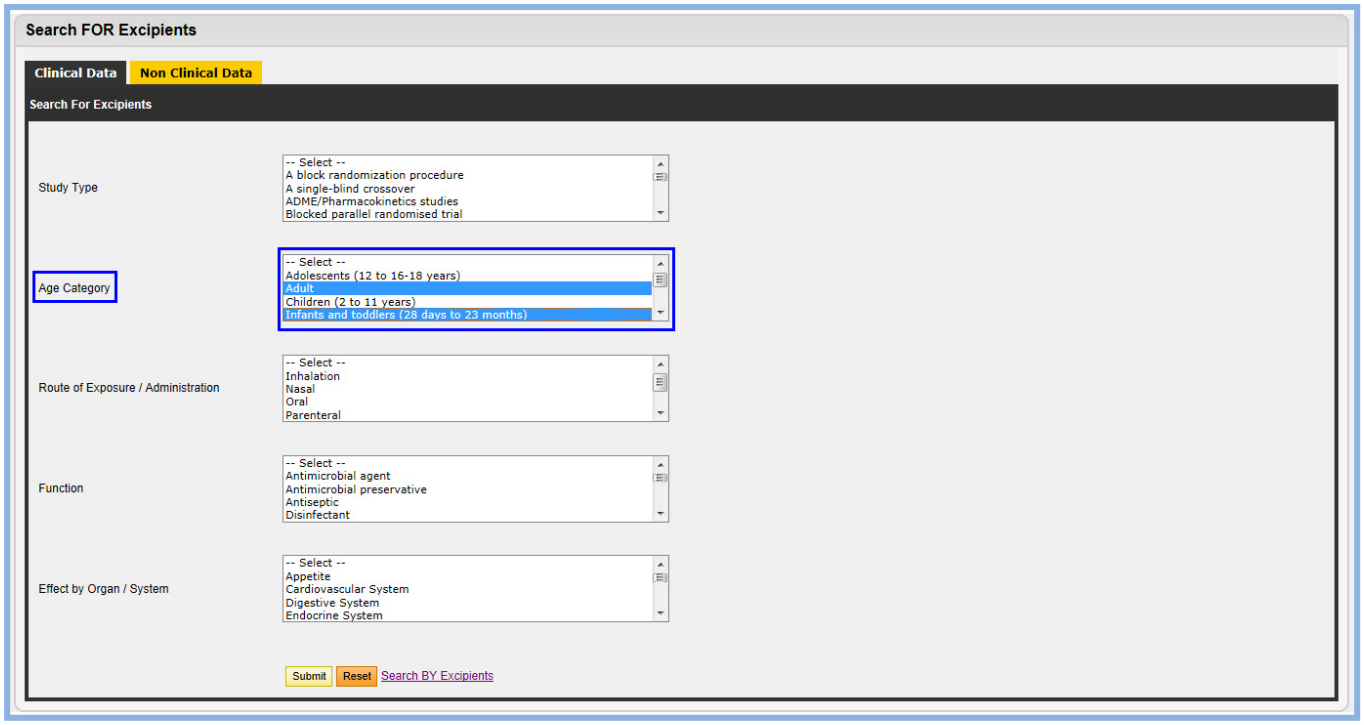


6.1.1.2 Age Category

"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.

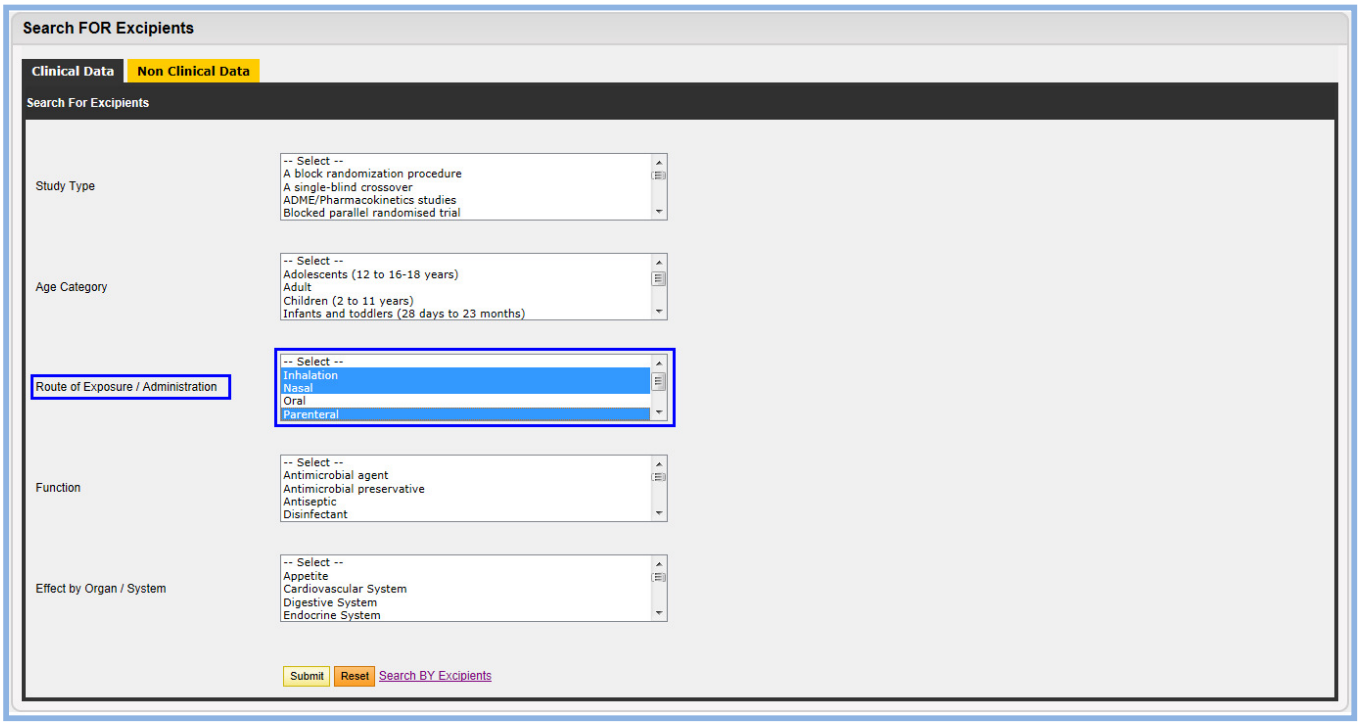


6.1.1.3 Route of Exposure / Administration

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

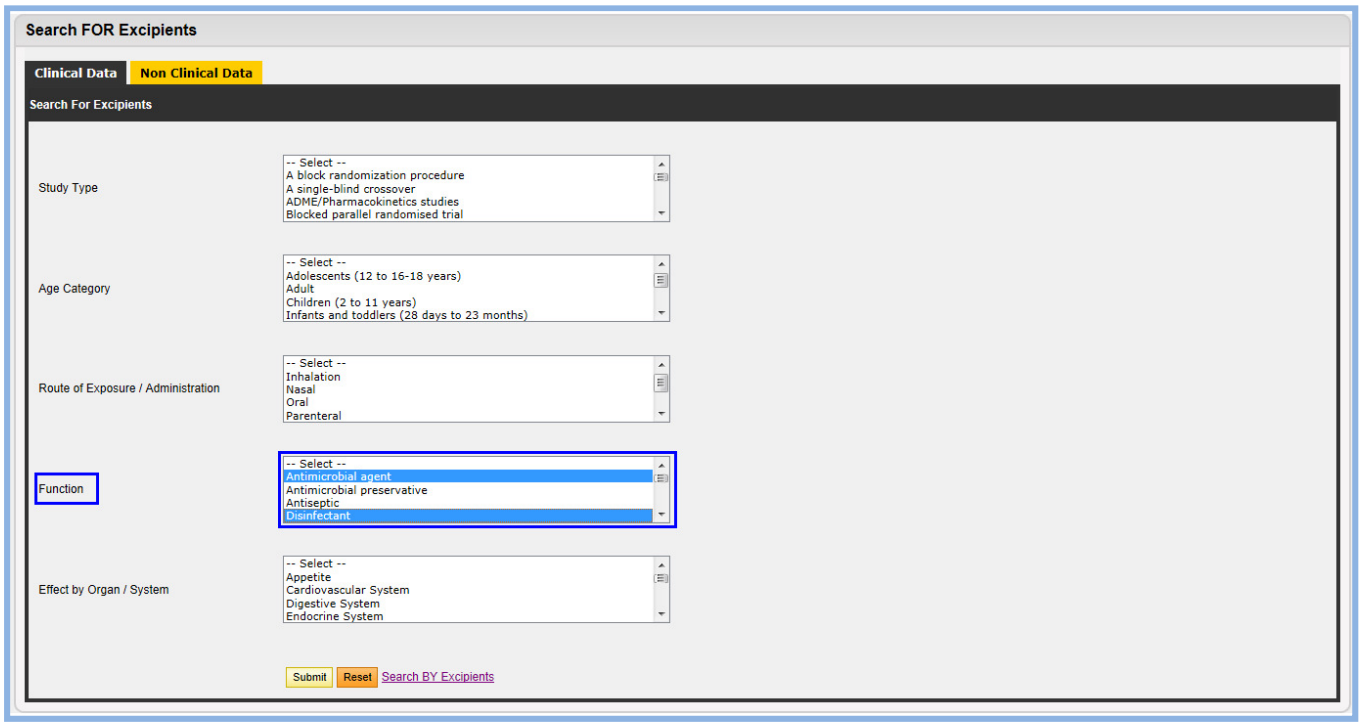
Example: Cutaneous, IV, Oral, Inhalation, Dermal, Implantation, Parenteral, Topical, Ocular, rectal, Intranasal.

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



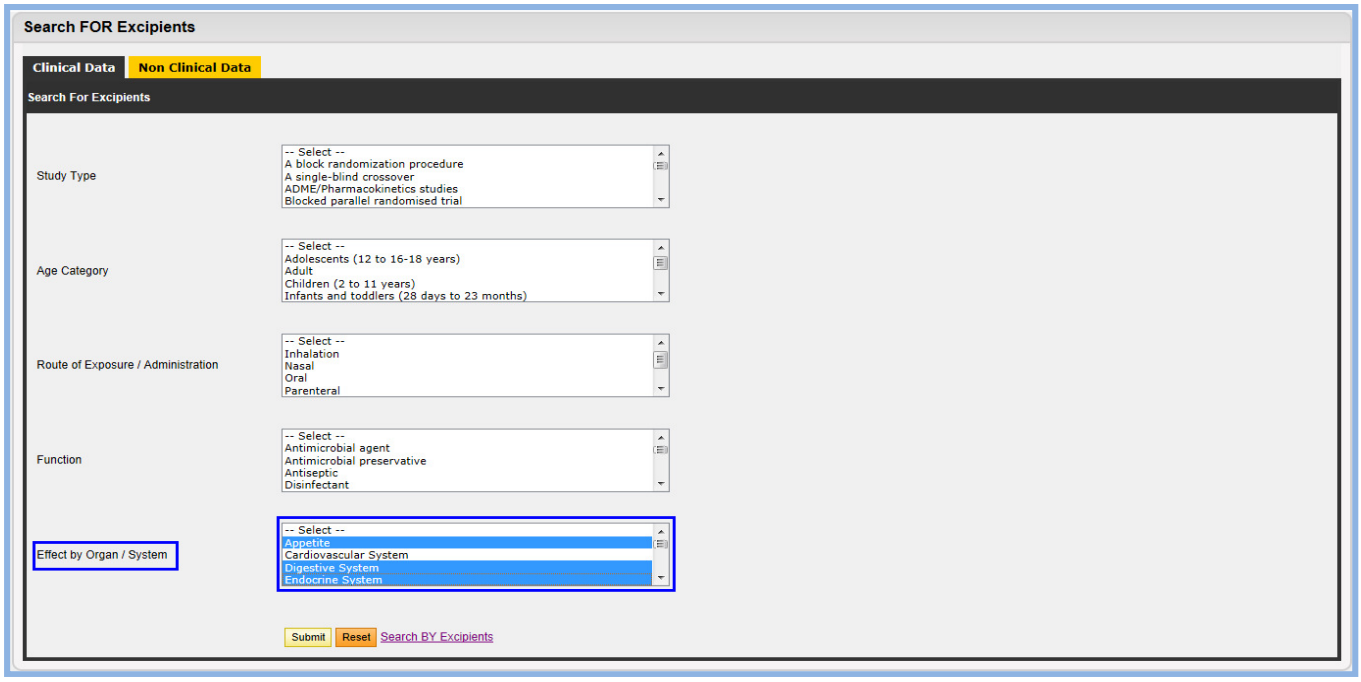
6.1.1.4 Function

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



6.1.1.5 Effect by Organ / System

Indicates on which organ or system the effects are observed



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

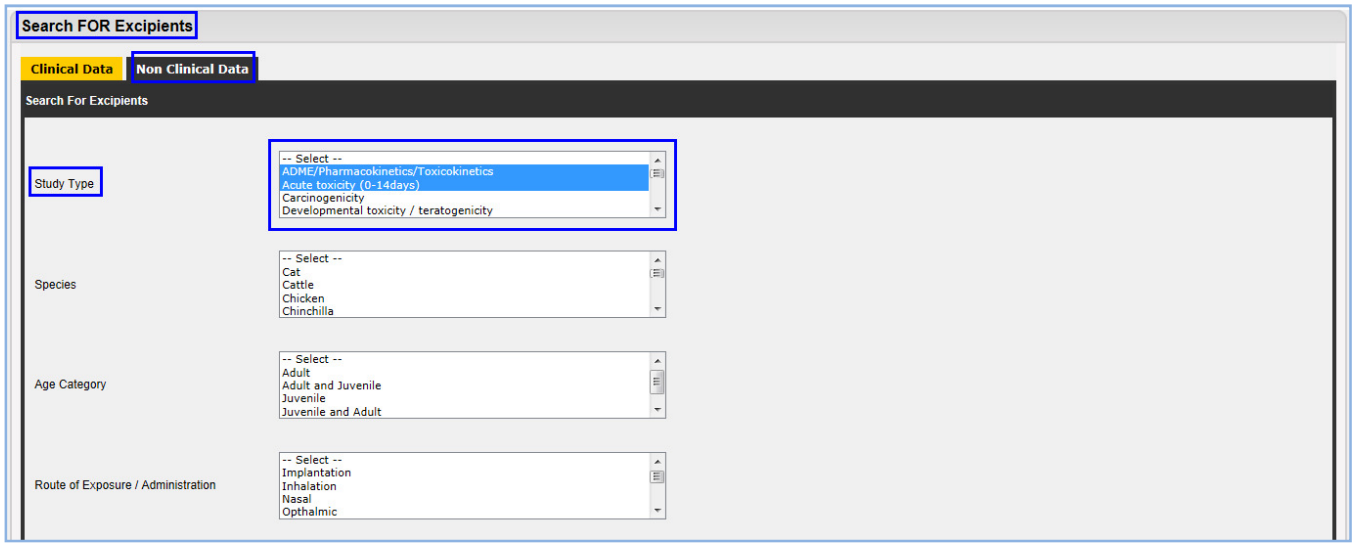
- Search by Excipients
    - Study Type
    - Species
    - Age Category
    - Route of Exposure/Administration
    - Function
    - Organ/System

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

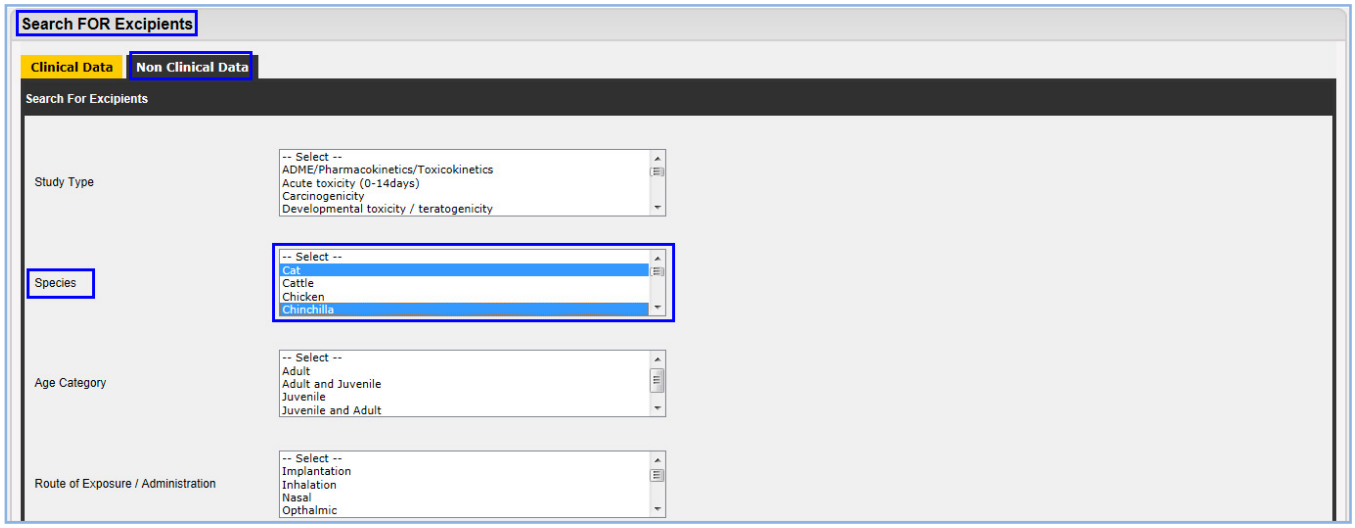
Study Type helps in providing the nature of investigations like Acute Toxicity, Experimental Animal Study, Eye Irritation, Ocular Toxicity etc;



6.2.1.2 Species

Species indicates the animal species used in the experiment.

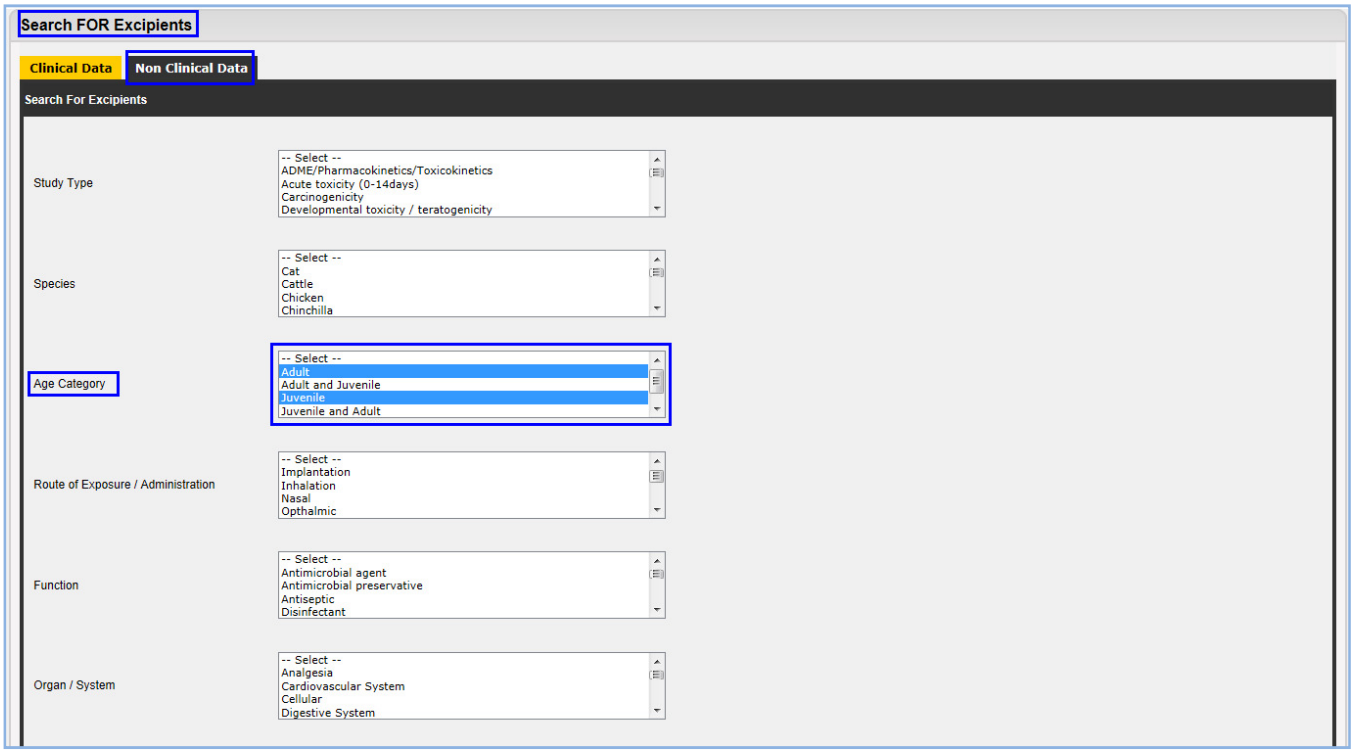
Example: rabbit, rat, sheep, cat, cattle, dog, gerbil, guinea pig, hamster, monkey, mouse, pig and other



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

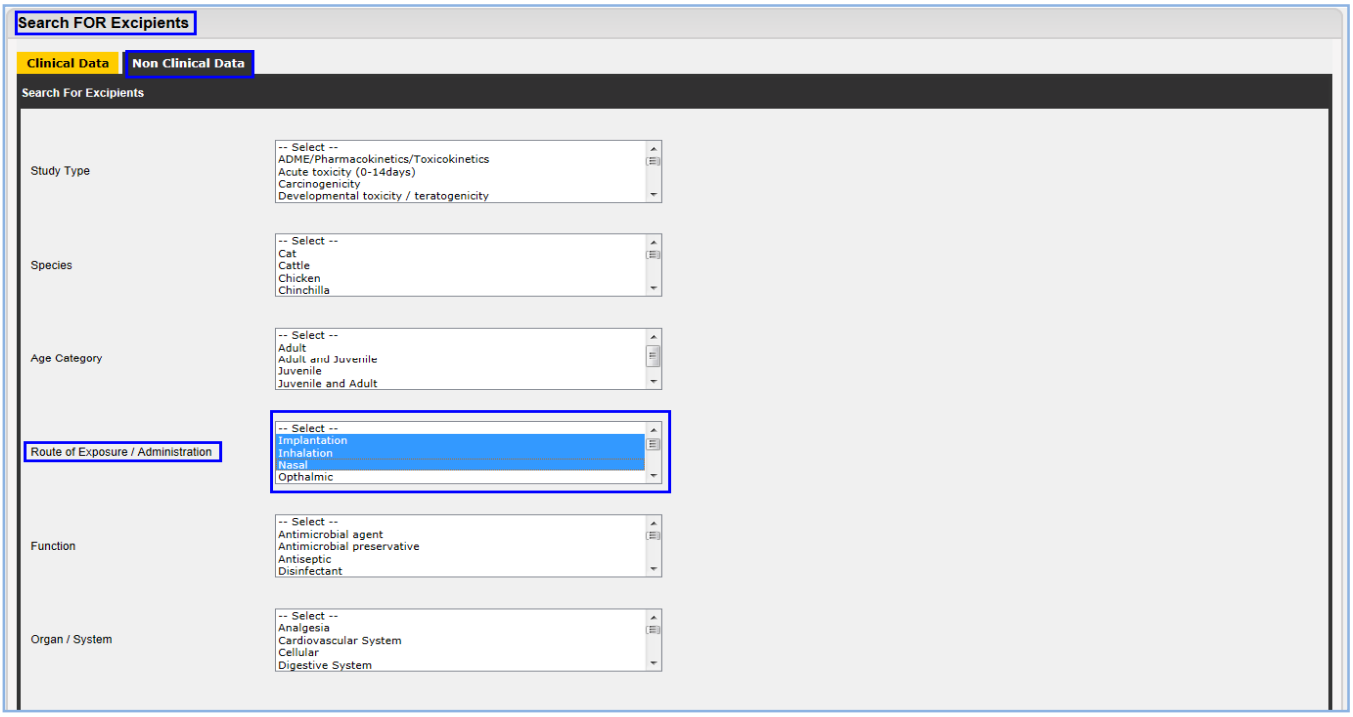
Example: Adults, Juvenile etc;



6.2.1.4 Route of Exposure / Administration

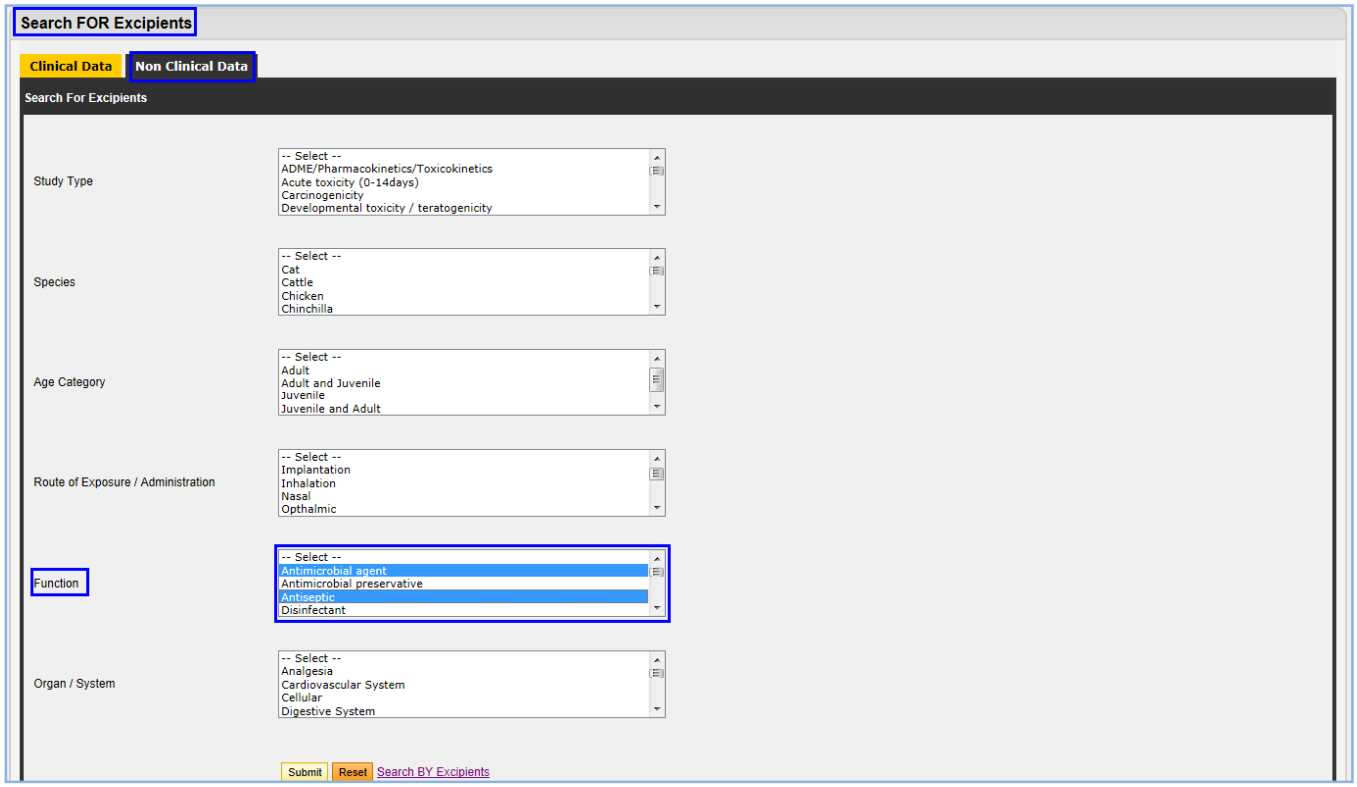
Route of Exposure/Administration indicates the part of the body through or into which, or the way in which, the excipient is introduced.

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



6.2.1.5 Function

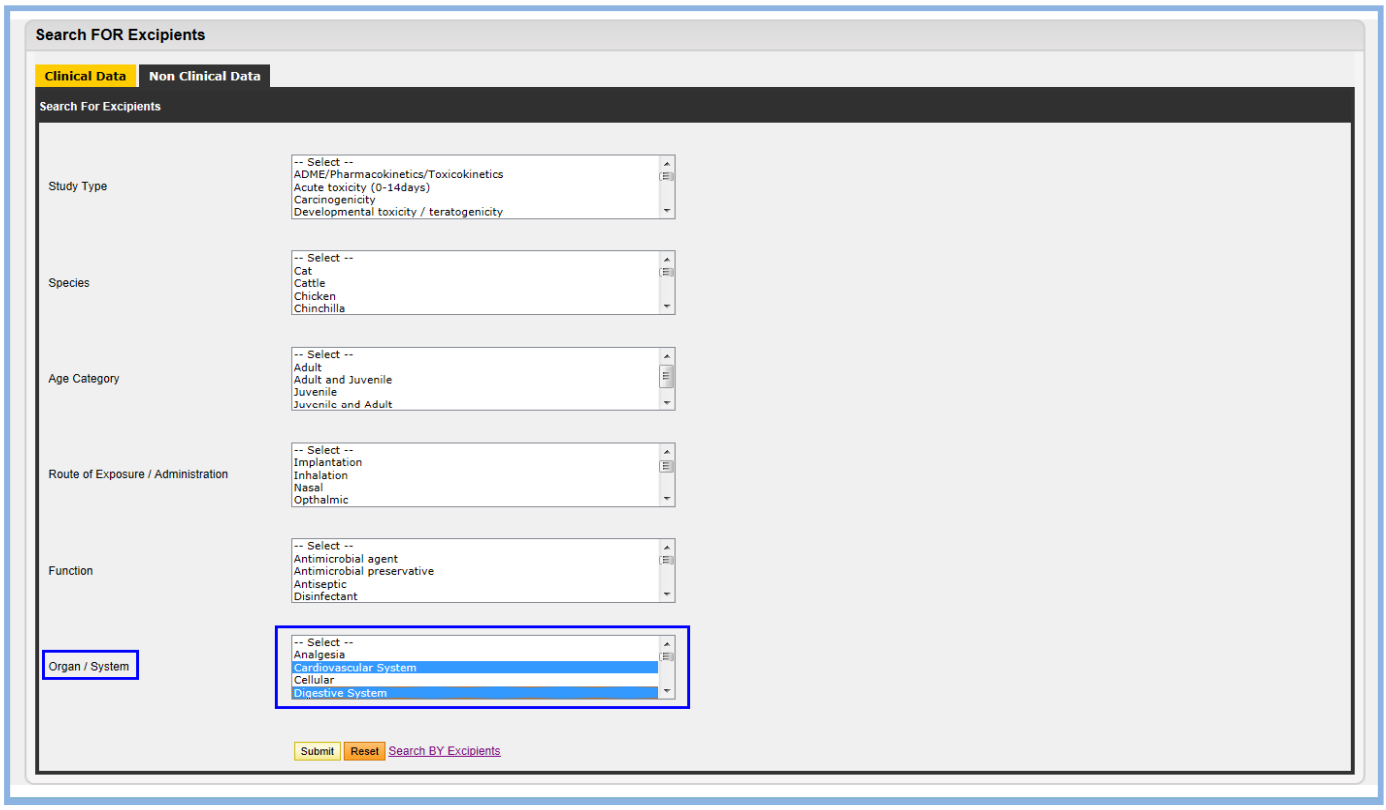
Functional Data helps to provide the information which is neither Clinical nor Preclinical data. It facilitates user to access the data based on the function values as shown below



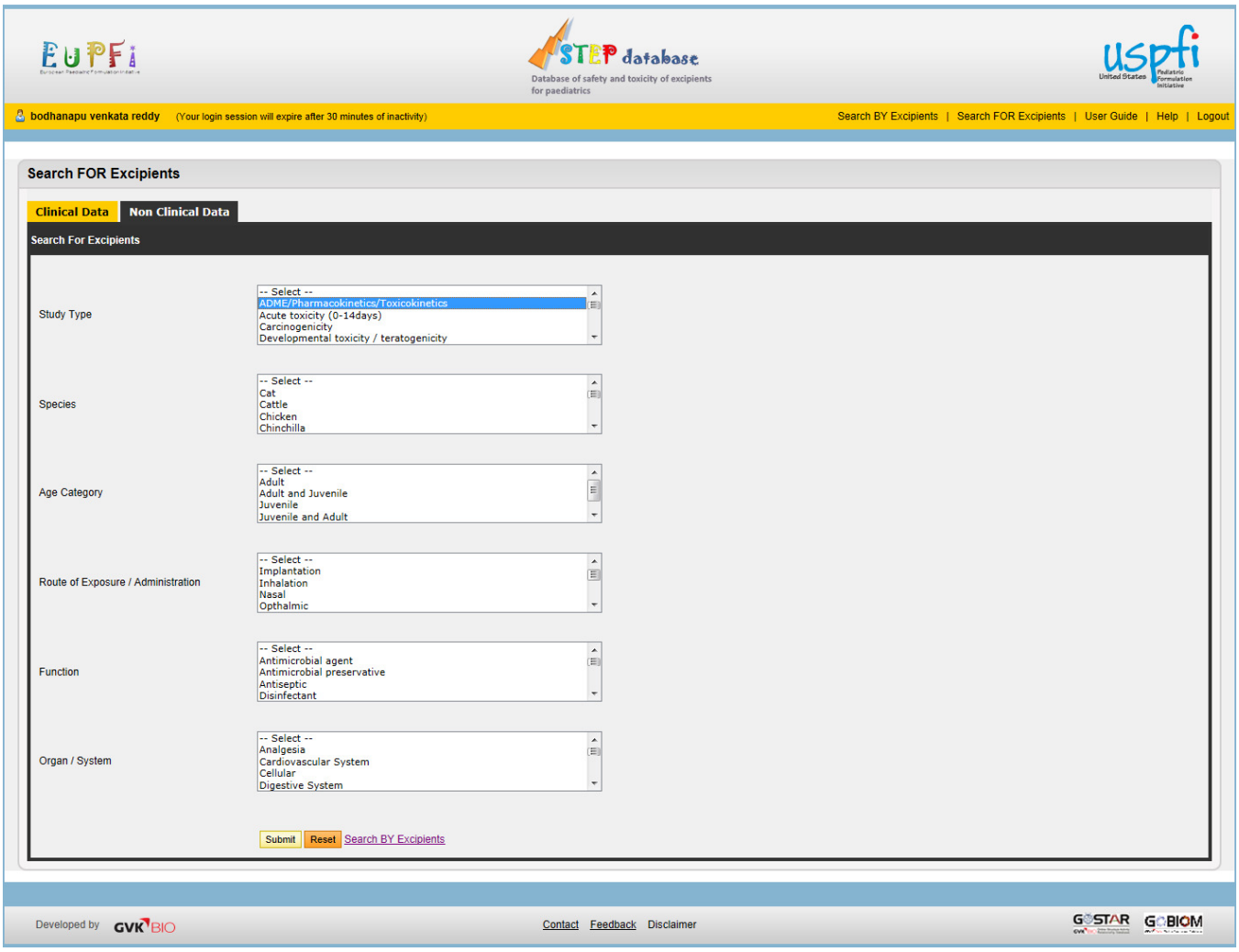
6.2.1.6 Organ/System

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

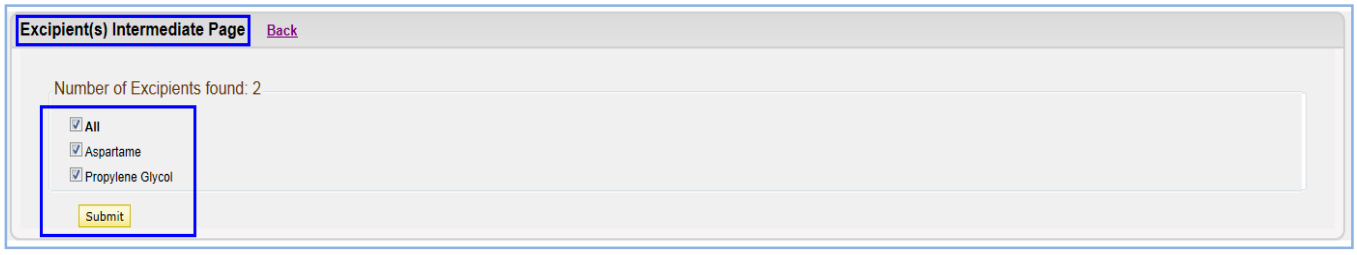
Example: Kidney, Brian, Cellular System, Renal, Liver, Cardiovascular etc.



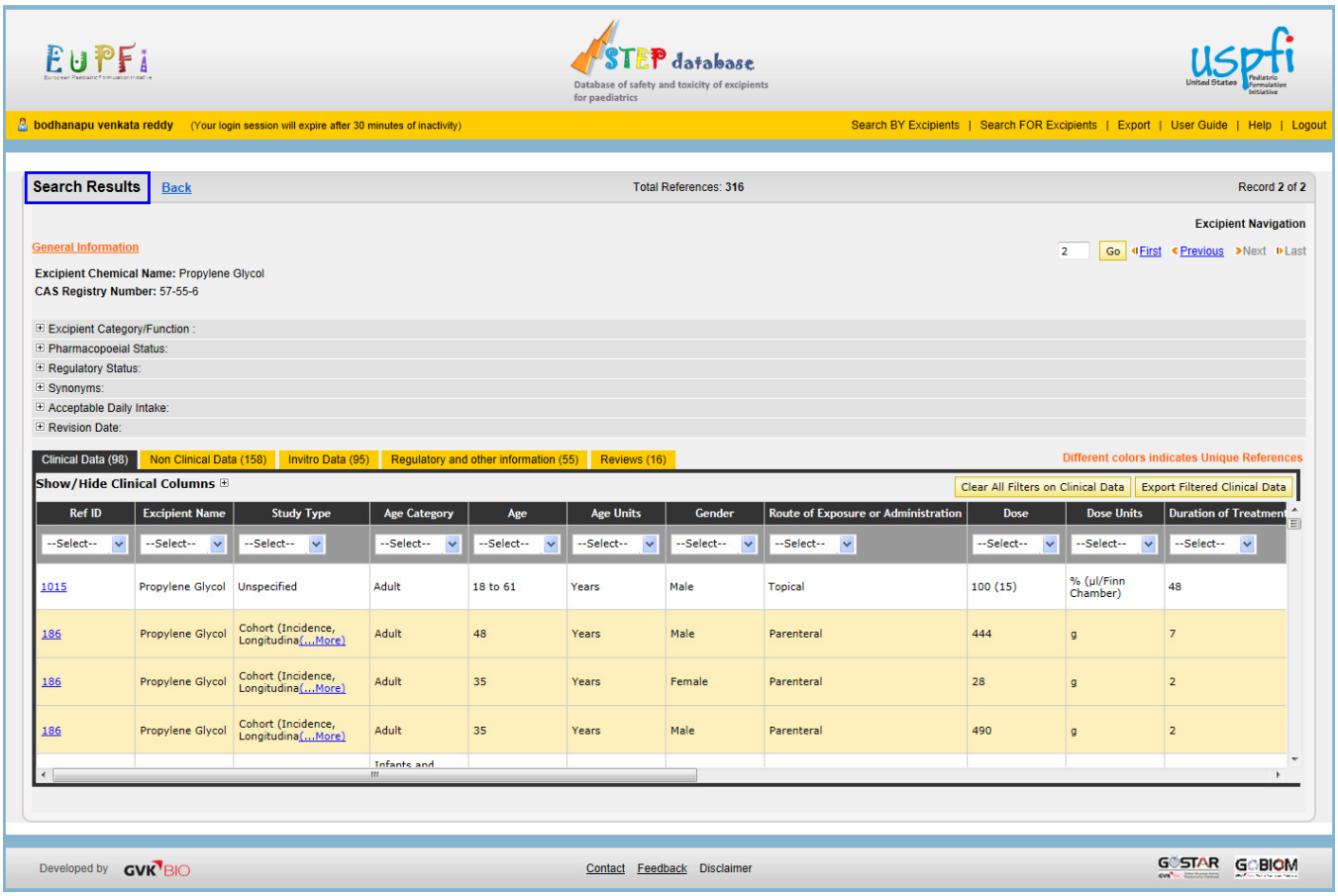
When user provides any search criteria in the “Non-Clinical Data” page and clicks “Submit” button as shown below



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



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



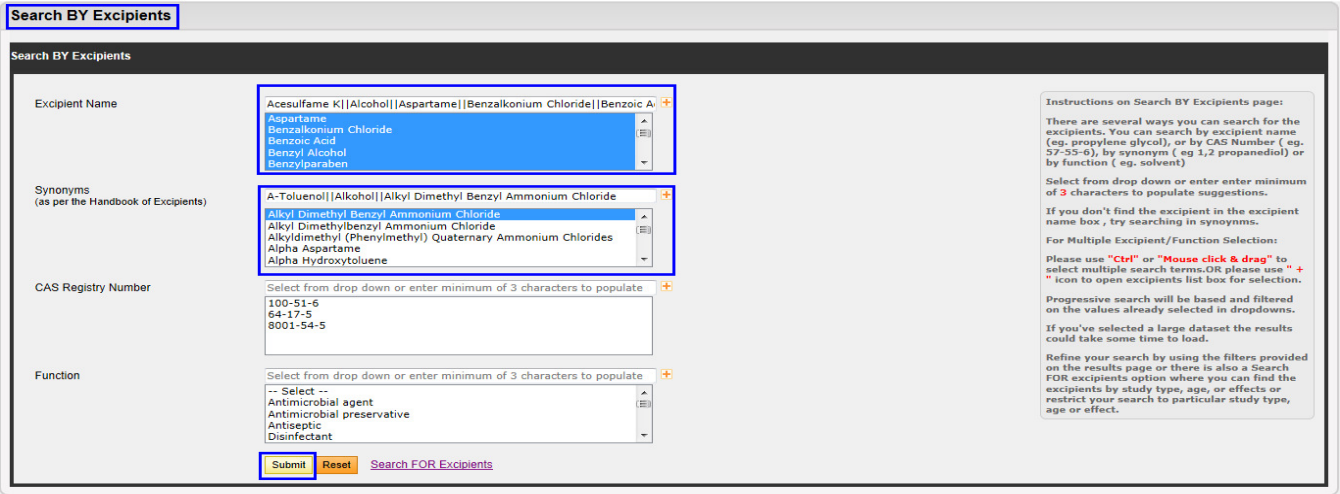
Note:

- 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.

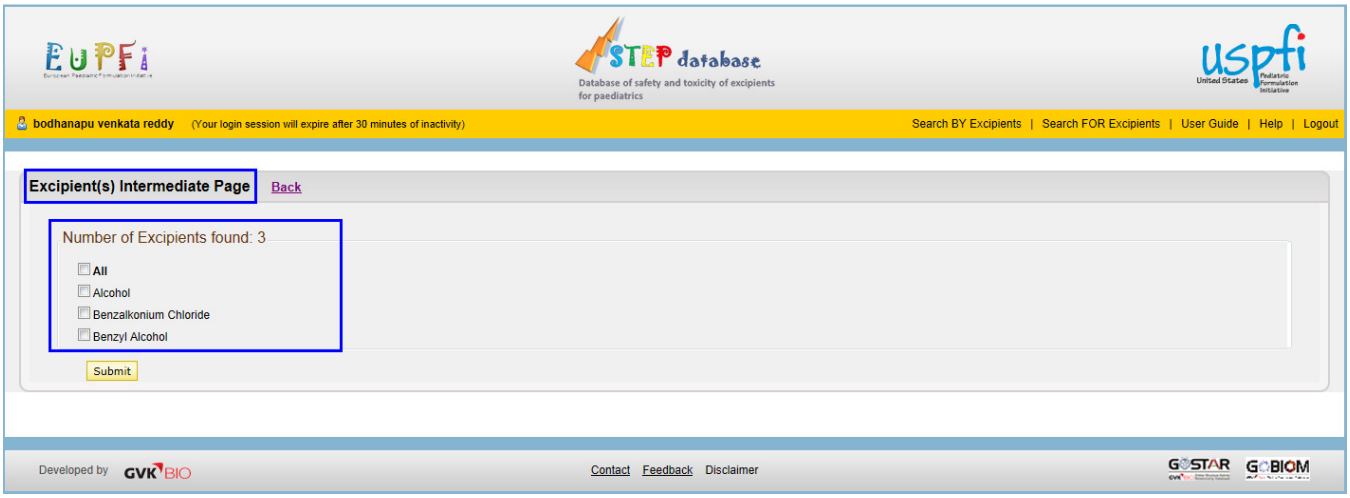
7 Excipient(s) Intermediate Details:

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:

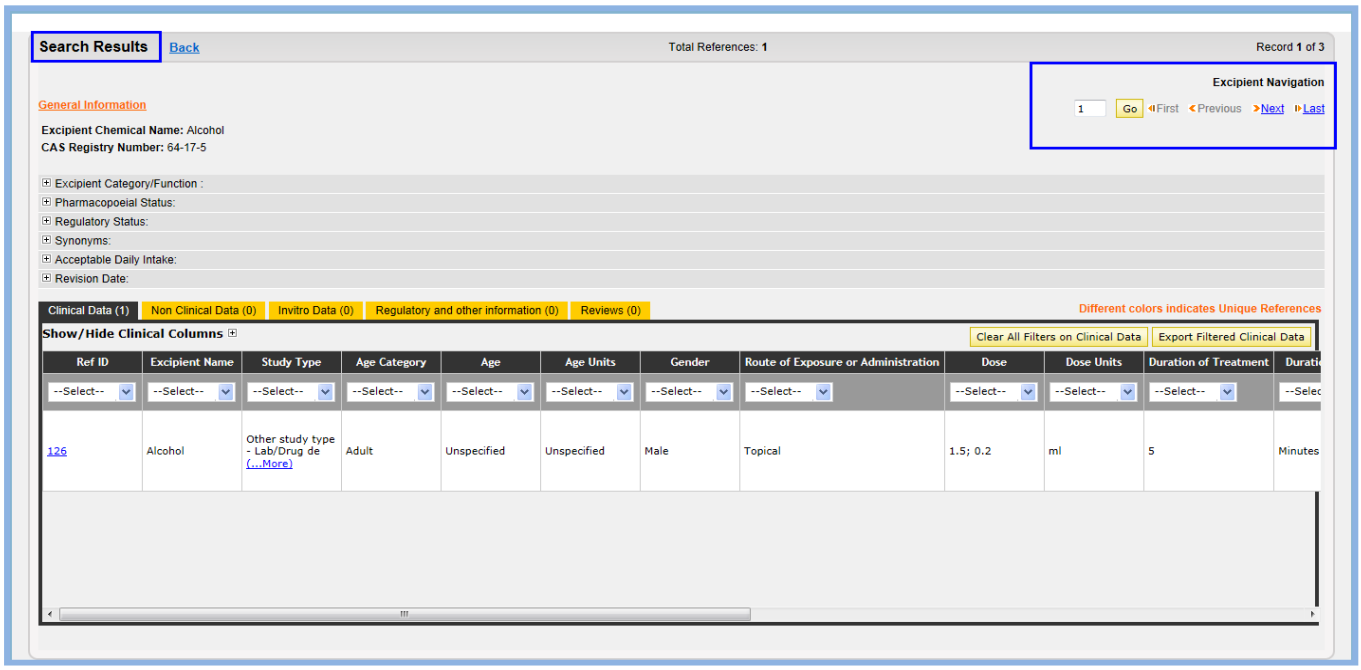


In search results if more than one Excipients are selected in the 'Search BY Excipients' or 'Search FOR Excipients' then "Excipient(s) Intermediate Page" appears as shown below.



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

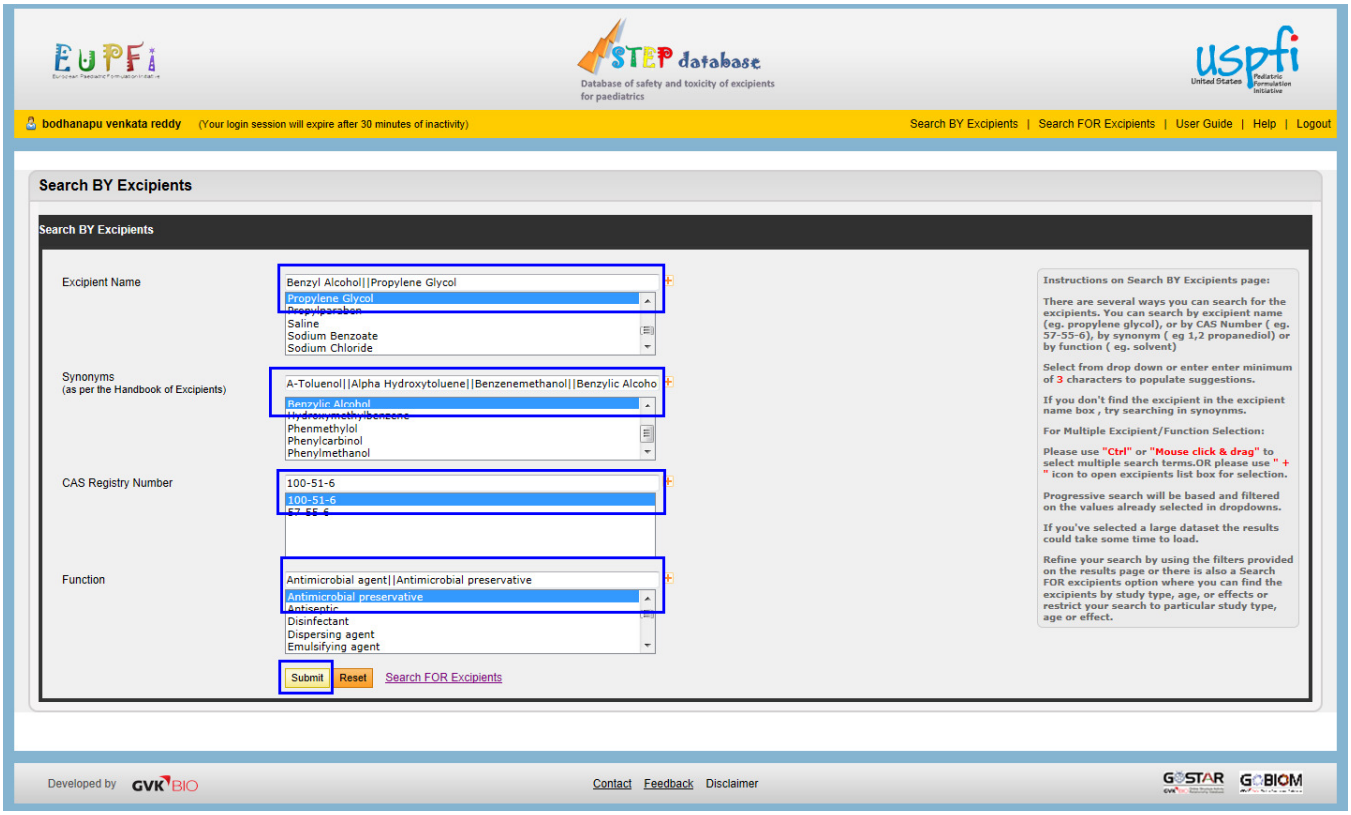
Excipient(s) Intermediate Details:



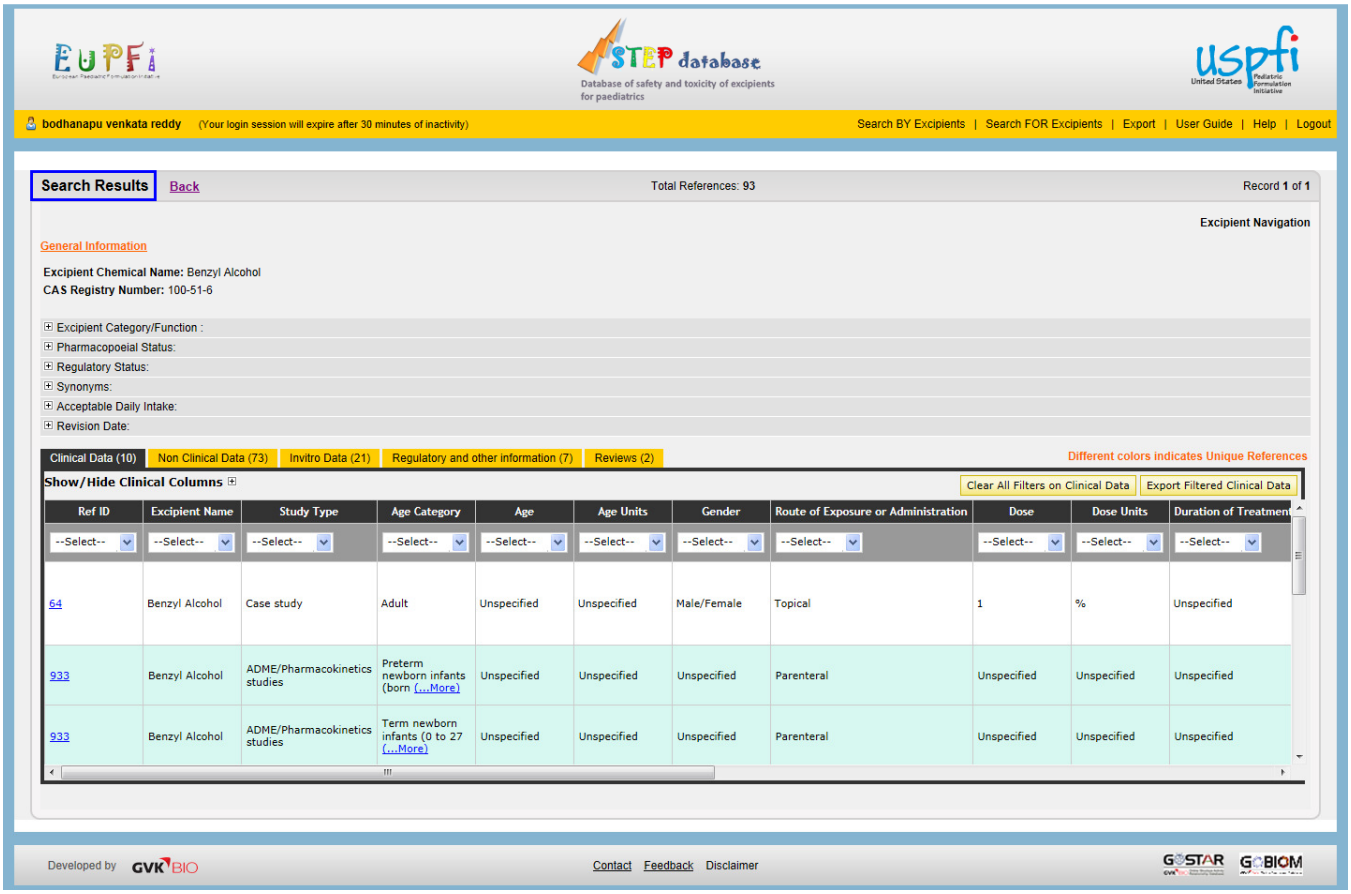
Based on the user selection of Excipients, the search results will be displayed for those Excipients.

8 Search Results

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



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.

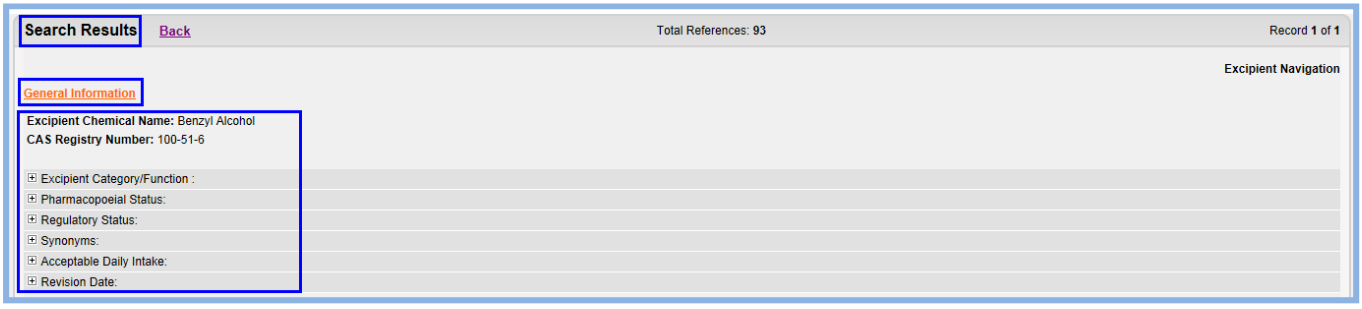


Search Results provides the result information in a categorical manner for that the information is categorized into the below data

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

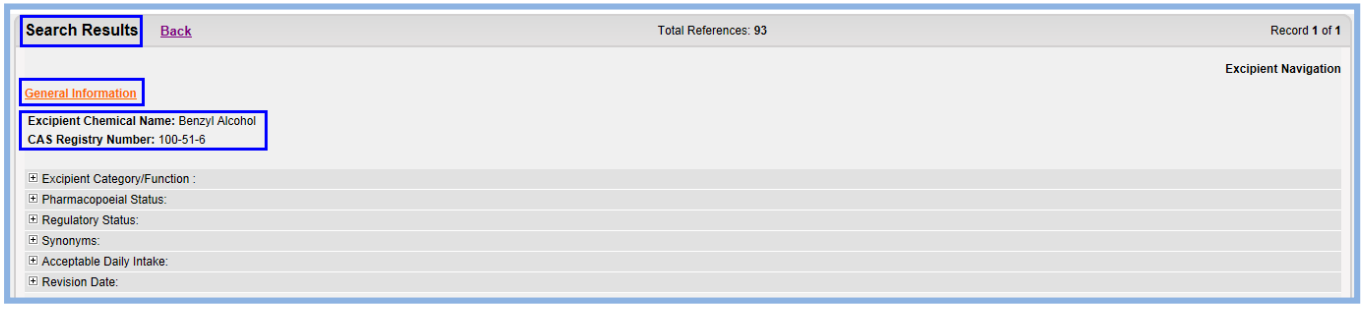
- ✓ Reviews

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

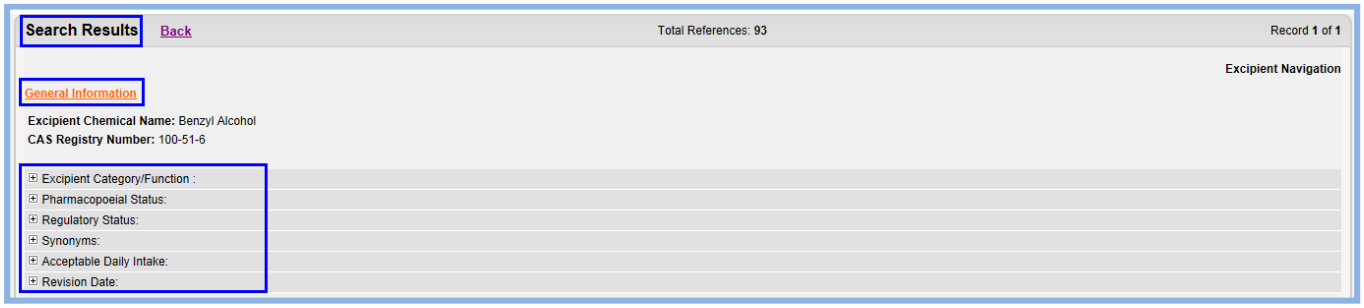


8.1 General Information

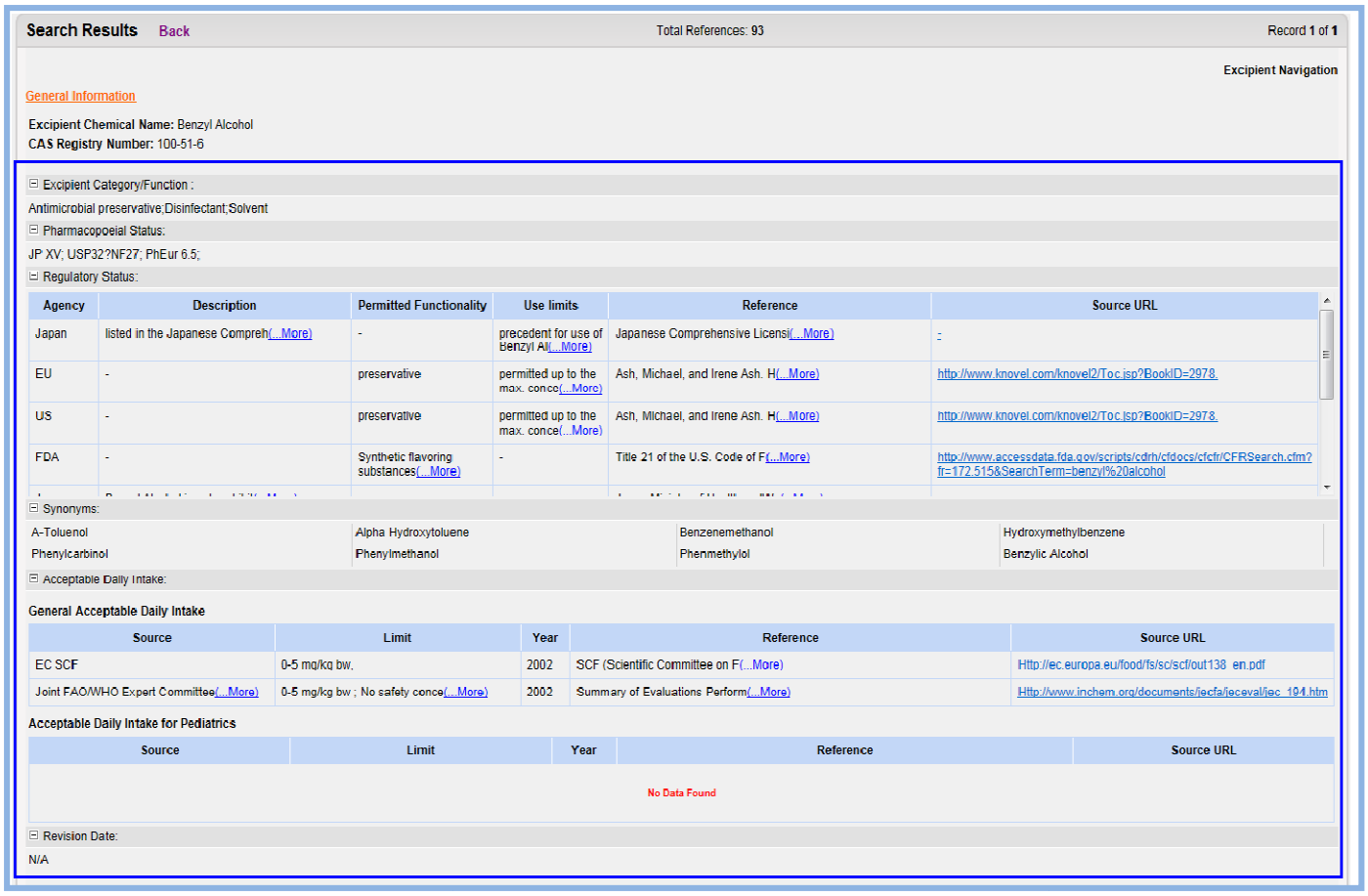
In the "Search Results" page considering the search criteria "General Information" provides the information about the corresponding Excipient along with the CAS Registry Number as shown below.



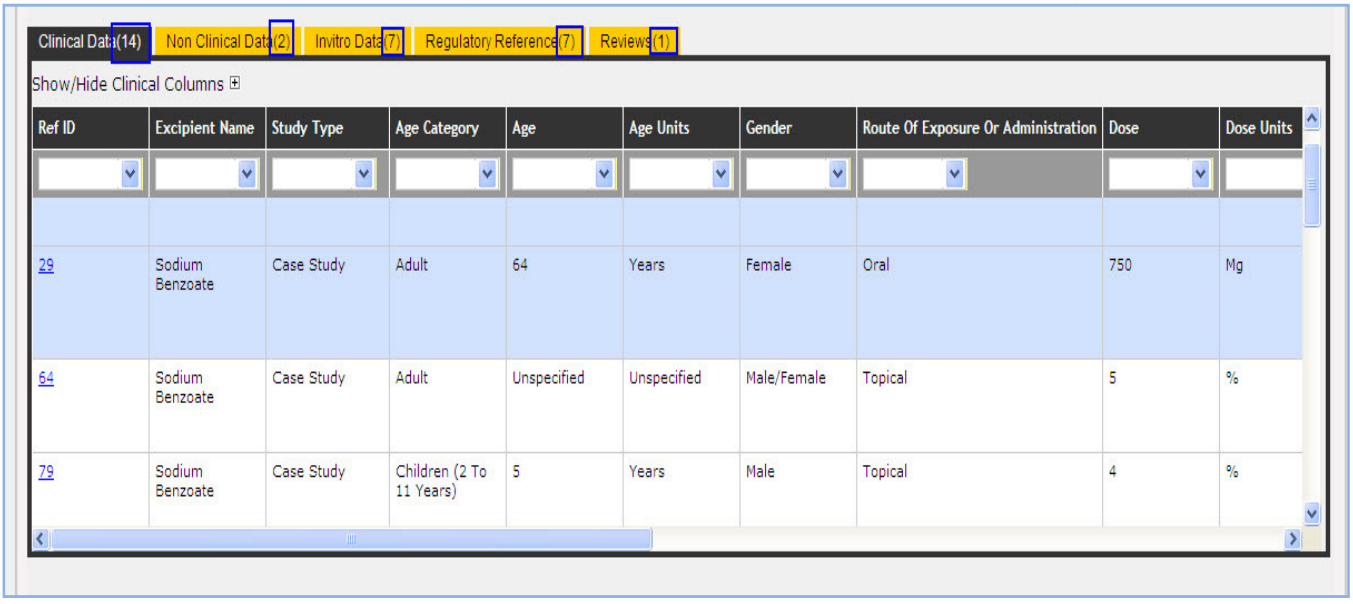
In the "General Information" along with "Excipient Chemical Name and CAS Registry Number" details regarding "Excipient Category/Function, Pharmacopoeial Status, Regulatory Status, Synonyms, Acceptable Daily intake, Revision Date" data is also available in the Collapsed mode by default in "Search Results"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



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



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

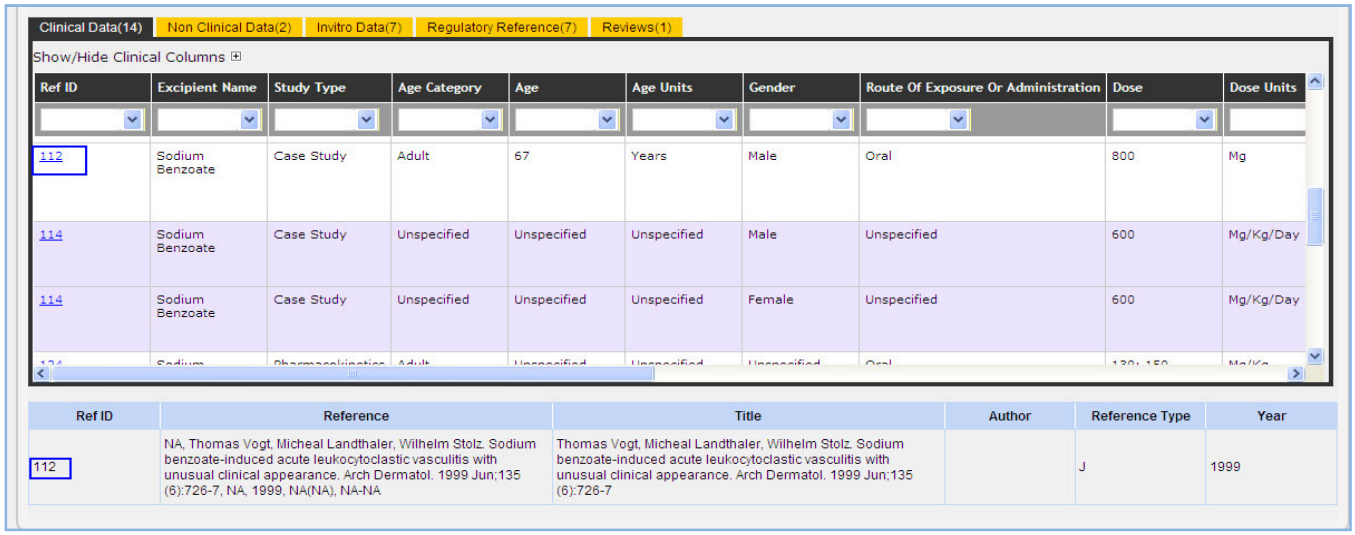


8.2 Clinical Data

Clinical data provides complete Clinical information of the excipient.

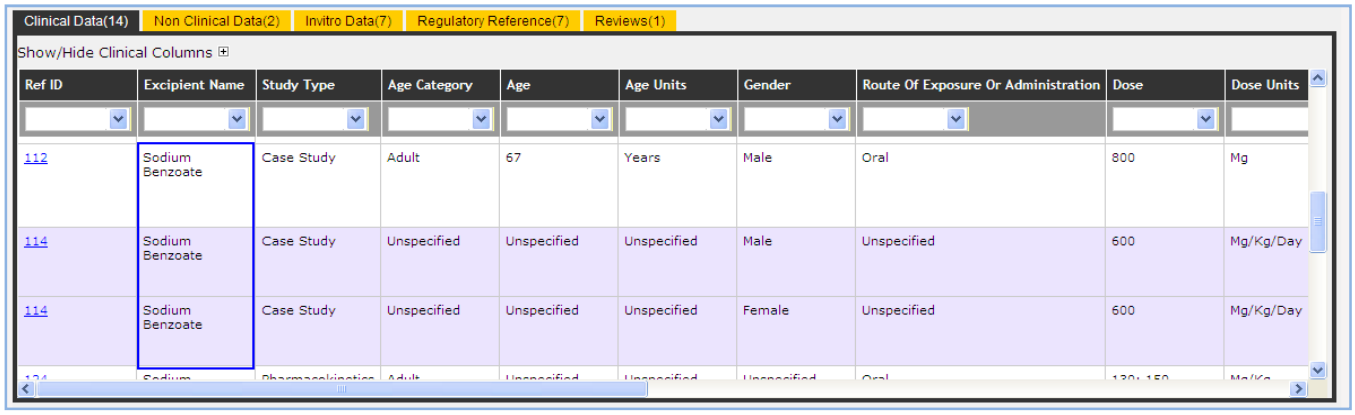
8.2.1 Reference ID

- 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



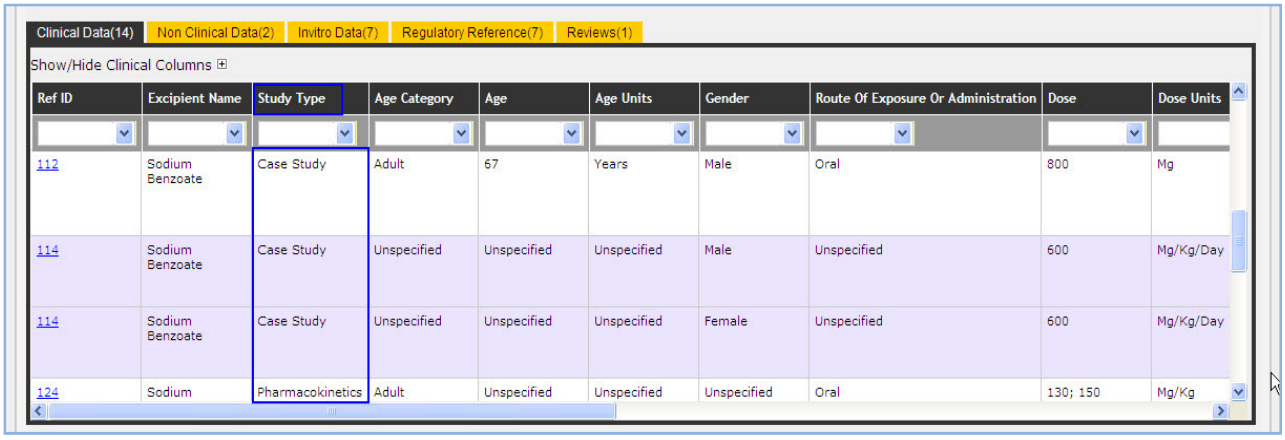
8.2.2 Excipient Name

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



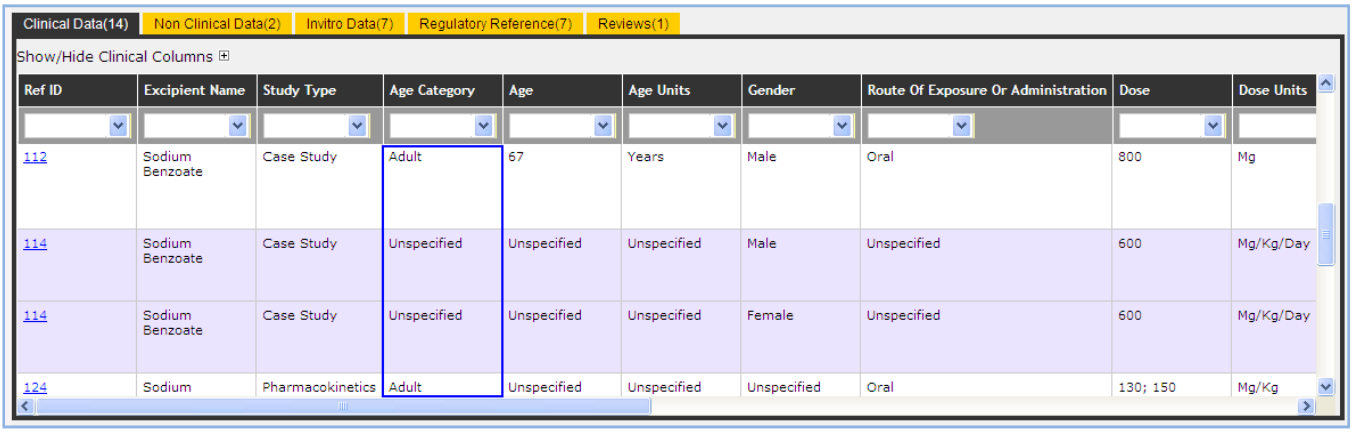
8.2.3 Study Type

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.



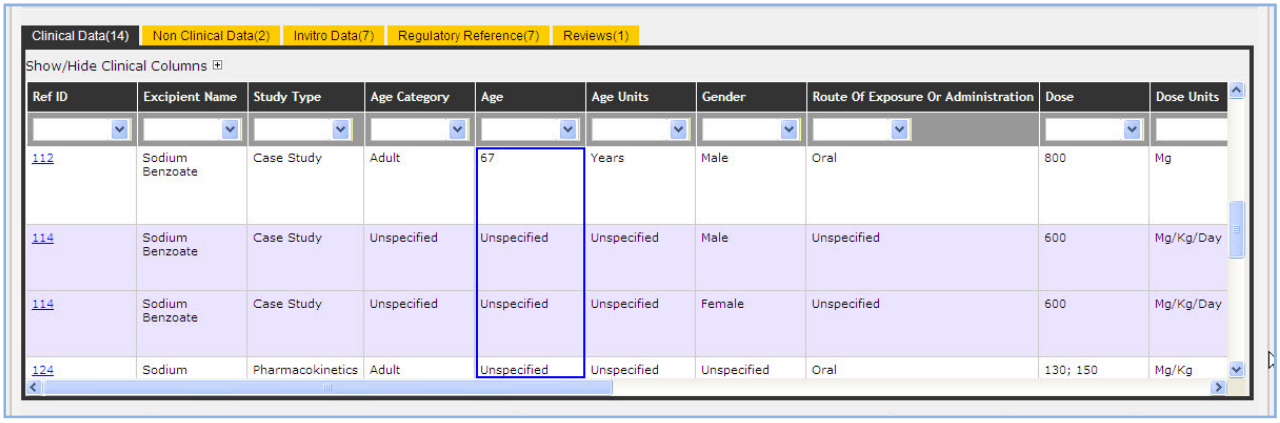
8.2.4 Age Category

“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



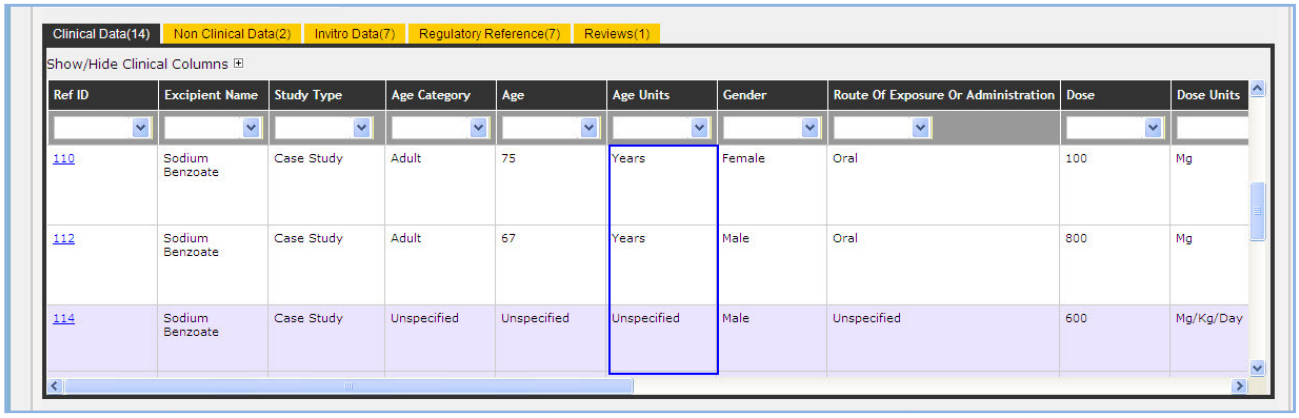
8.2.5 Age

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



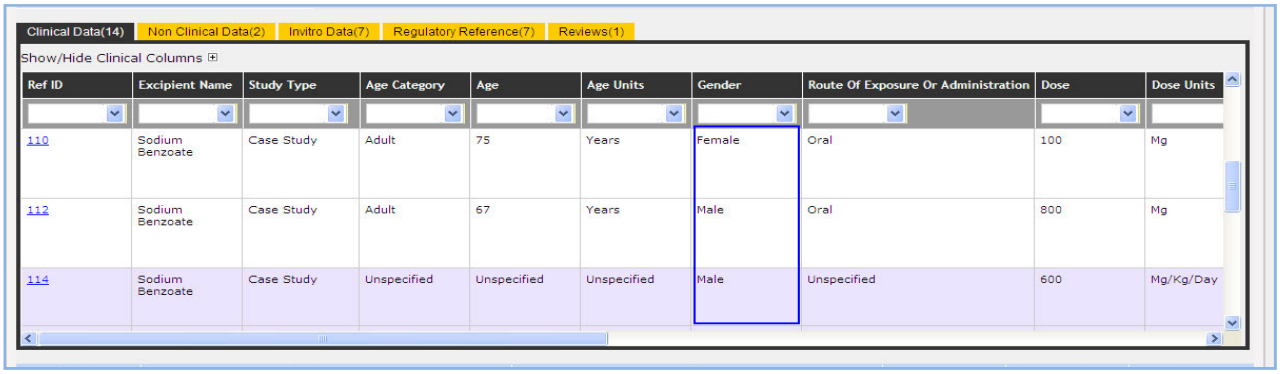
8.2.6 Age Units

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



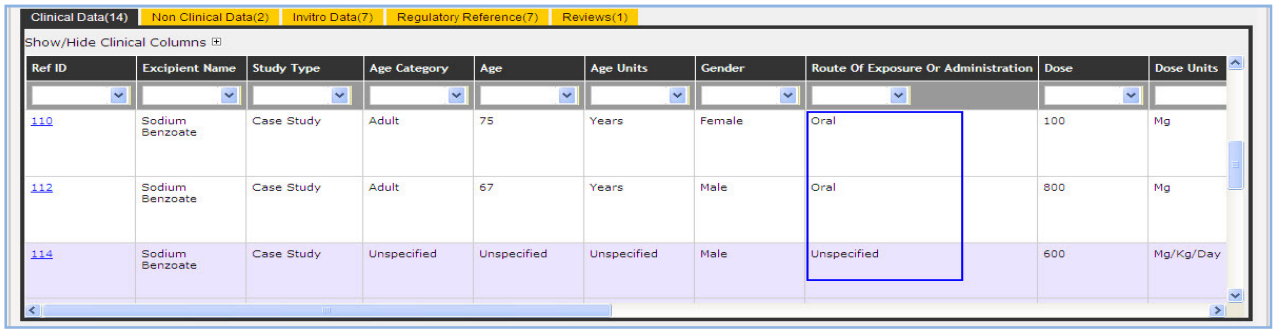
8.2.7 Gender

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



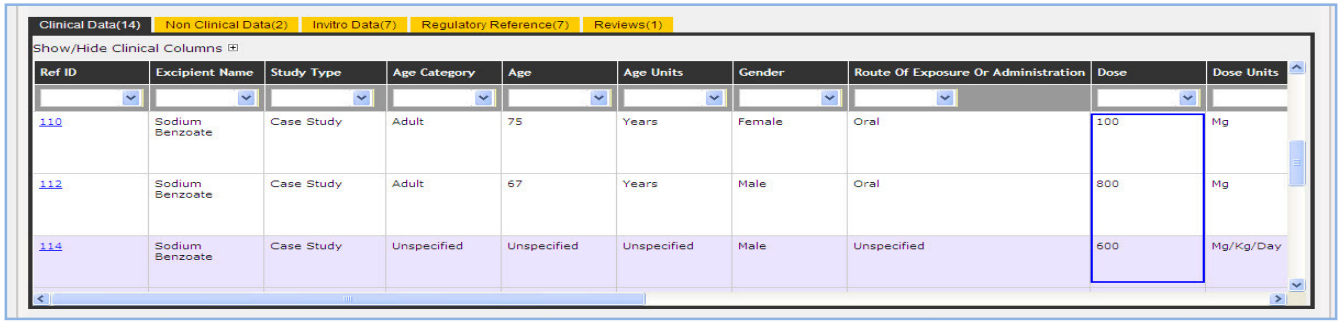
8.2.8 Route of Exposure or Administration

"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.



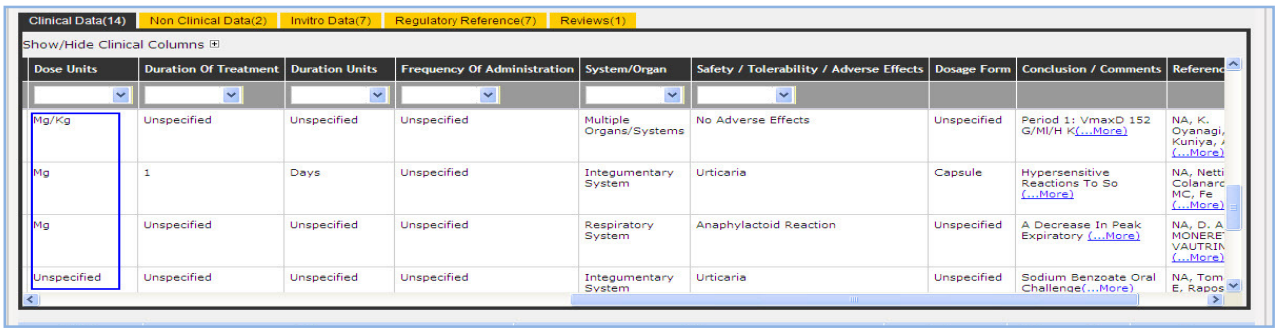
8.2.9 Dose

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.



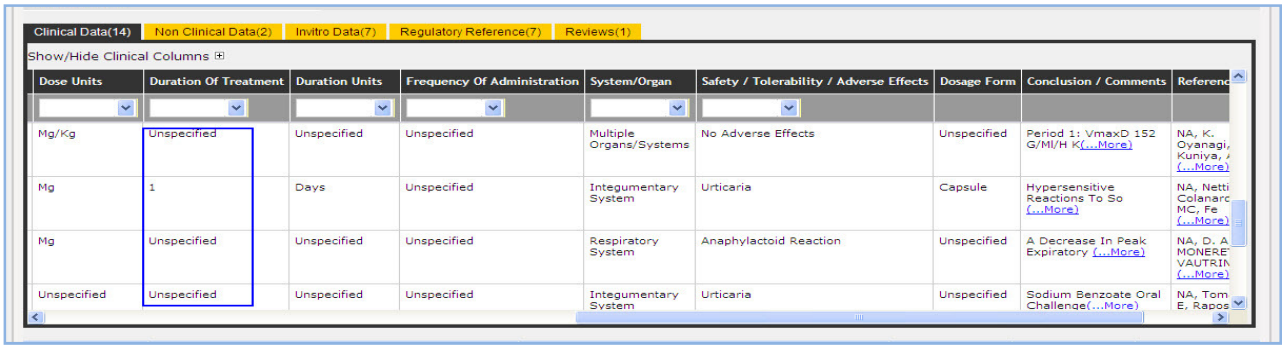
8.2.10 Dose Units

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



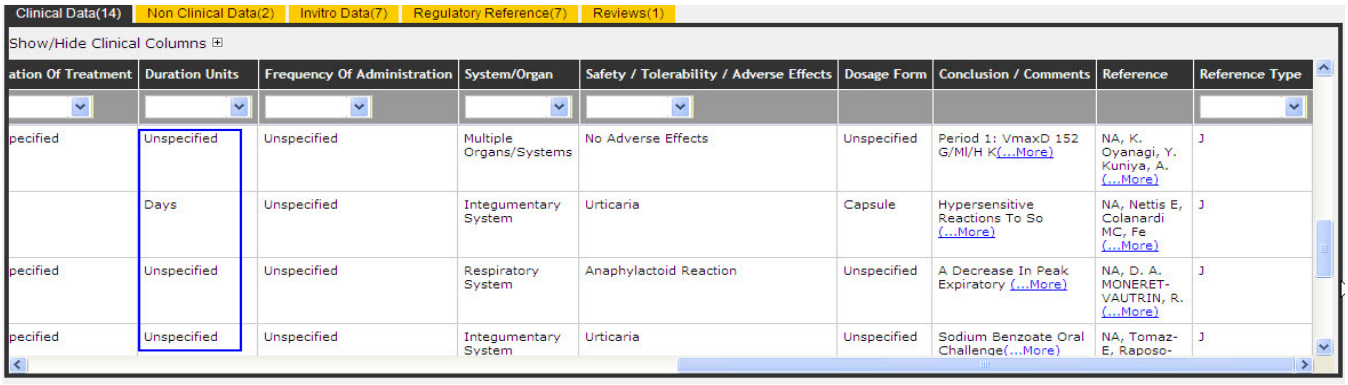
8.2.11 Duration of Treatment

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



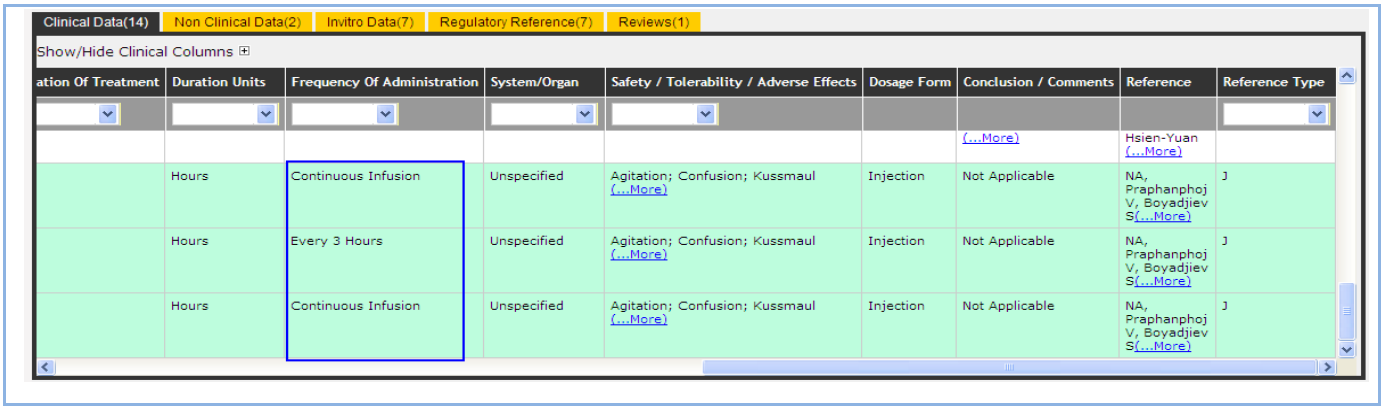
8.2.12 Duration Units

Displays duration of the dose in units



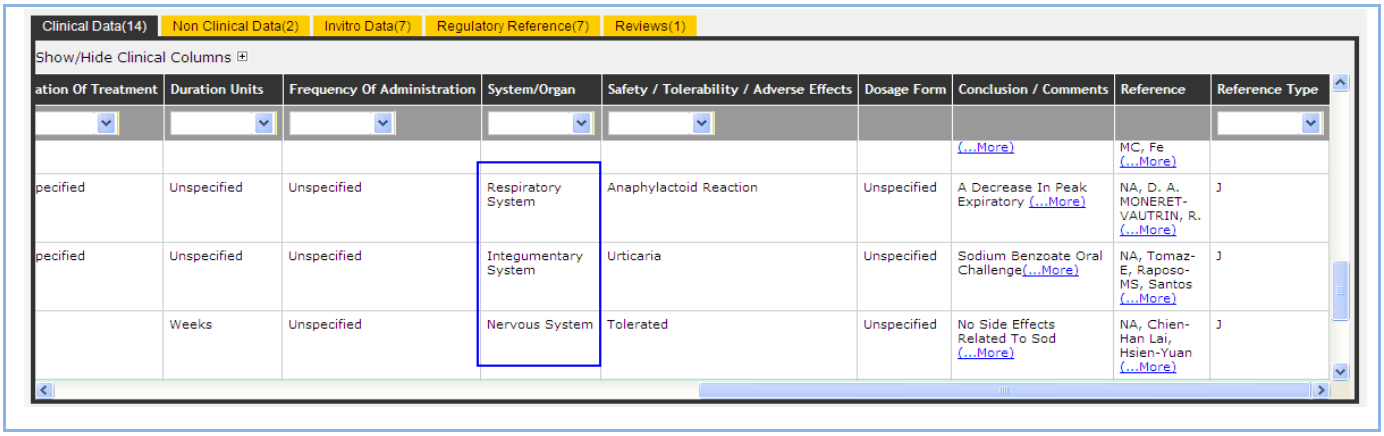
8.2.13 Frequency of Administration

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



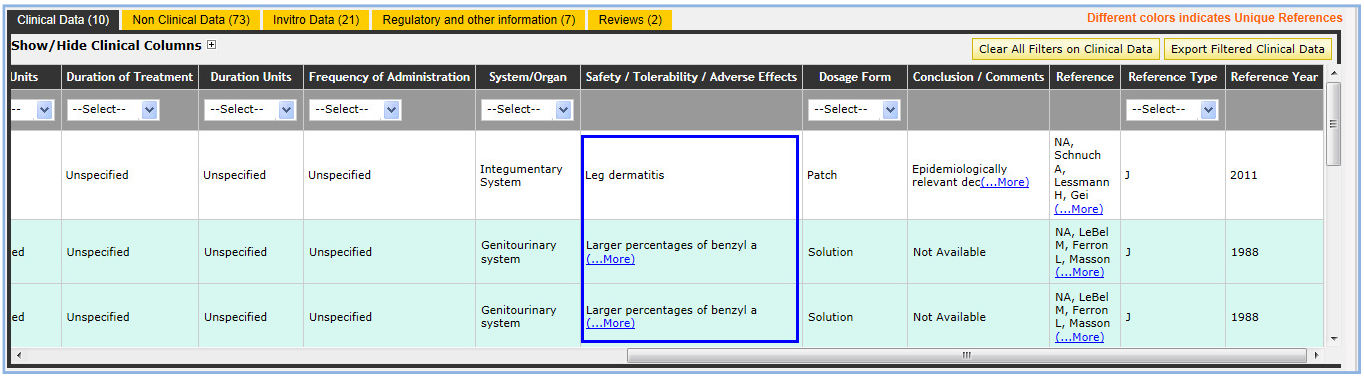
8.2.14 System/Organ

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

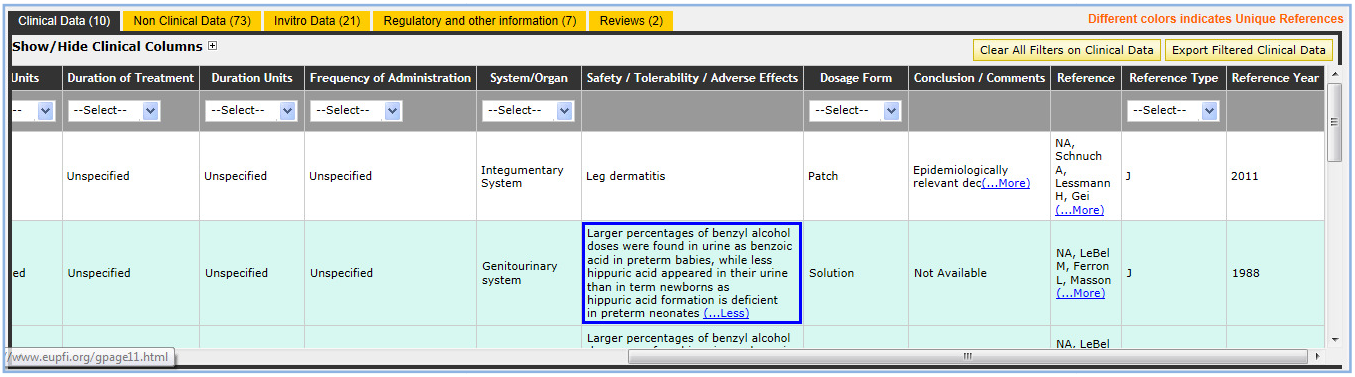


8.2.15 Safety / Tolerability / Adverse Effects

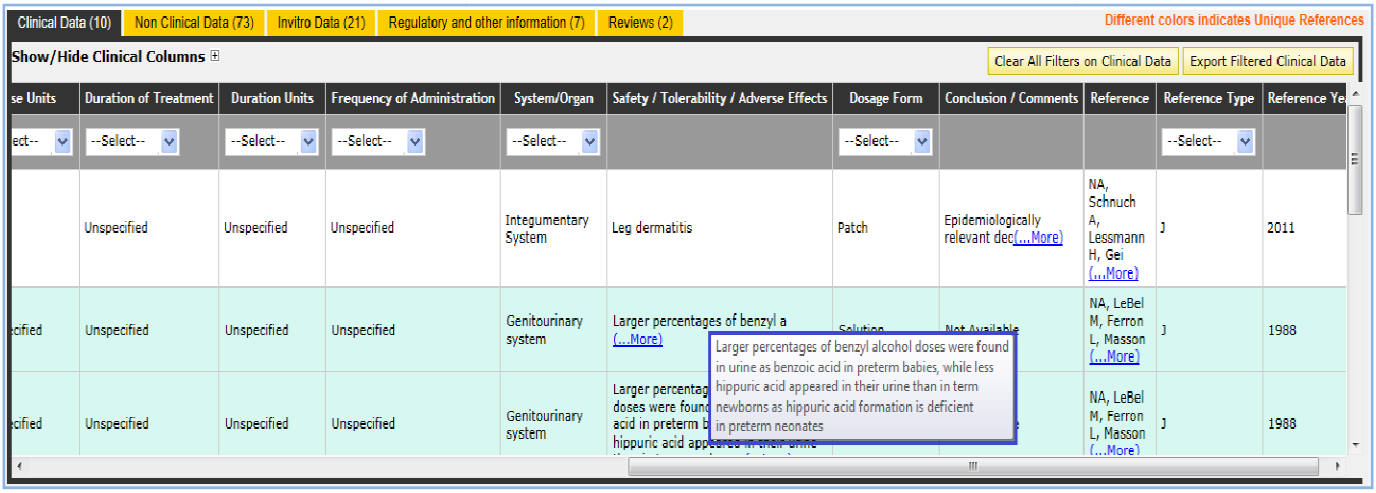
It displays the adverse effects that are in the excipient appears in this column as shown below.



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

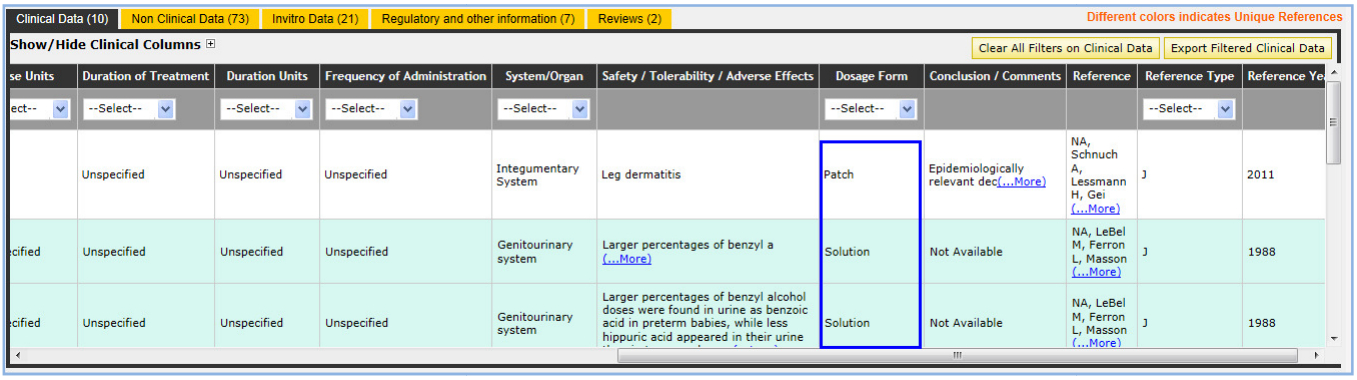


Mouse hover on “More” link also displays the complete information of the “Adverse Effects” in a tool tip as shown below.



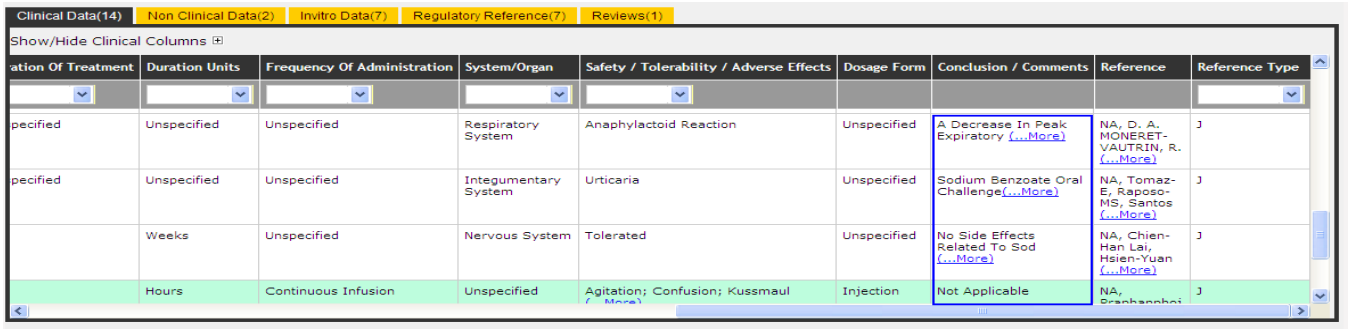
8.2.16 Dosage Form

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



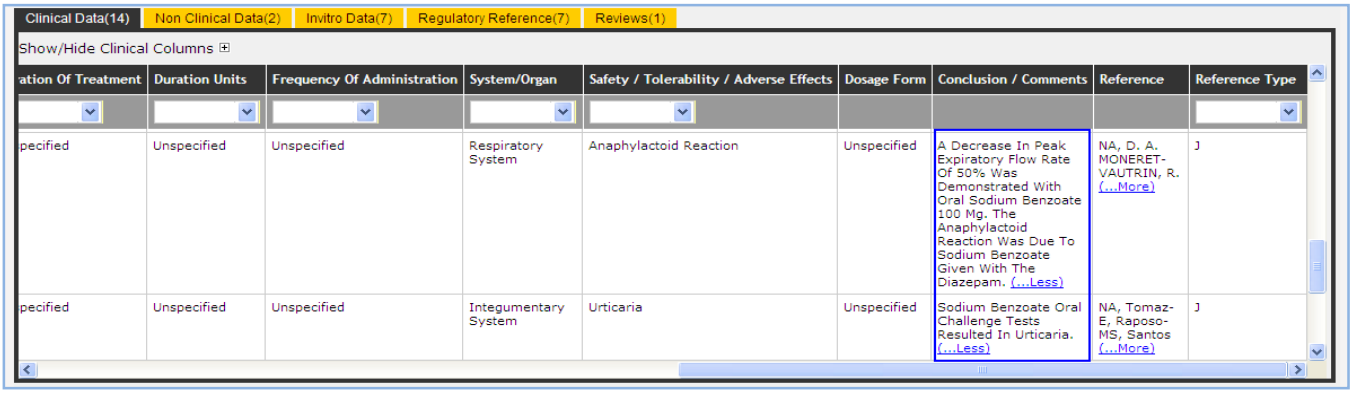
8.2.17 Conclusions/Comments

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.



ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
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(...More)	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,	J

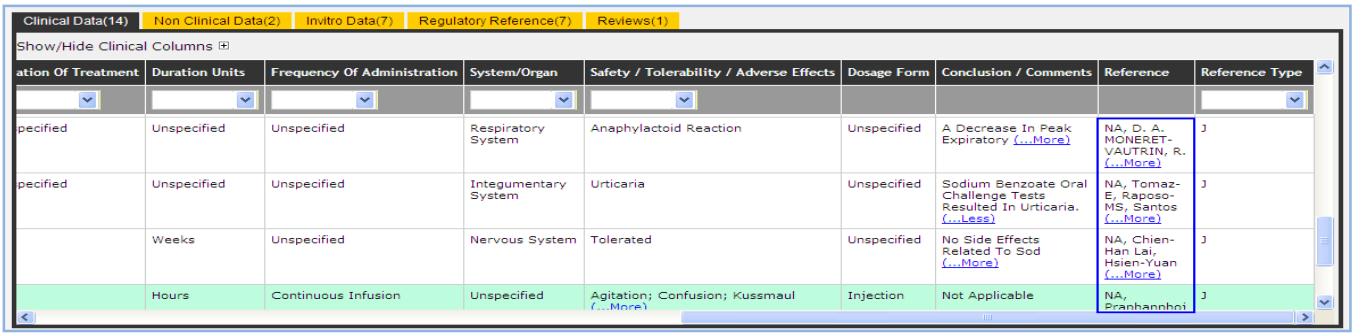
Click “More” link then complete comments data appears as shown below.



ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
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

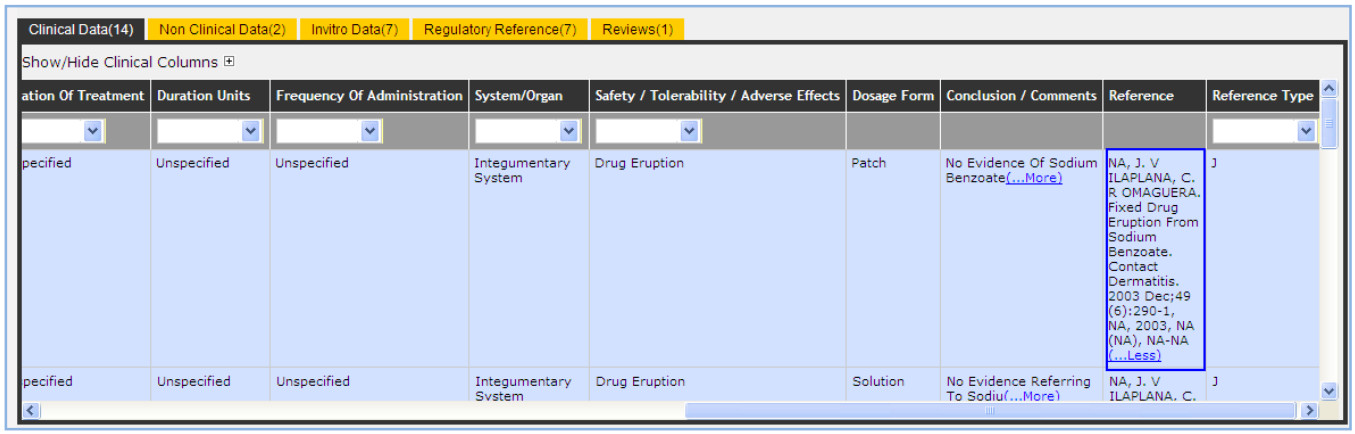
8.2.18 References

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.



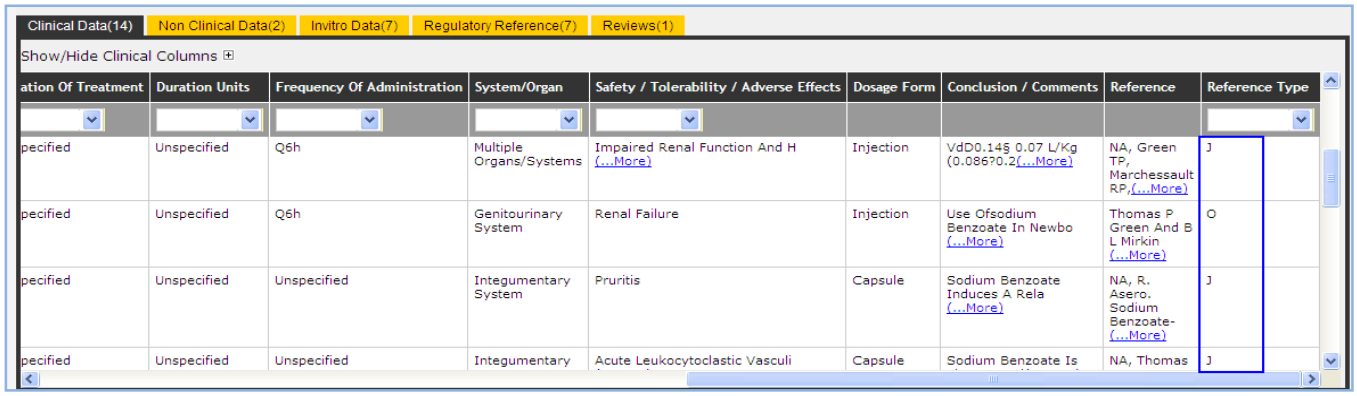
ation Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
pecified	Unspecified	Unspecified	Respiratory System	Anaphylactoid Reaction	Unspecified	A Decrease In Peak Expiratory (...More)	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,	J

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



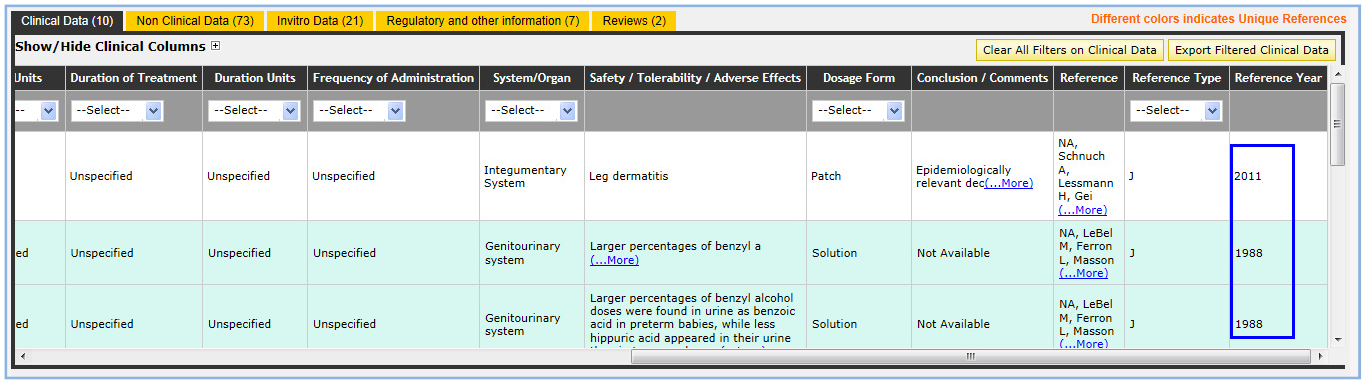
8.2.19 Reference Type

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;



8.2.20 Reference Year

Reference Year Indicator specifies the year of that particular reference



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.

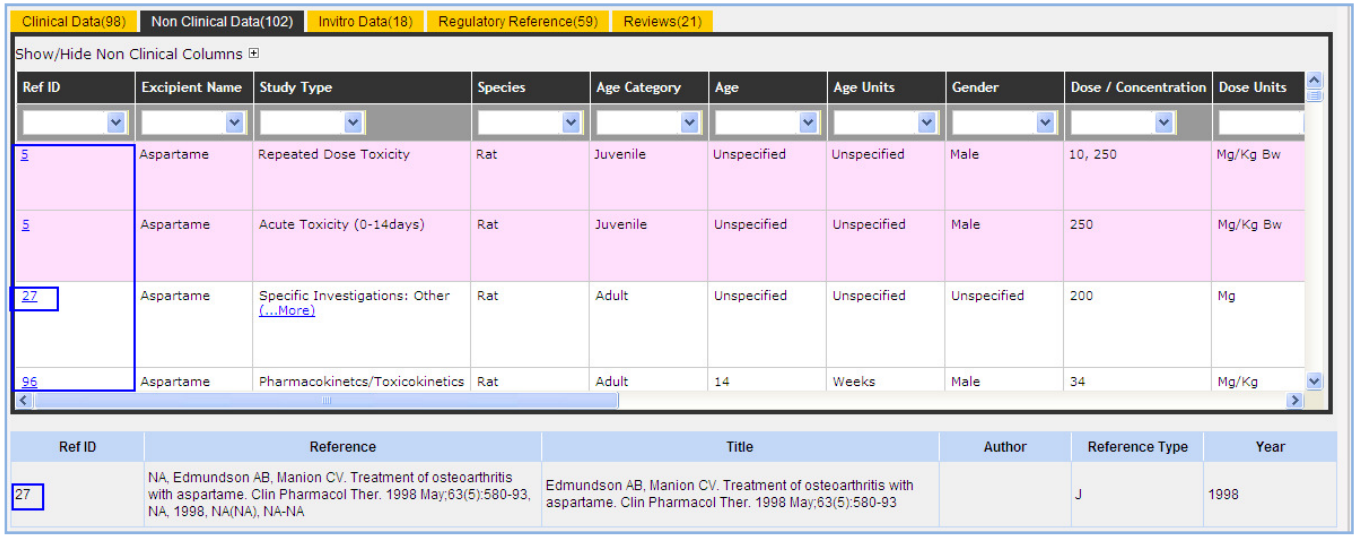
8.3 Non Clinical Data

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

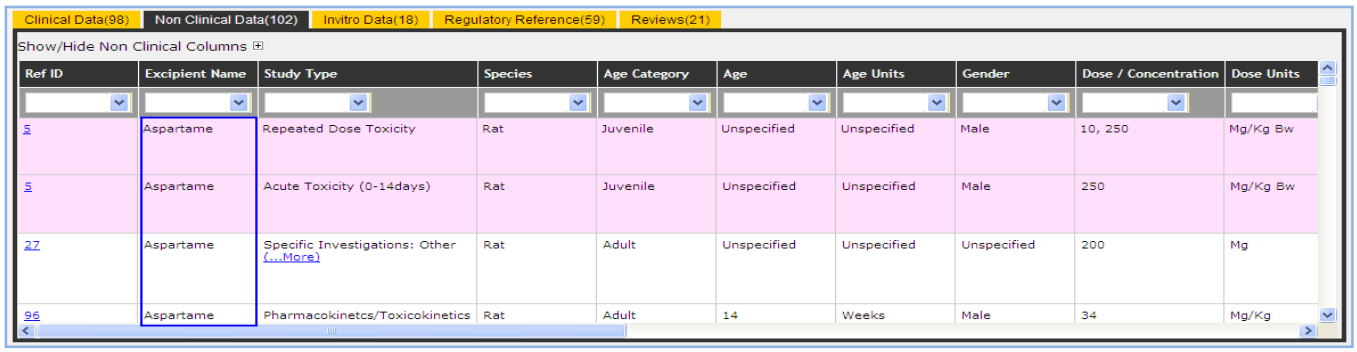
Non-Clinical data provides complete Non-Clinical information of the excipient.

- 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



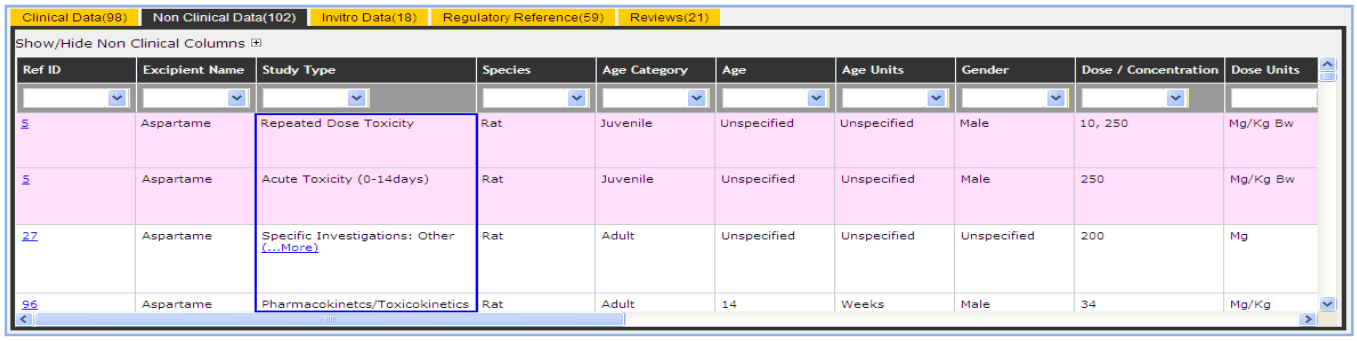
8.3.2 Excipient Name

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



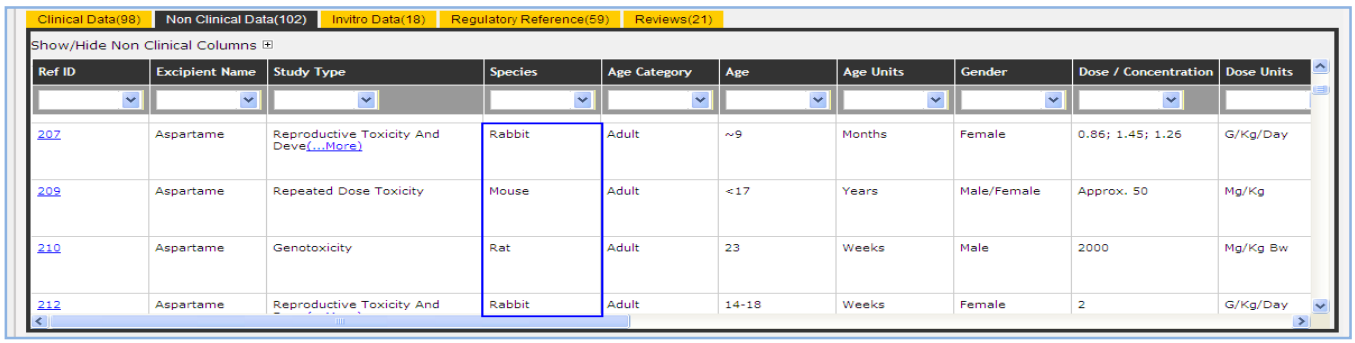
8.3.3 Study Type

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.



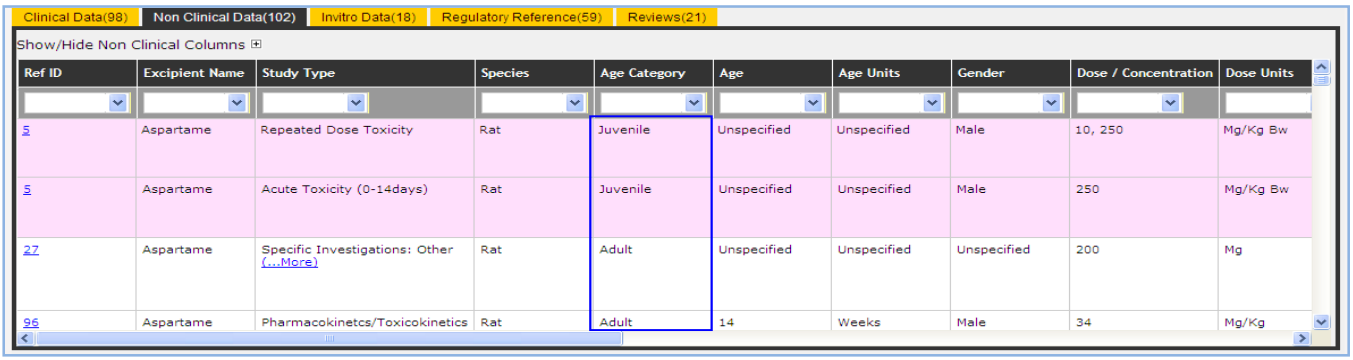
8.3.4 Species

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



8.3.5 Age Category

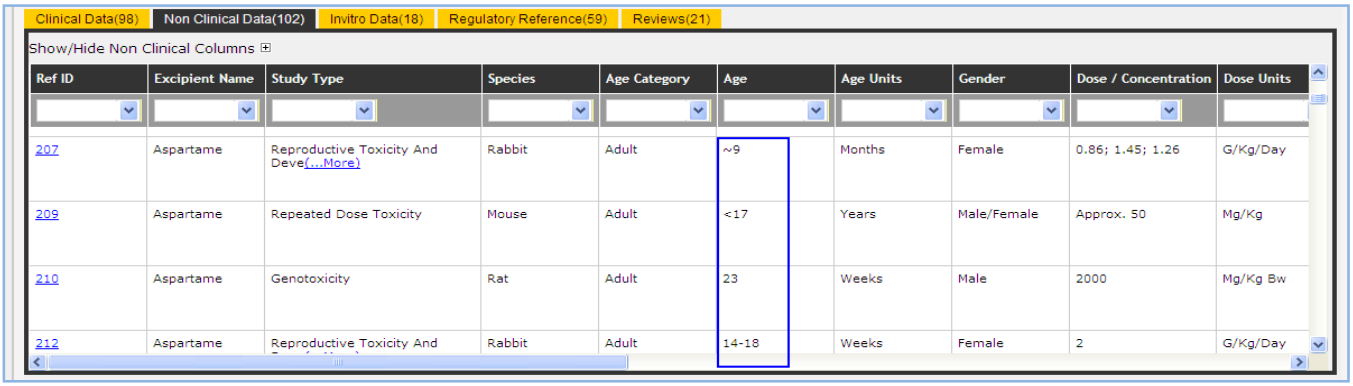
"Age Category" indicates is classified as per ICH classification (CPMP/ICH/2711/99).Based on the age category the relevant group name in indicated. Depending upon the search criteria the corresponding age category information will appear under "Age Category" column as shown below.



Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
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

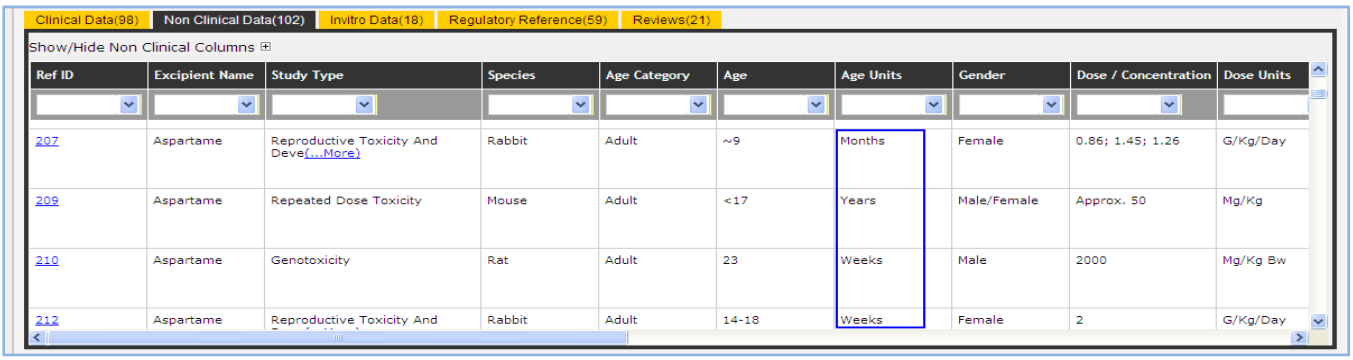
Age provides numerical entry for age in its corresponding column as shown below



Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
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

8.3.7 Age Units

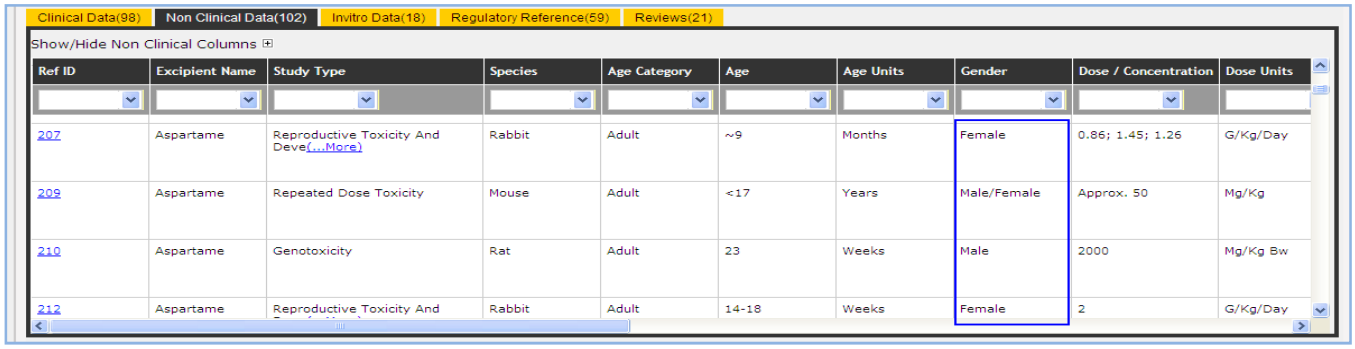
Displays the unit for Age- provides in years, months etc; as shown below



Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentration	Dose Units
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

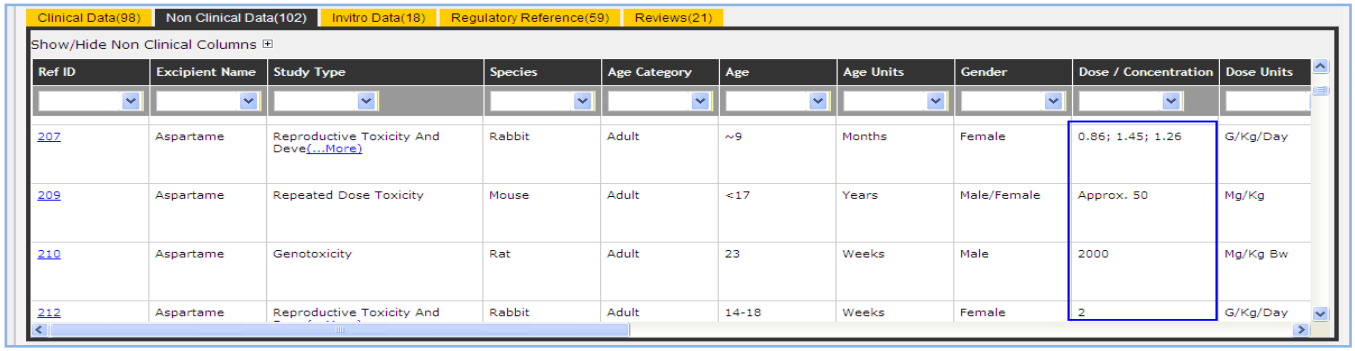
8.3.8 Gender

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



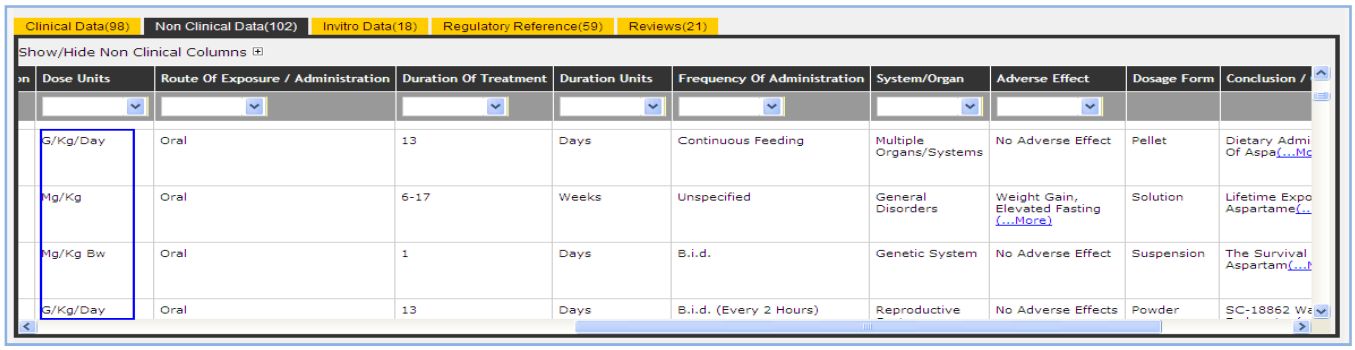
8.3.9 Dose/Concentration

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.



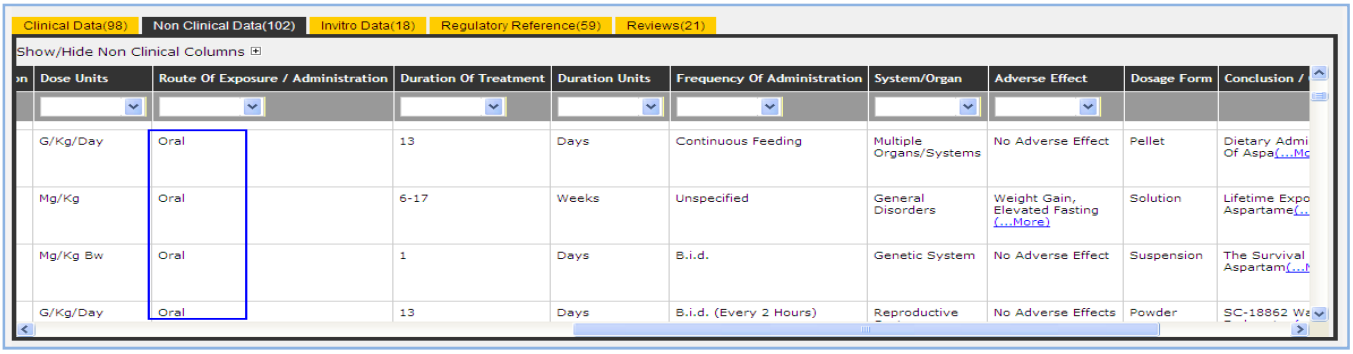
8.3.10 Dose Units

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



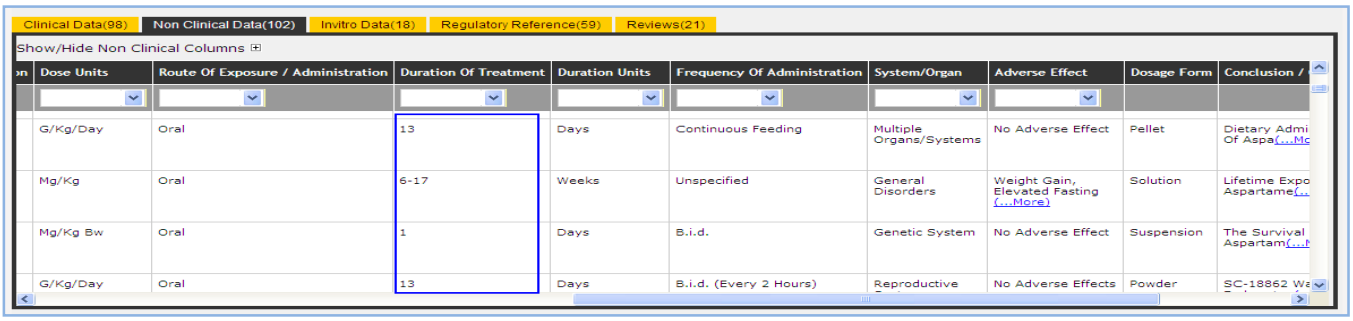
8.3.11 Route of Exposure or Administration

"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.



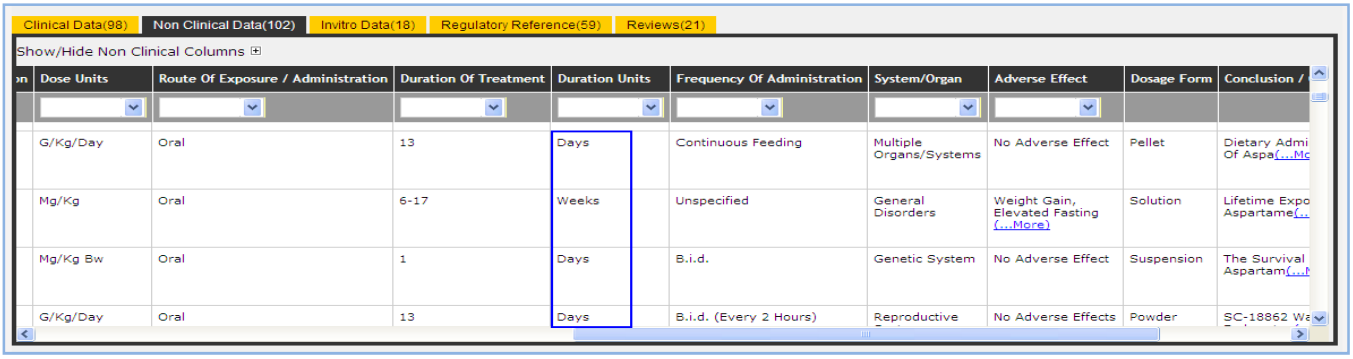
8.3.12 Duration of Treatment

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



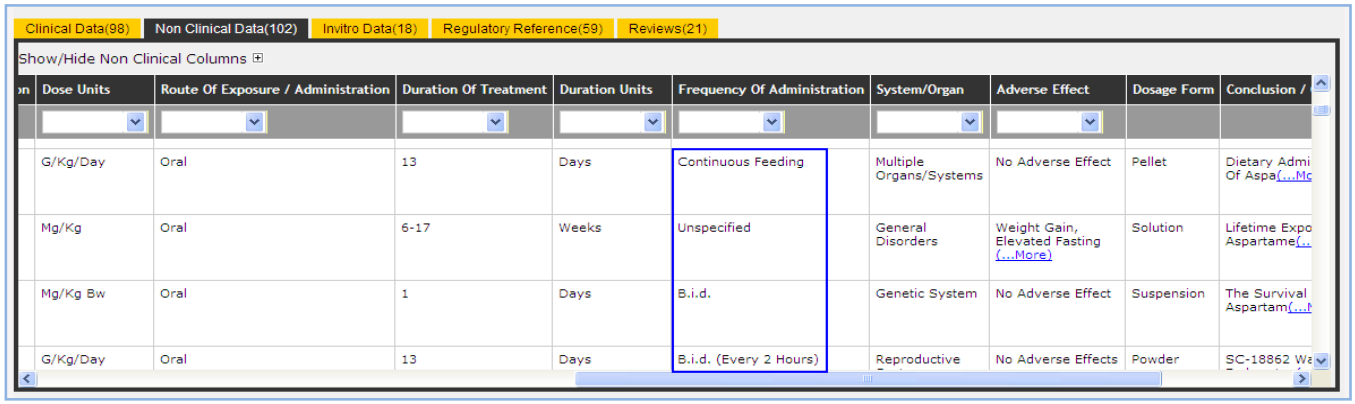
8.3.13 Duration Units

Displays duration of the dose in units



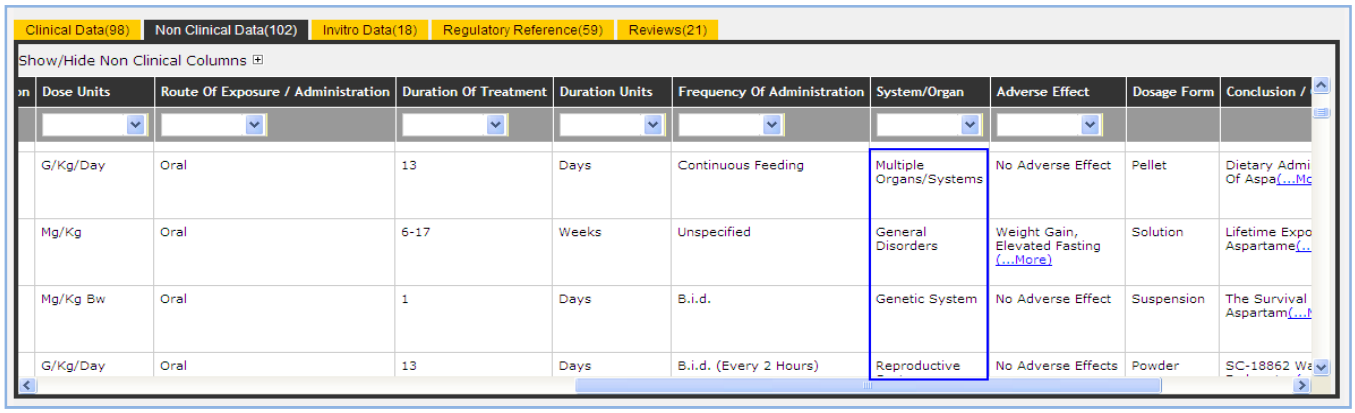
8.3.14 Frequency of Administration

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



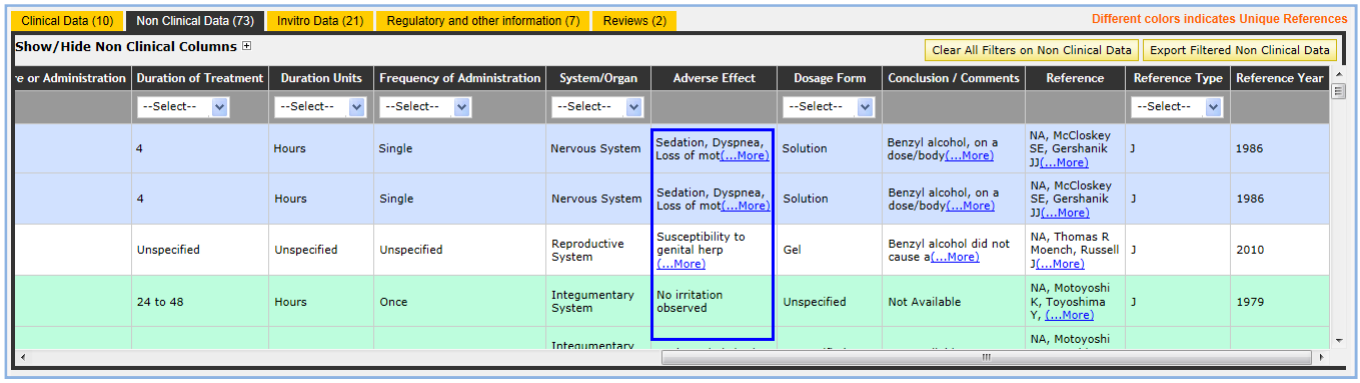
8.3.15 System/Organ

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



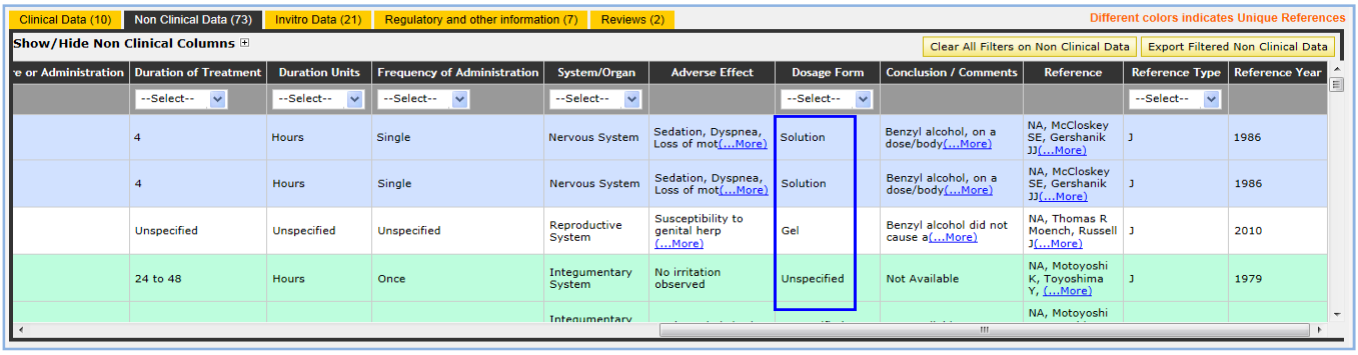
8.3.16 Adverse effects

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



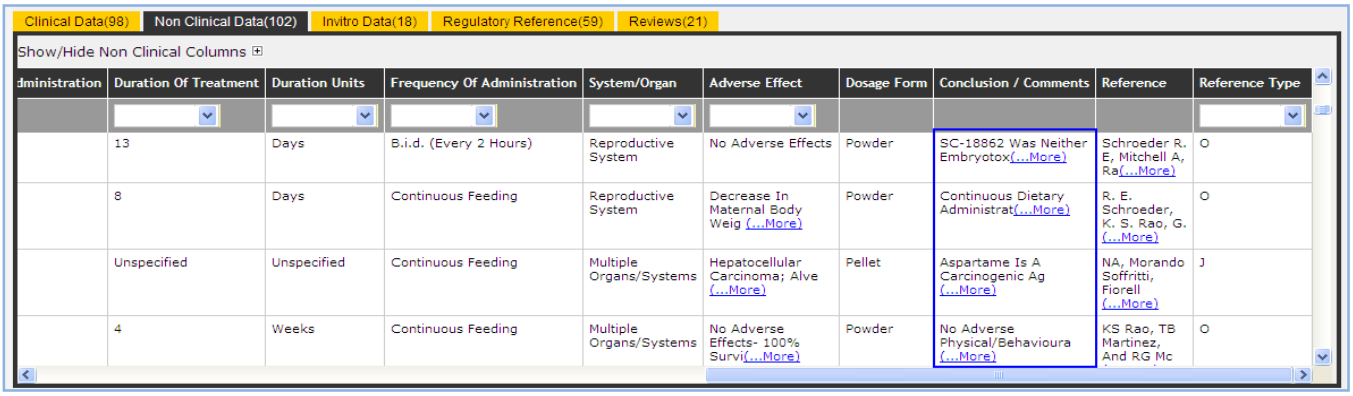
8.3.17 Dosage Form

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

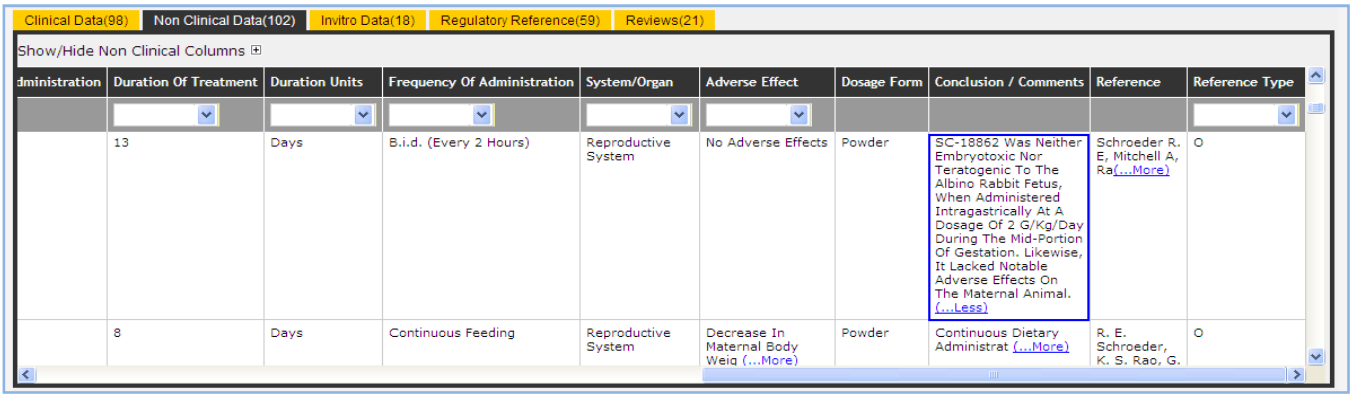


8.3.18 Conclusions/Comments

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.

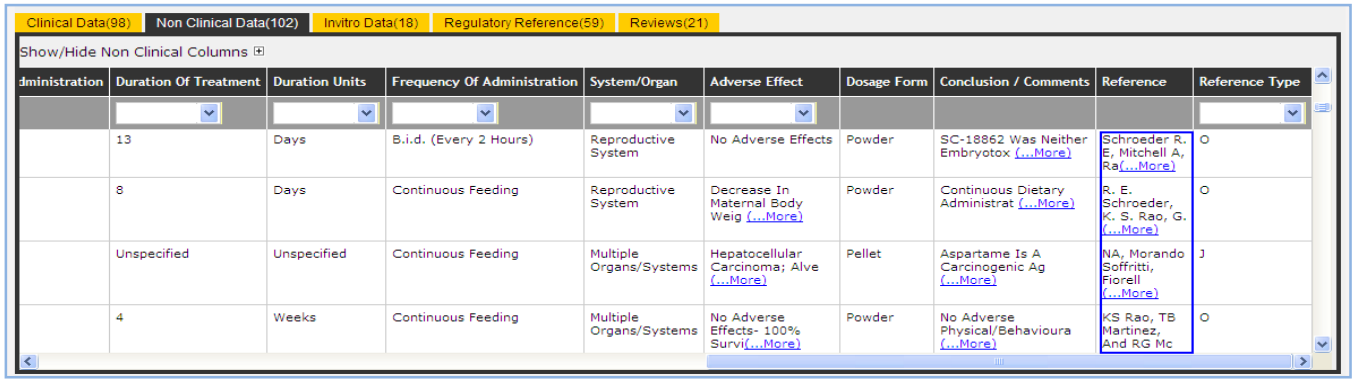


Click “More” link then complete comments data appears as shown below.

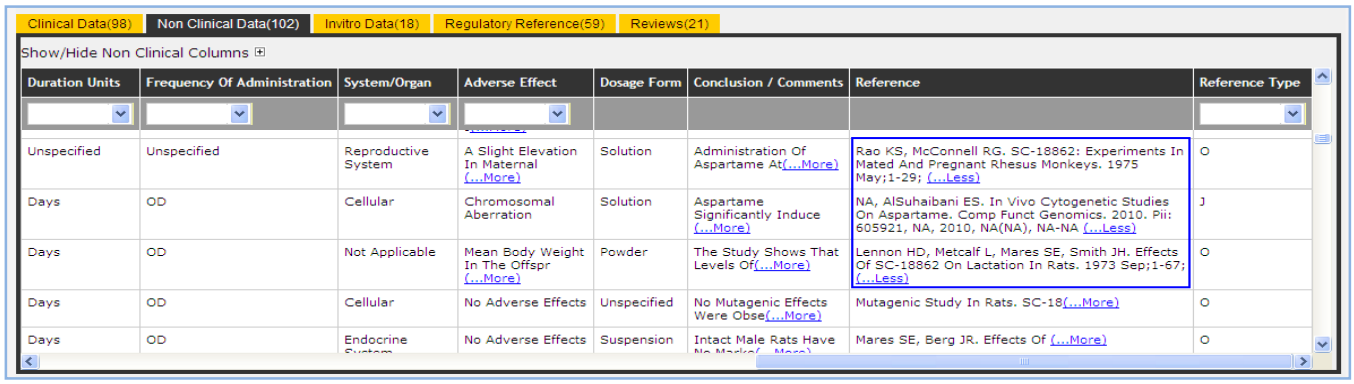


8.3.19 References

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.

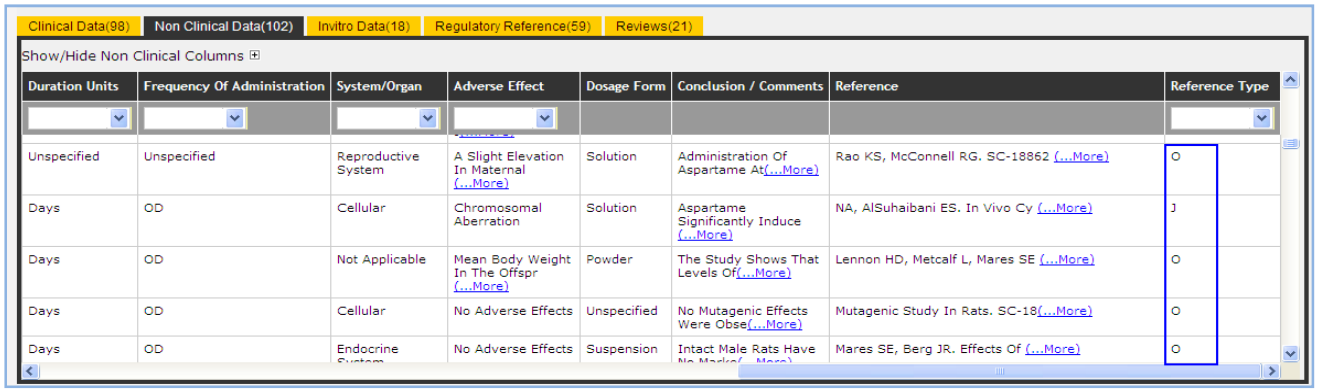


Click “More” link then complete reference information appears as shown below.



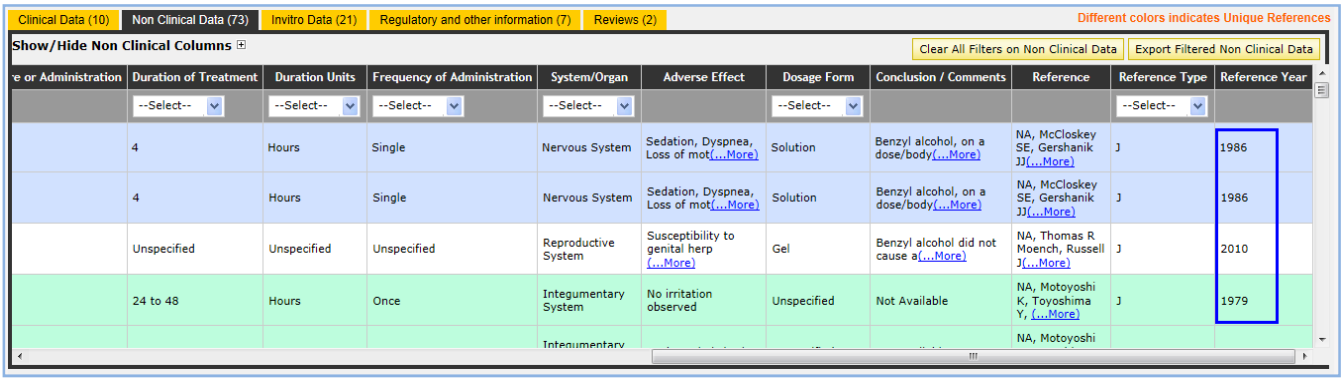
8.3.20 Reference Type

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;



8.3.21 Reference Year

Reference Year Indicator specifies the year of that particular reference



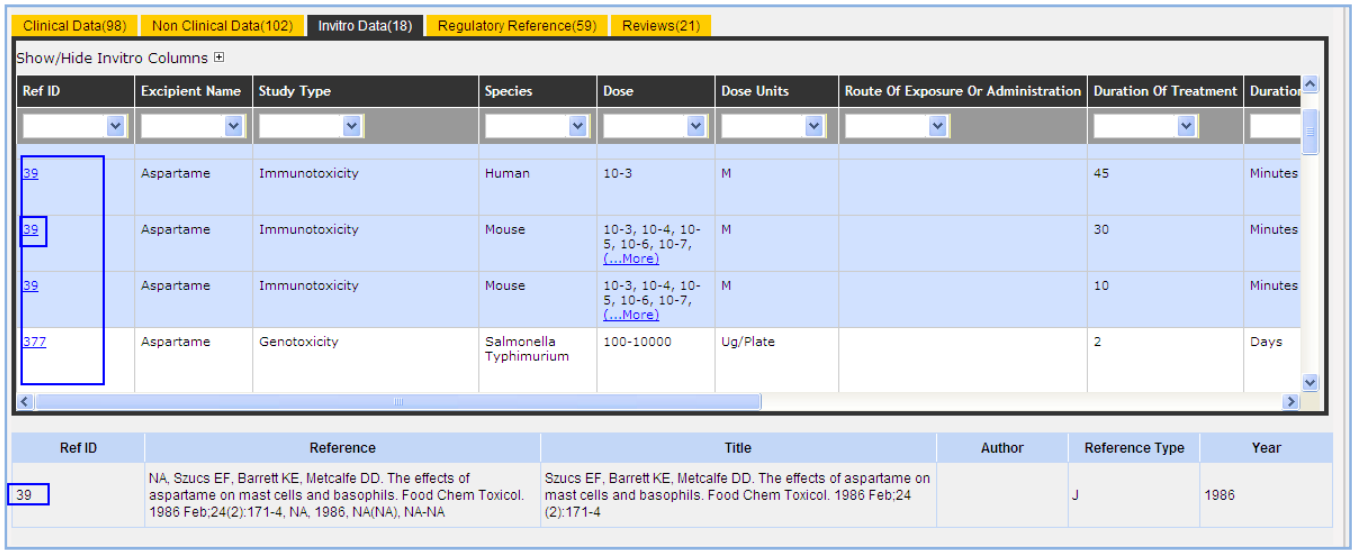
8.4 Invitro data

Invitro Data provides the complete information about the

8.4.1 Ref ID

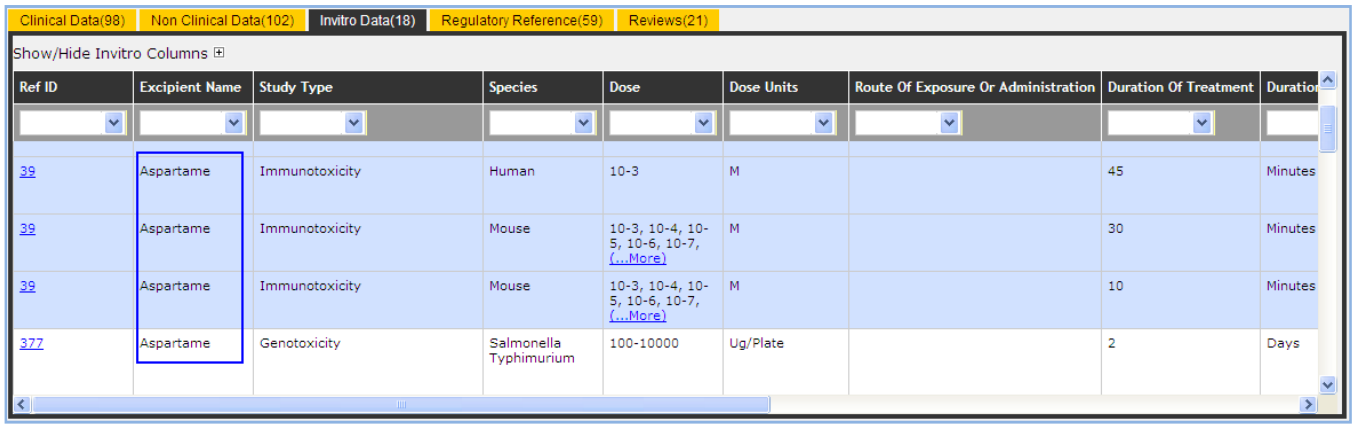
Invitro provides complete Invitro information of the excipient.

- 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



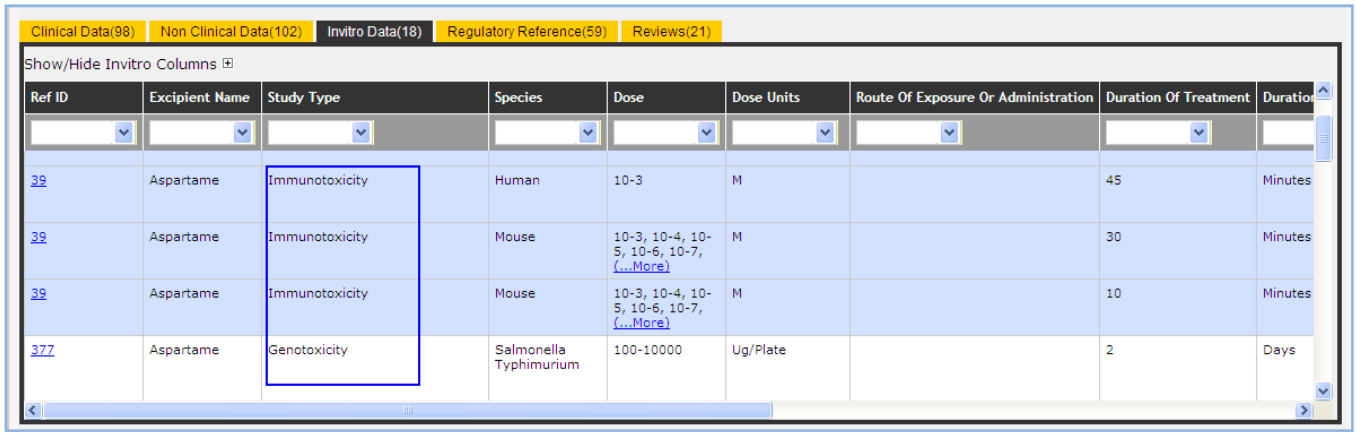
8.4.2 Excipient Name

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



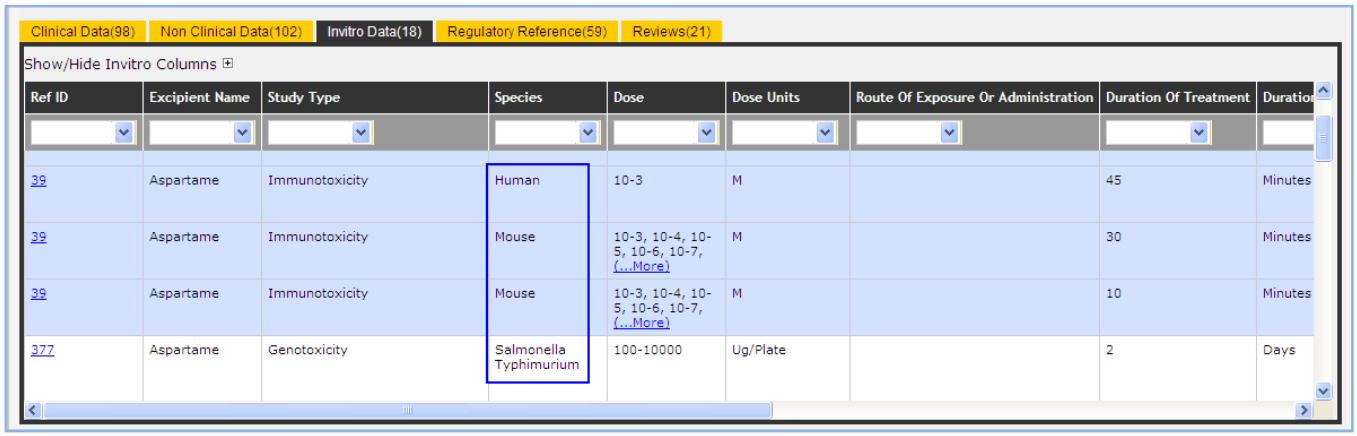
8.4.3 Study Type

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.



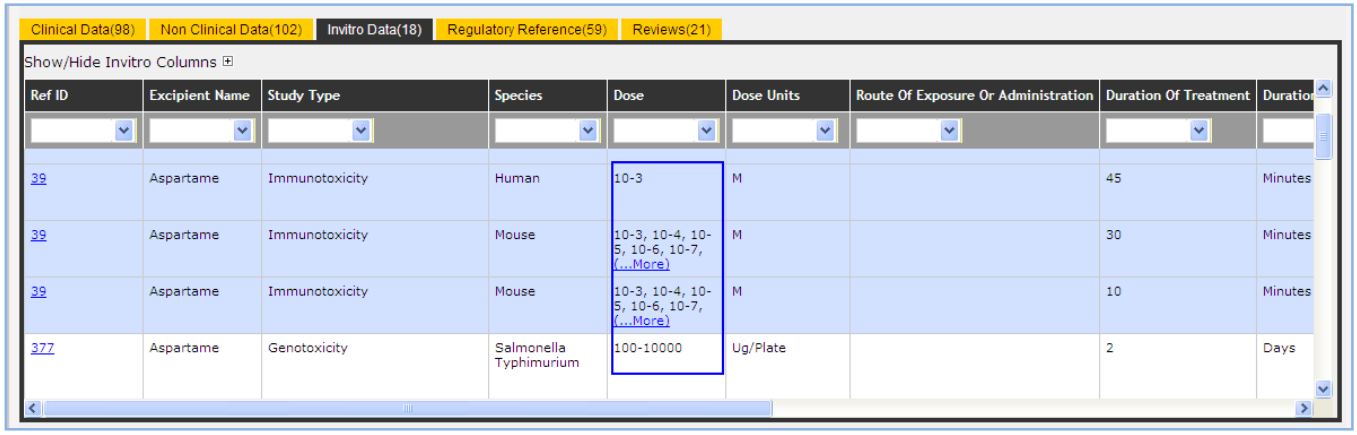
8.4.4 Species

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



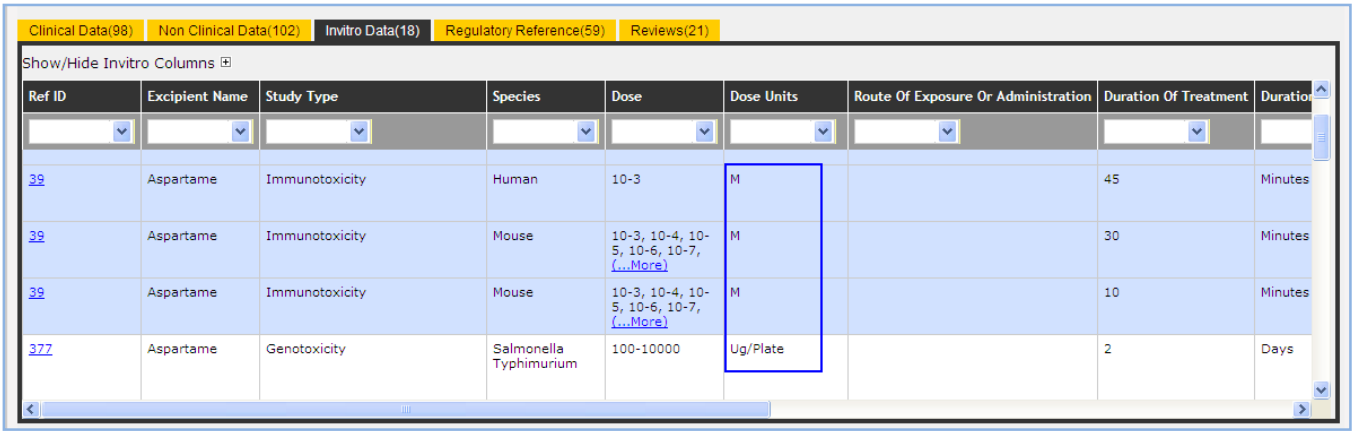
8.4.5 Dose

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.



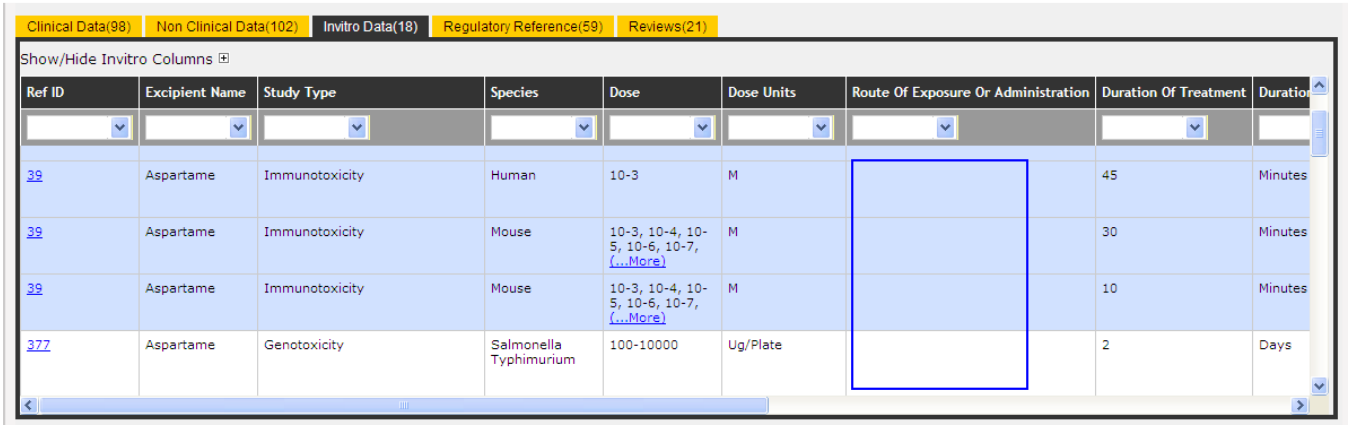
8.4.6 Dose Units

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



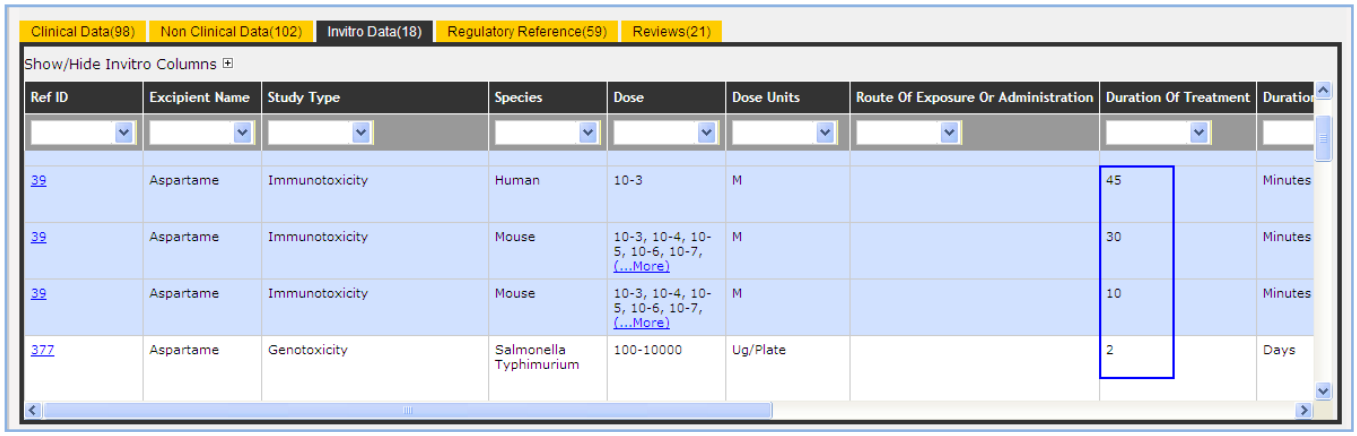
8.4.7 Route of Exposure or Administration

"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.



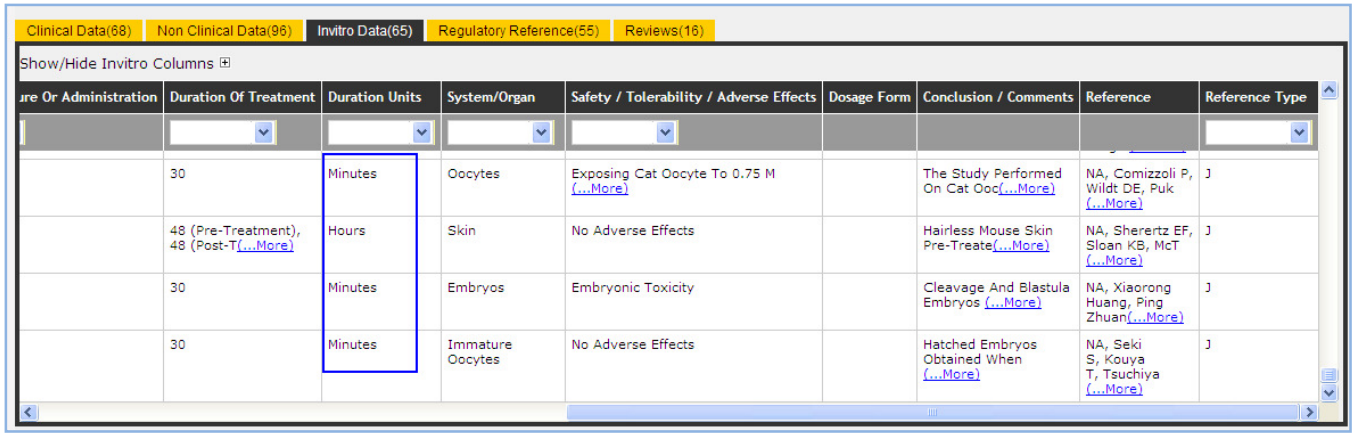
8.4.8 Duration of Treatment

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



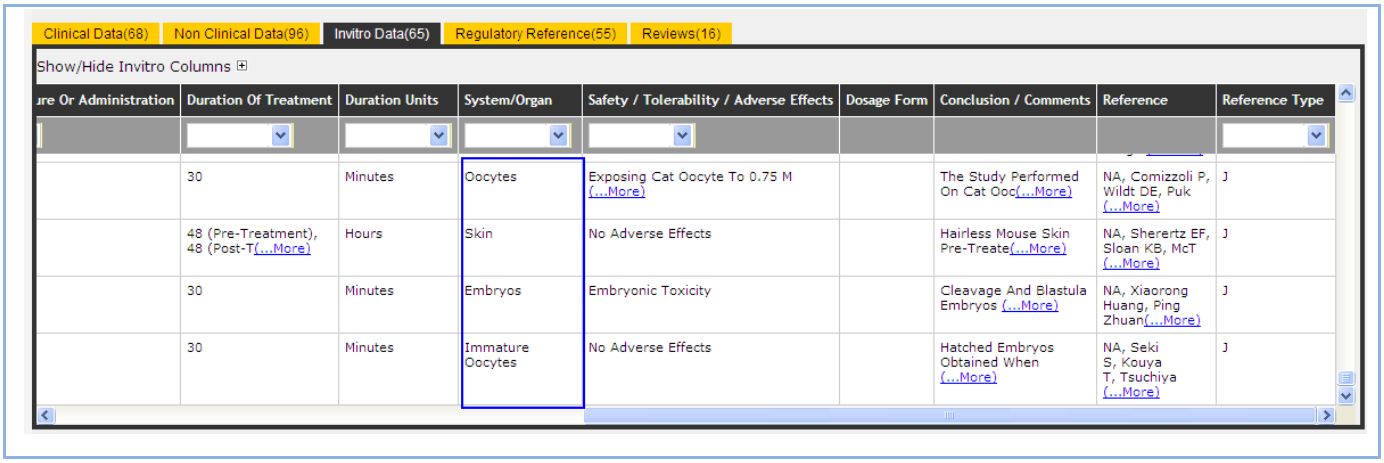
8.4.9 Duration Units

Displays duration of the dose in units



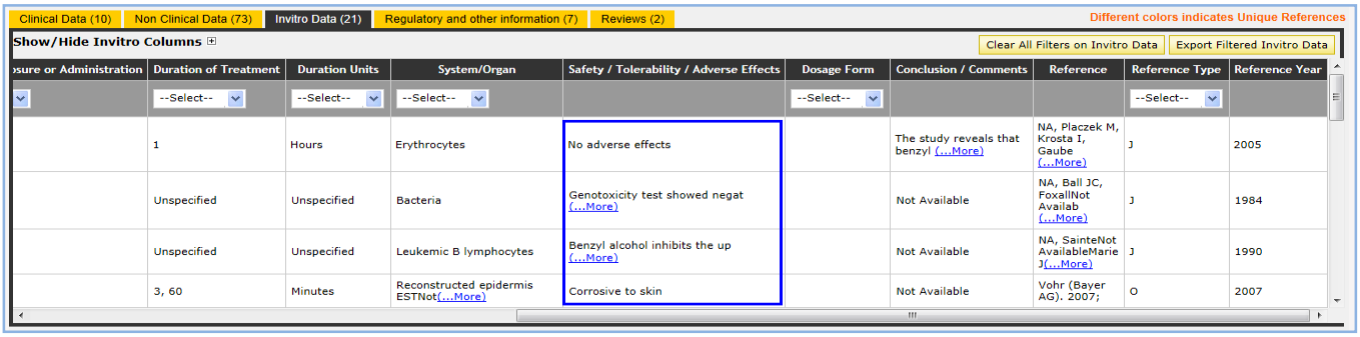
8.4.10 System/Organ

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



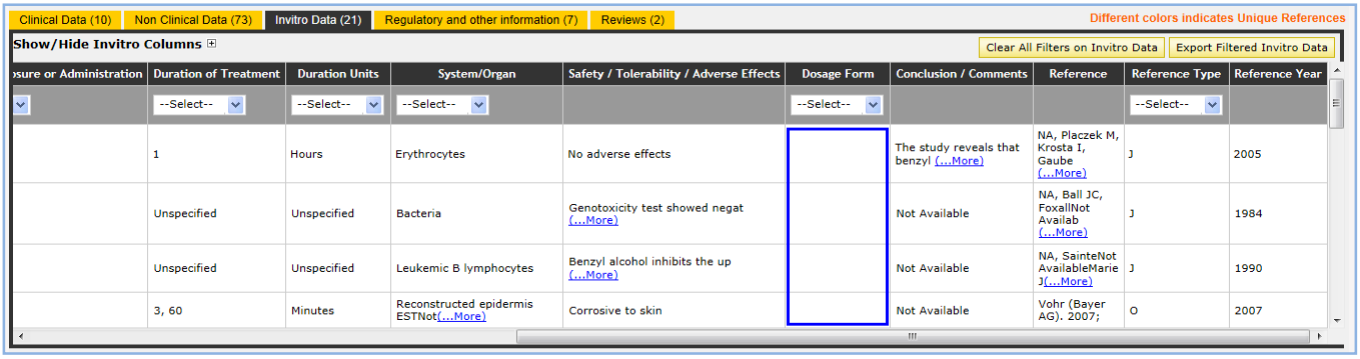
8.4.11 Safety/Tolerability/Adverse Effects

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



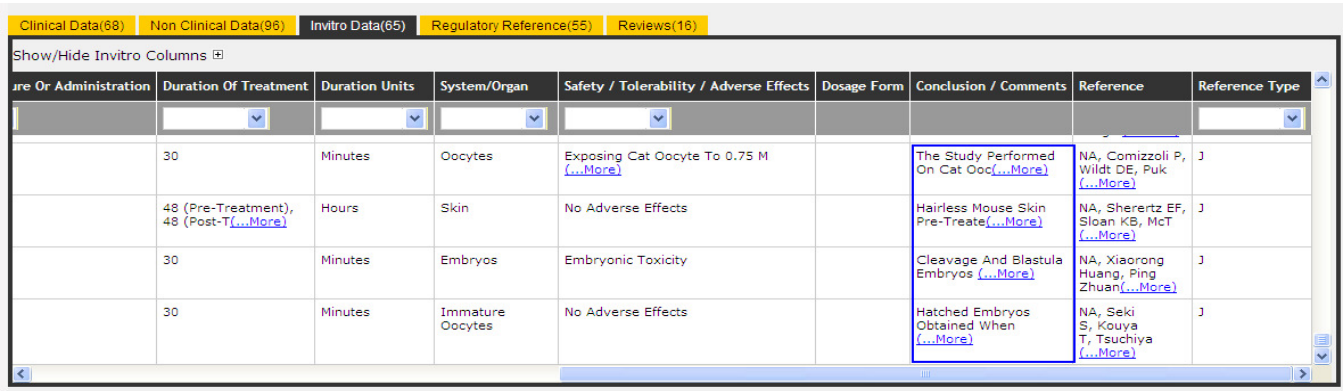
8.4.12 Dosage Form

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

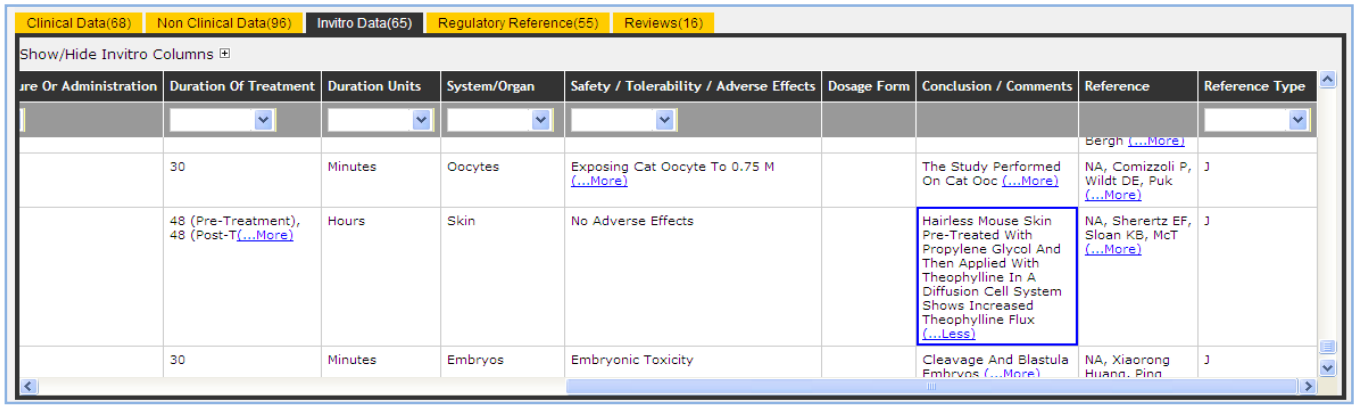


8.4.13 Conclusions/Comments

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.

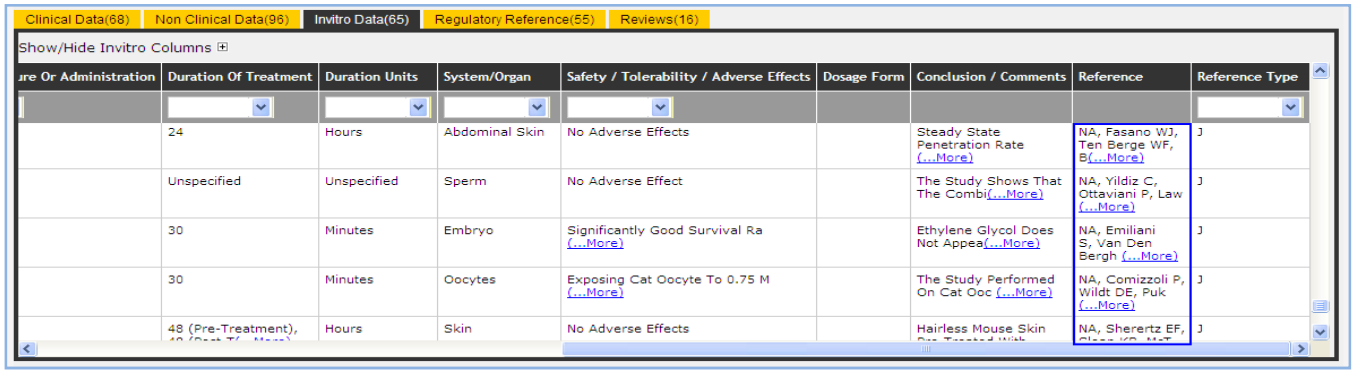


Click “More” link then complete comments data appears as shown below.

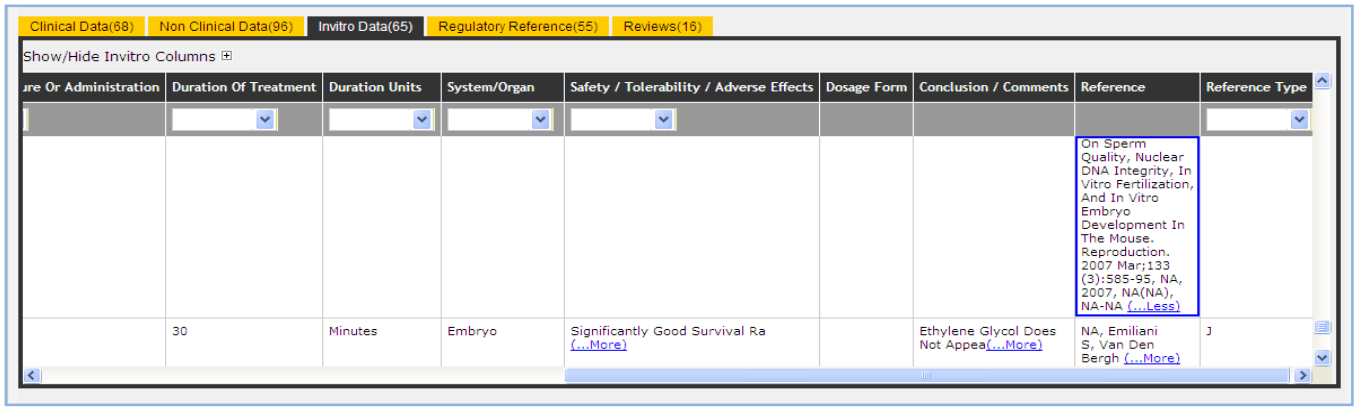


8.4.14 References

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.

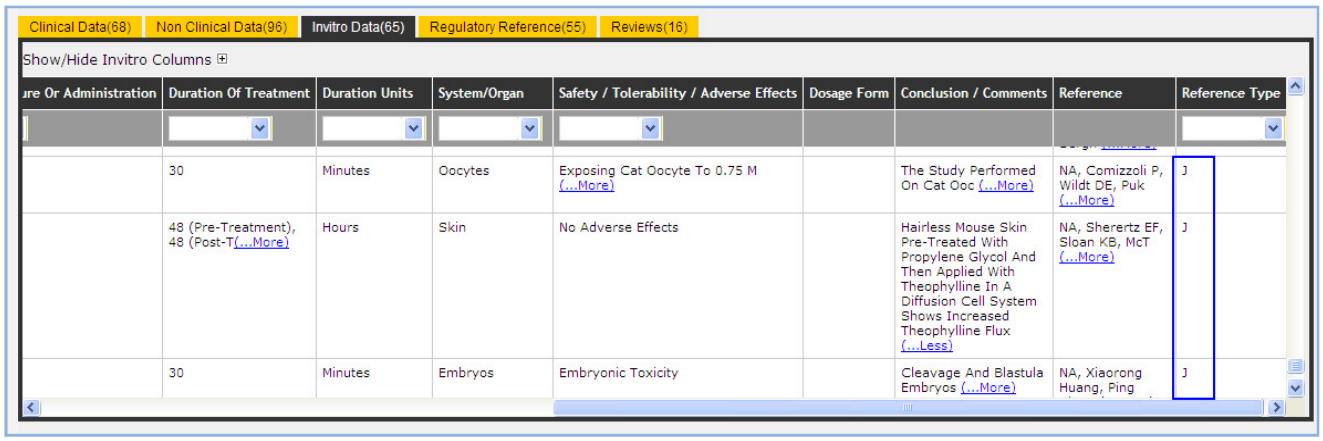


Click “More” link then complete reference information appears as shown below.



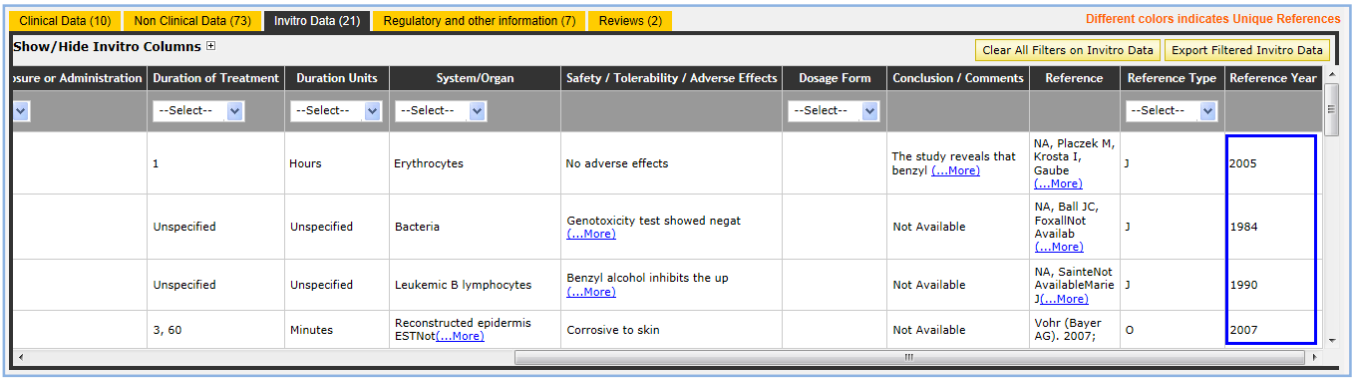
8.4.15 Reference Type

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;



8.4.16 Reference Year

Reference Year Indicator specifies the year of that particular reference



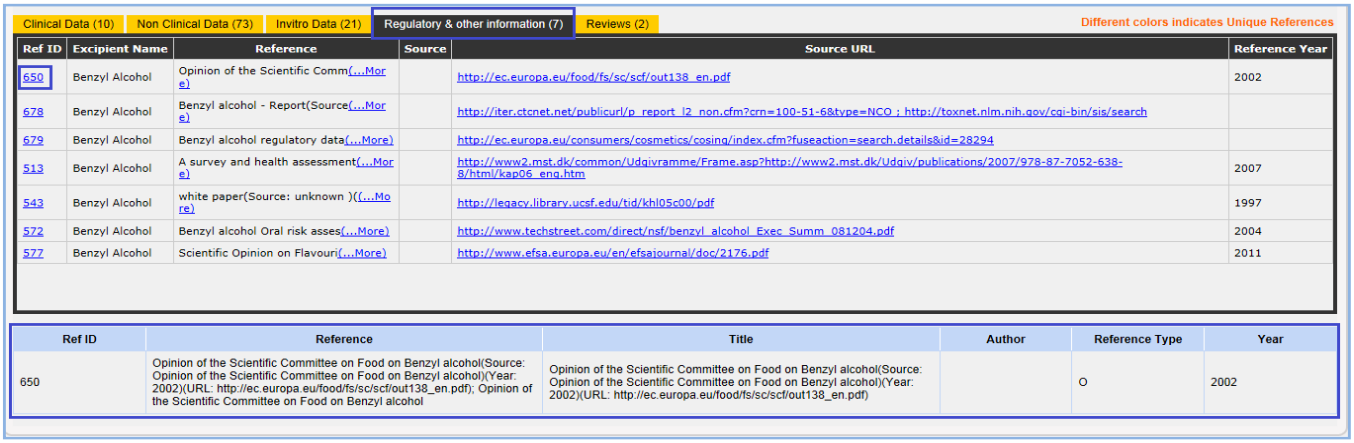
8.5 Regulatory & other information

'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

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



Clinical Data (10) | Non Clinical Data (73) | Invitro Data (21) | Regulatory & other information (7) | Reviews (2)

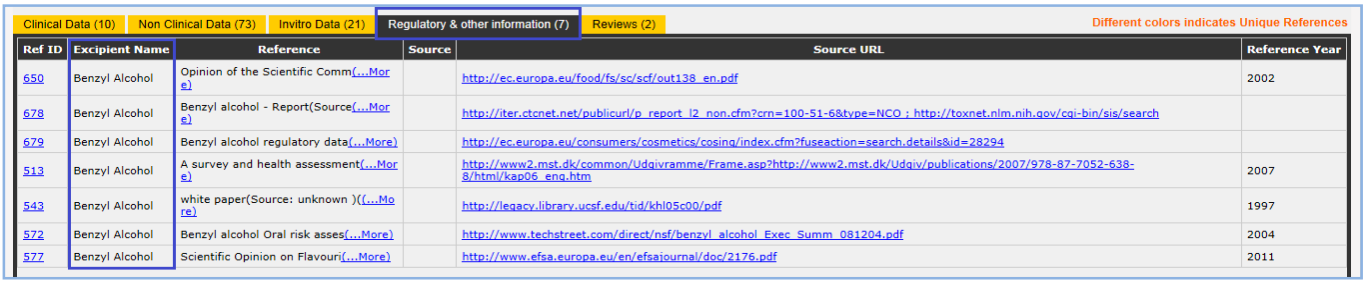
Different colors indicates Unique References

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
577	Benzyl Alcohol	Scientific Opinion on Flavouri(...More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

Ref ID	Reference	Title	Author	Reference Type	Year
650	Opinion of the Scientific Committee on Food on Benzyl alcohol(Source: Opinion of the Scientific Committee on Food on Benzyl alcohol)(Year: 2002)(URL: http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf); Opinion of the Scientific Committee on Food on Benzyl alcohol	Opinion of the Scientific Committee on Food on Benzyl alcohol(Source: Opinion of the Scientific Committee on Food on Benzyl alcohol)(Year: 2002)(URL: http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf)		O	2002

8.5.2 Excipient Name

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



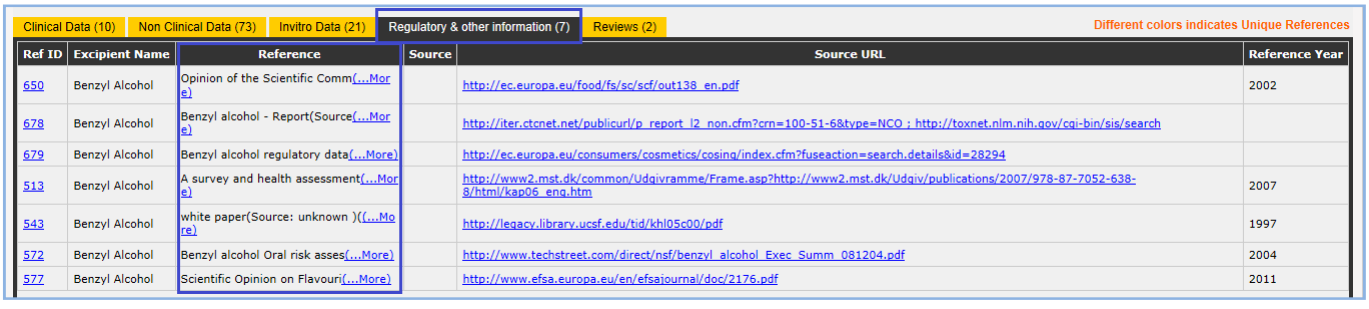
Clinical Data (10) | Non Clinical Data (73) | Invitro Data (21) | Regulatory & other information (7) | Reviews (2)

Different colors indicates Unique References

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
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.



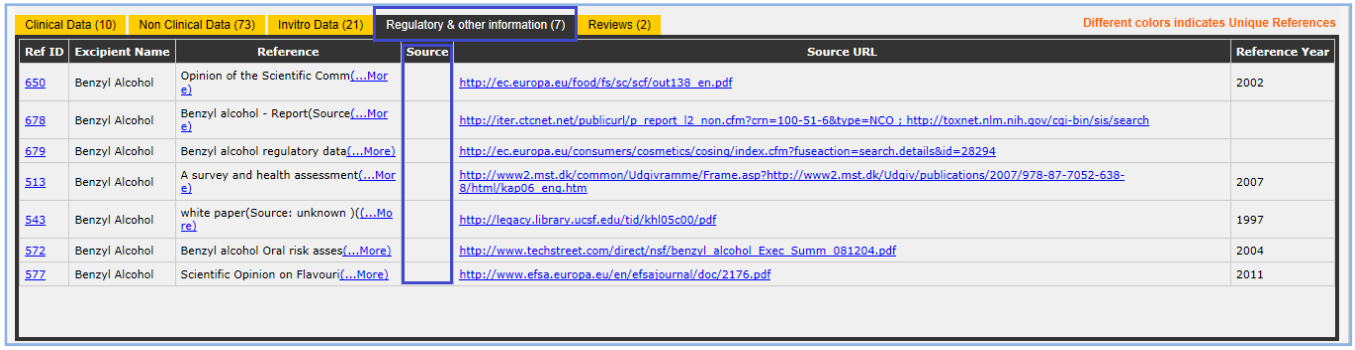
Clinical Data (10) | Non Clinical Data (73) | Invitro Data (21) | Regulatory & other information (7) | Reviews (2)

Different colors indicates Unique References

Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
577	Benzyl Alcohol	Scientific Opinion on Flavouri(...More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

8.5.4 Source

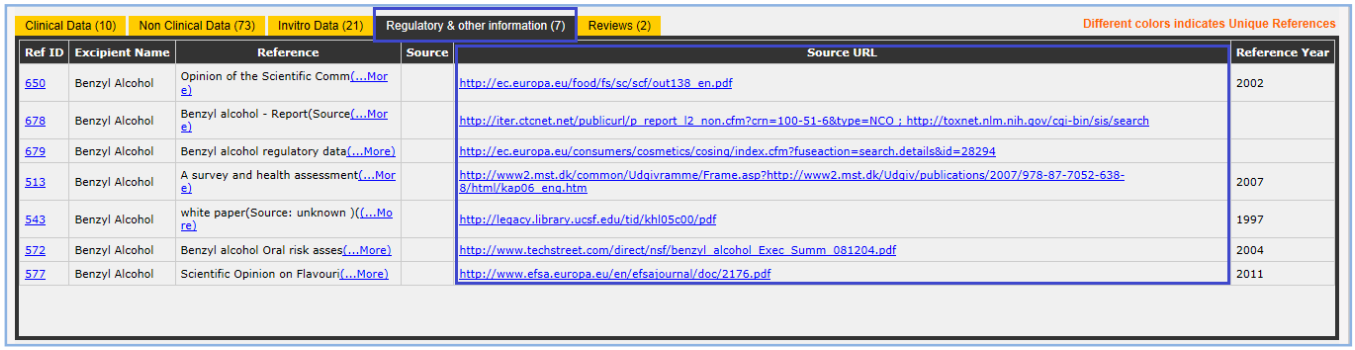
Source indicates from which the Reference information is extracted.



Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
577	Benzyl Alcohol	Scientific Opinion on Flavouri(...More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

8.5.5 Source URL

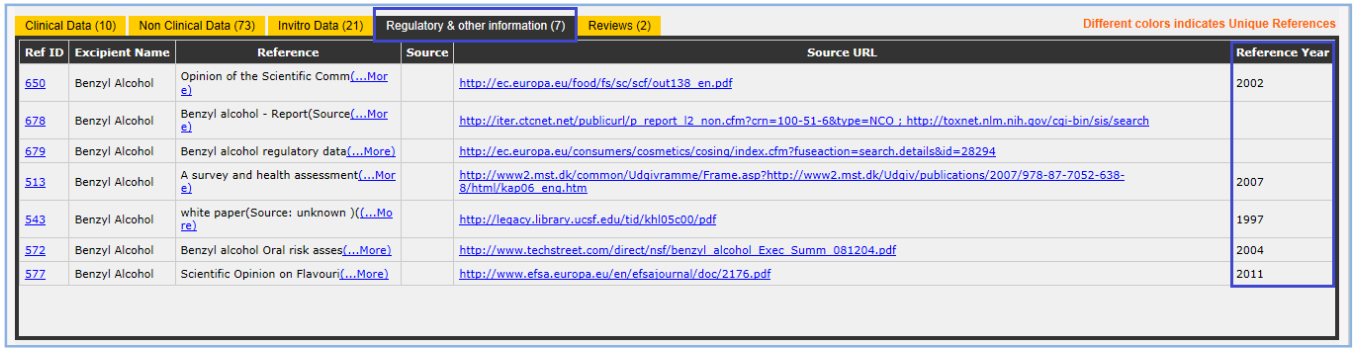
Source URL indicates from which the Reference information is extracted.



Ref ID	Excipient Name	Reference	Source	Source URL	Reference Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
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 Year
650	Benzyl Alcohol	Opinion of the Scientific Comm(...More)		http://ec.europa.eu/food/fs/sc/scf/out138_en.pdf	2002
678	Benzyl Alcohol	Benzyl alcohol - Report(Source(...More)		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	
679	Benzyl Alcohol	Benzyl alcohol regulatory data(...More)		http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.details&id=28294	
513	Benzyl Alcohol	A survey and health assessment(...More)		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
543	Benzyl Alcohol	white paper(Source: unknown)((...More)		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
577	Benzyl Alcohol	Scientific Opinion on Flavouri(...More)		http://www.efsa.europa.eu/en/efsajournal/doc/2176.pdf	2011

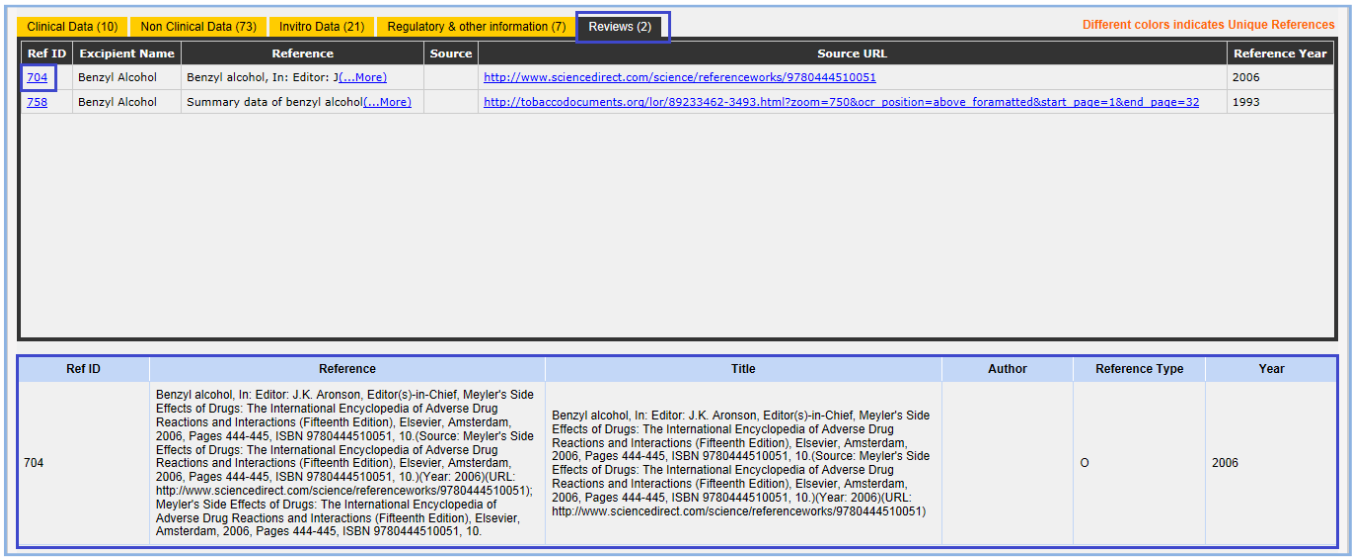
8.6 Reviews

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



8.6.2 Excipient Name

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

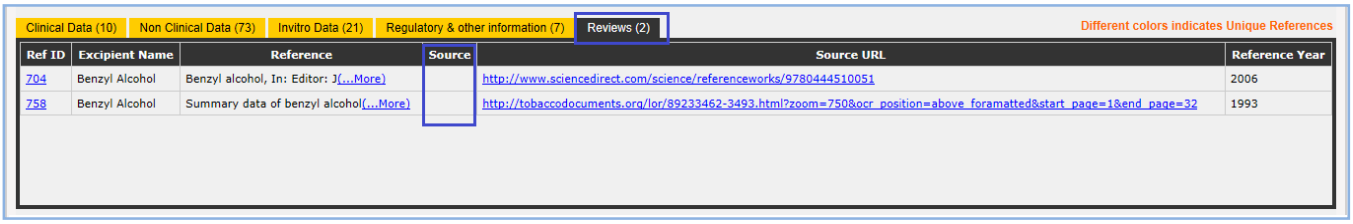
8.6.3 References

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.

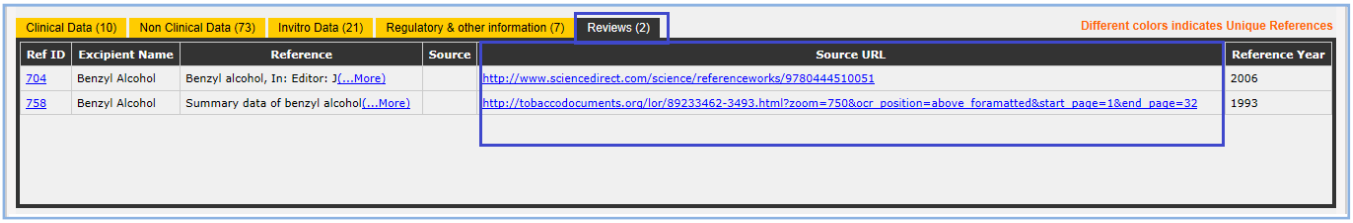
8.6.4 Source

Source indicates from which the Reference information is extracted.



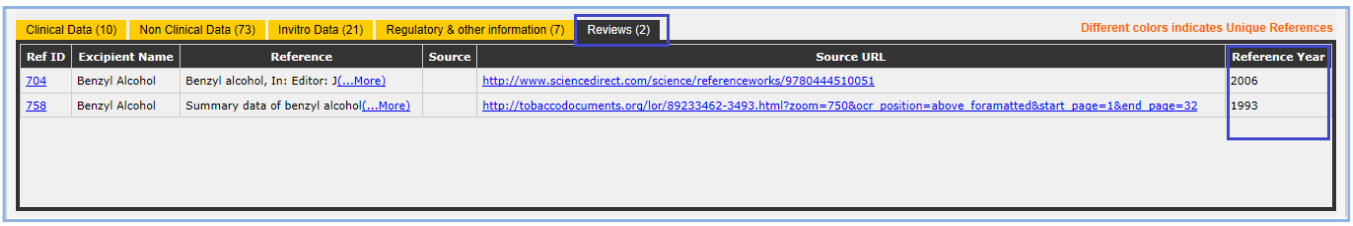
8.6.5 Source URL

Source URL indicates from which the Reference information is extracted.



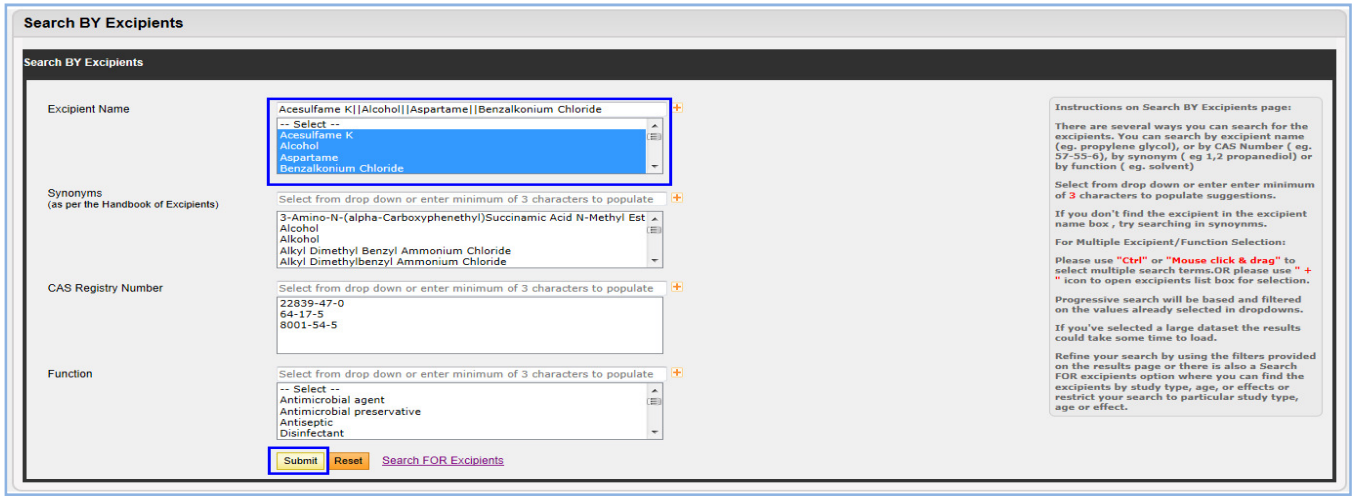
8.6.6 Reference Year

Reference Year Indicator specifies the year of that particular reference

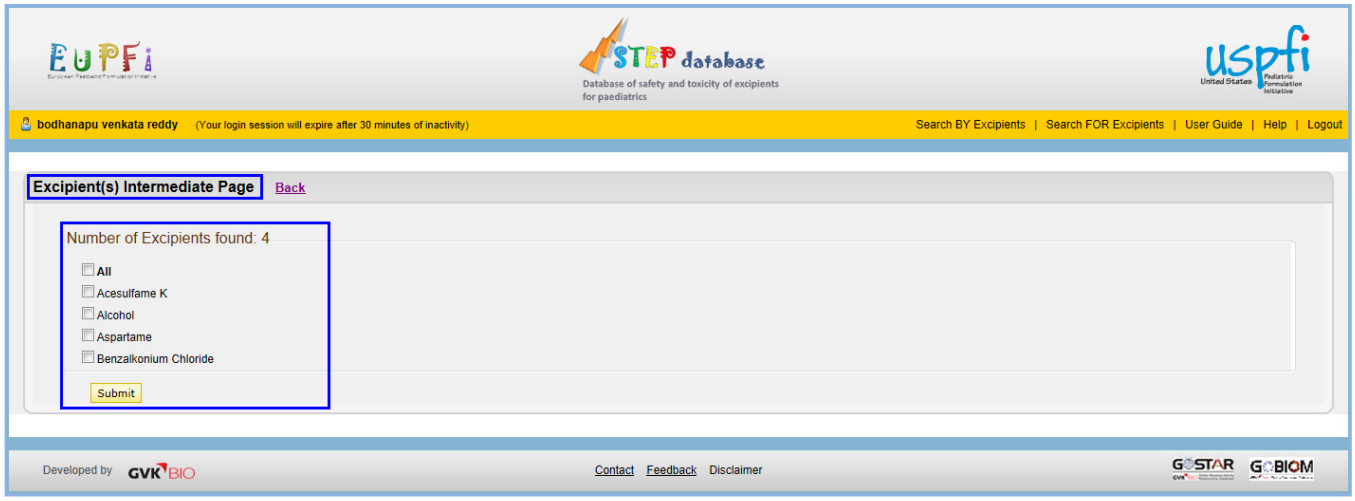


8.7 Customization using Filters

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

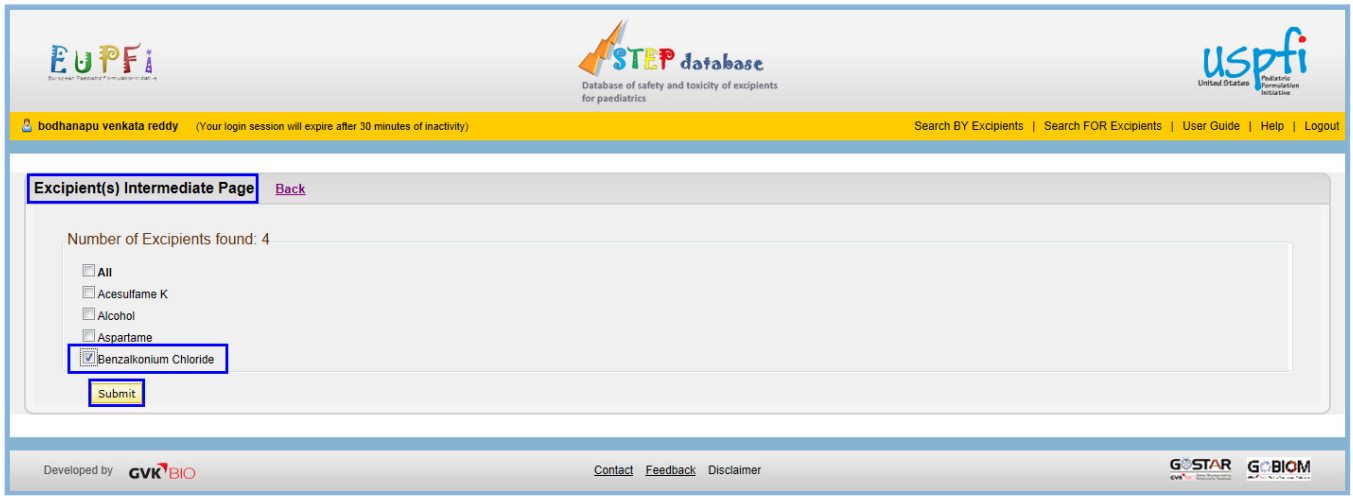


Then click “Submit” button then below page appears

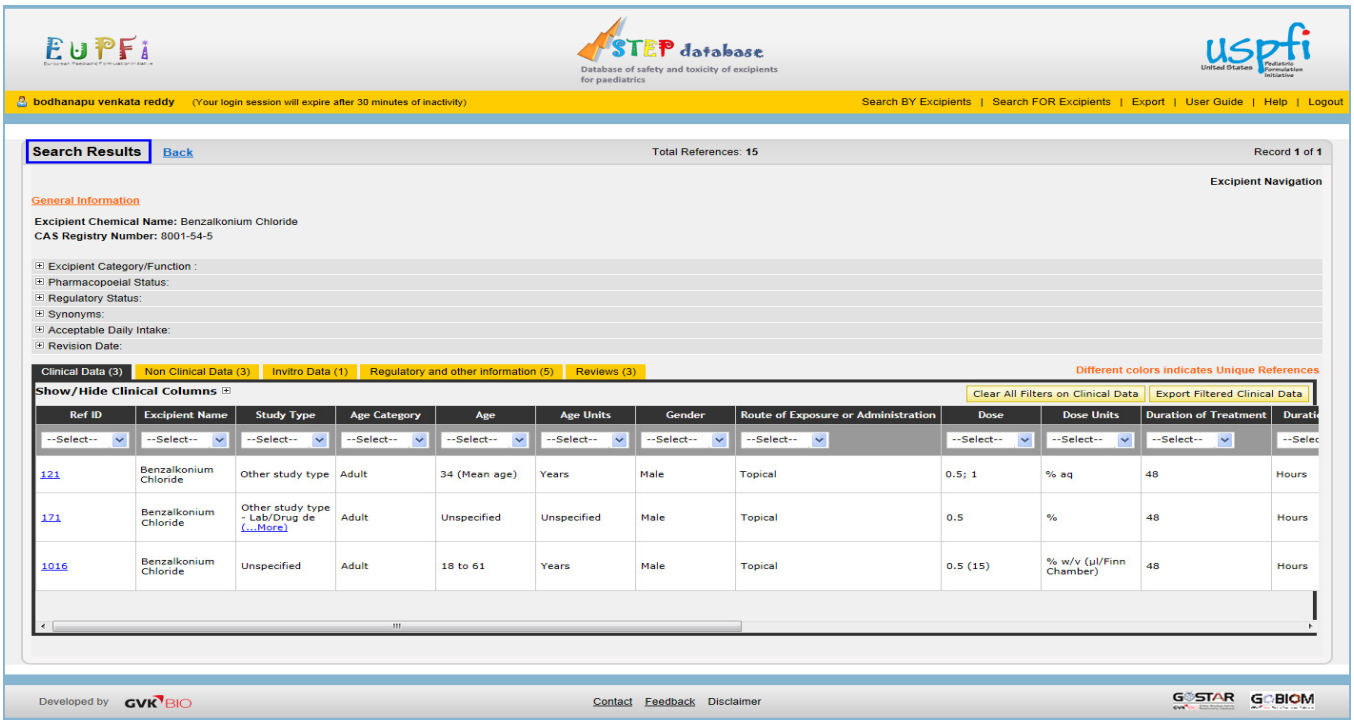


In the above page user is allowed to select one or more than one excipient name using check boxes

As shown below

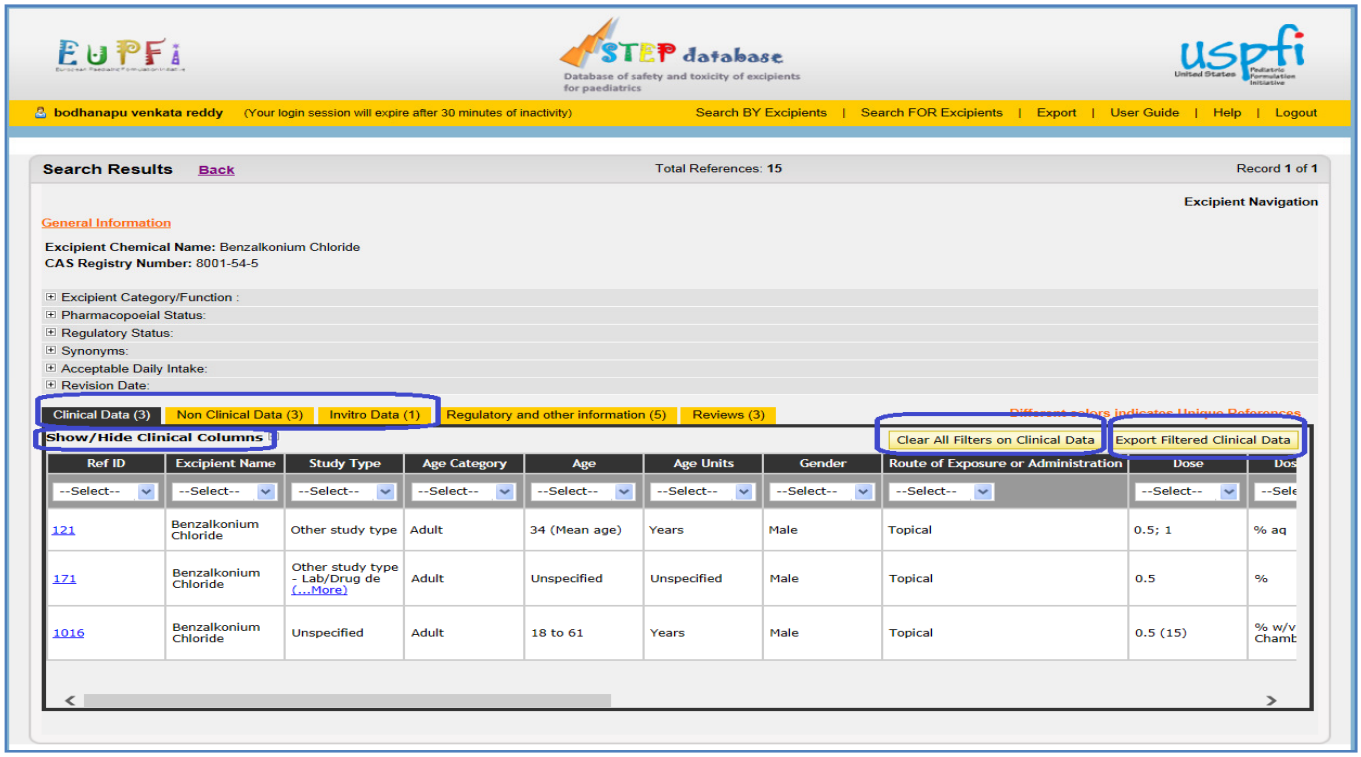


Click "Submit" to retrieve the results. Then the "Search Results" page appears as shown below



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

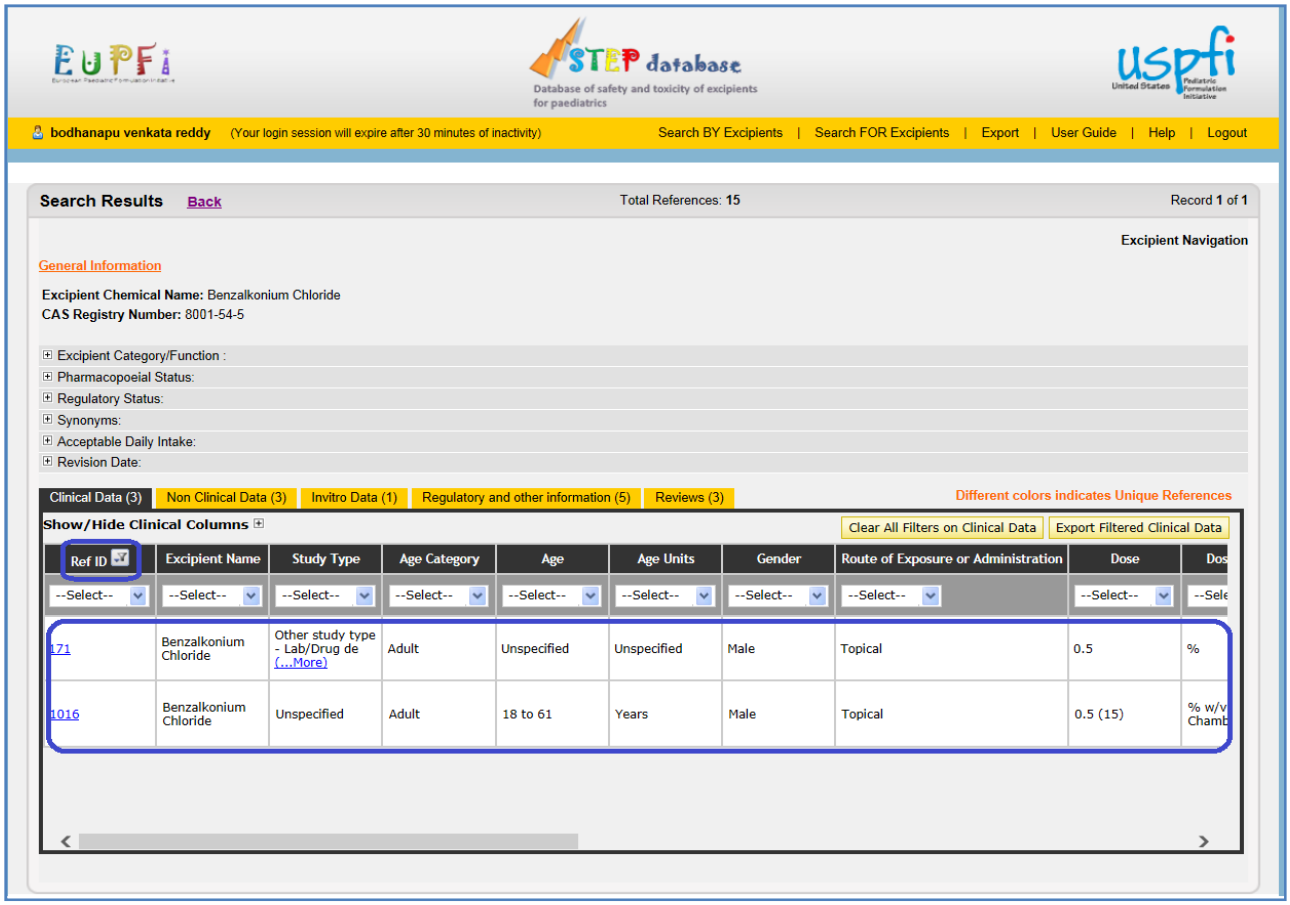
a. Horizontally (Row wise) Filtering.
b. Vertically (Column wise) Filtering.



A. Horizontal (Row wise) Filtering:

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

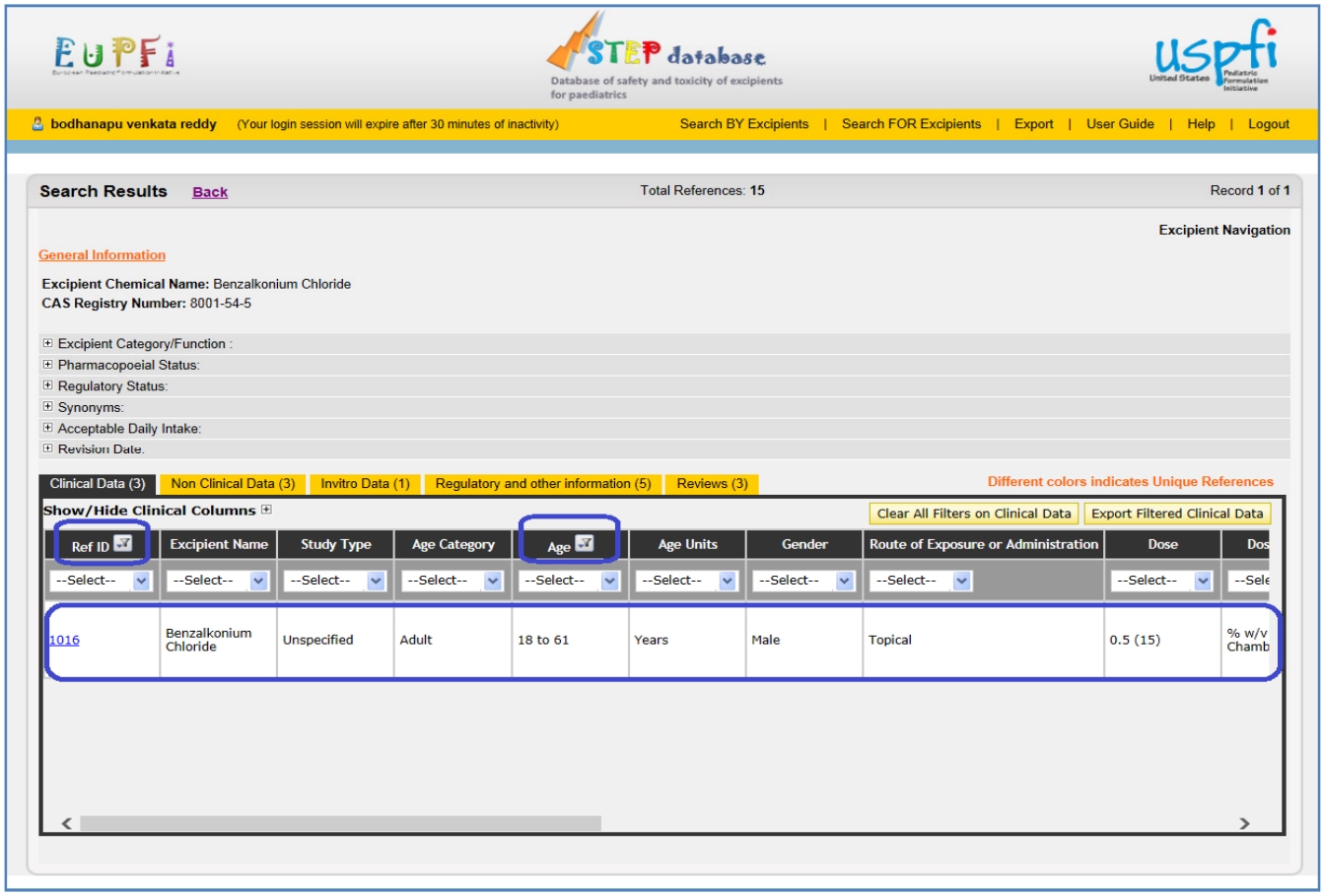
a. User is applying the filtering criteria on any one of the columns, say Ref ID as shown below.



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.

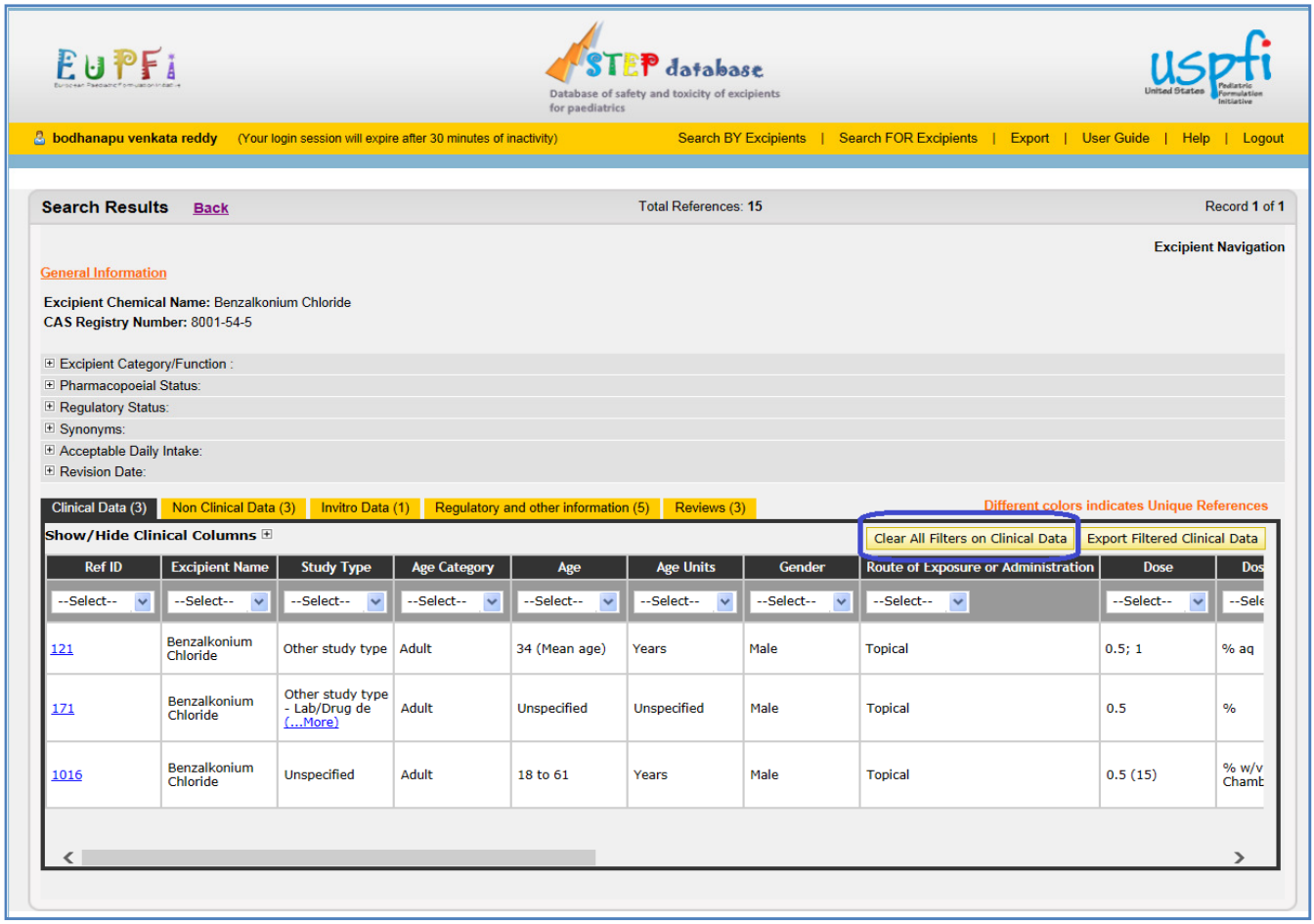


Filter criteria is on ‘Ref ID’ with ‘171, 1016’ value and ‘Age’ with ’18 to 61’ value.

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.



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:

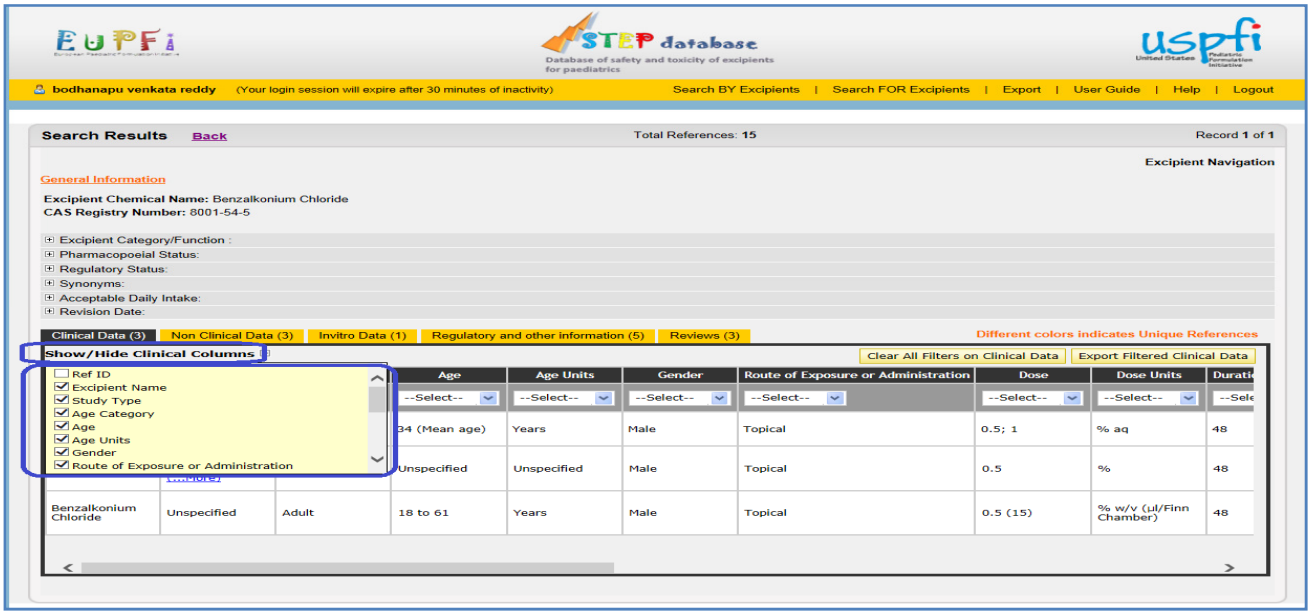
1. User can identify the filter(s) applied field(s) by observing the filter image(s) beside the field(s) name.
2. Once the filter is applied on the particular filter then again user wants to apply the filter on the same field then the only values which are visible are available in the dropdown to filter 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;

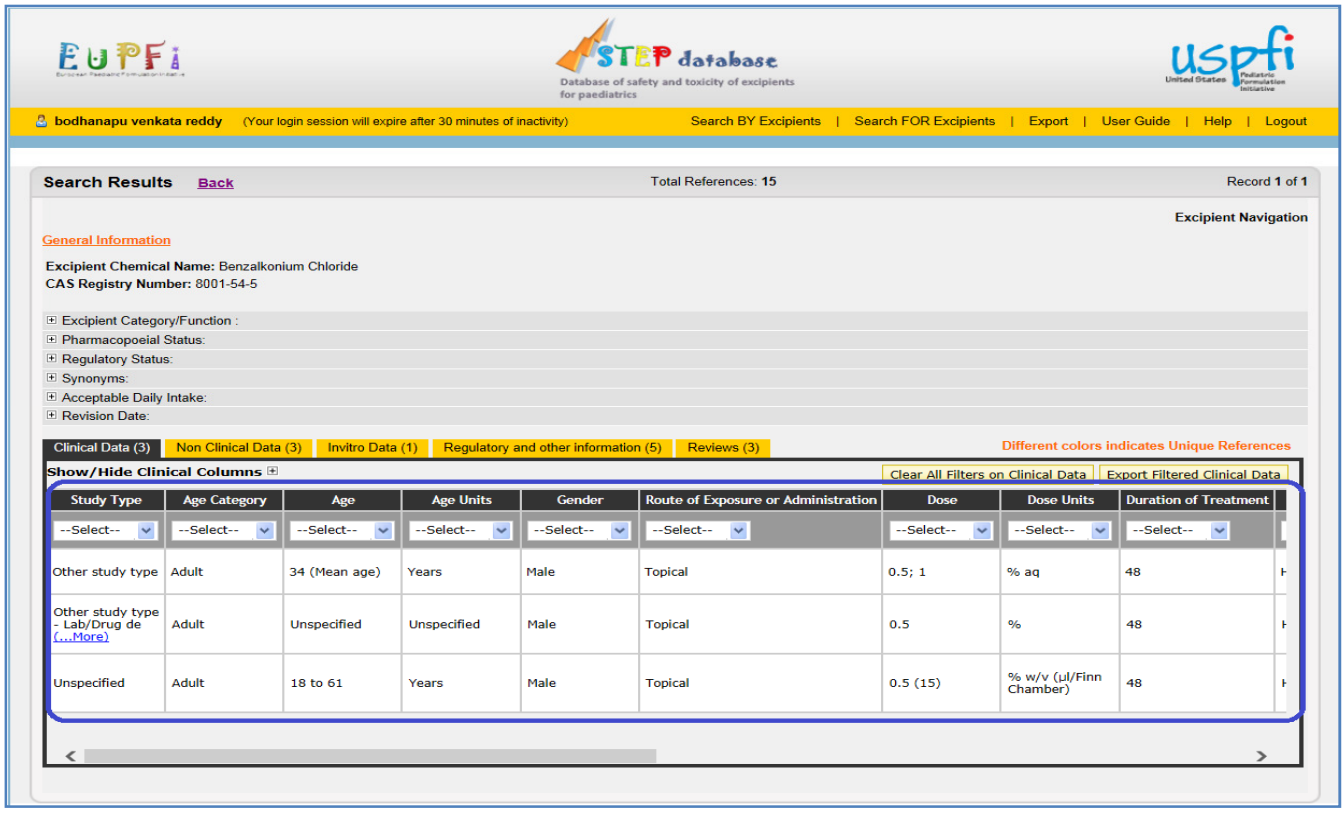
Proposed functionality is as below.

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



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.

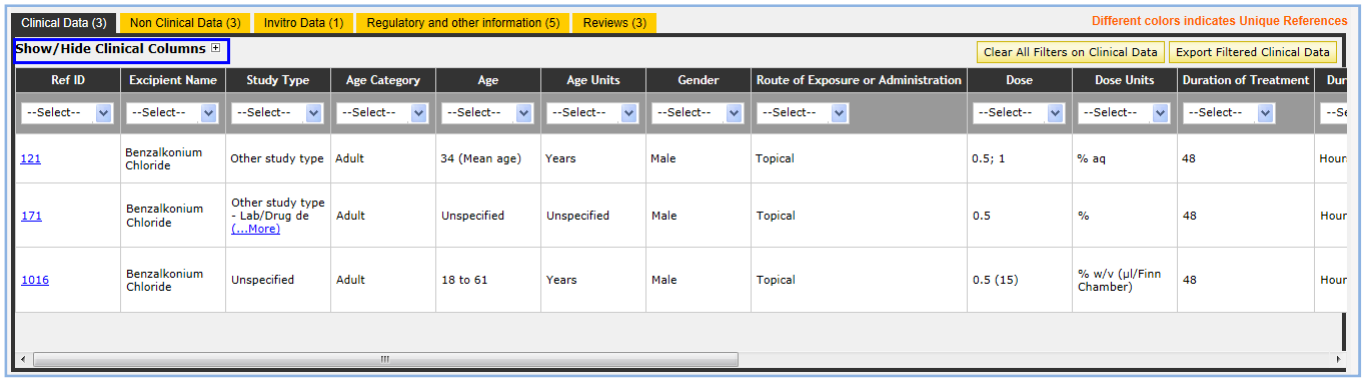


This will be applicable for all the fields in the Clinical Data tab where ever it is applicable.

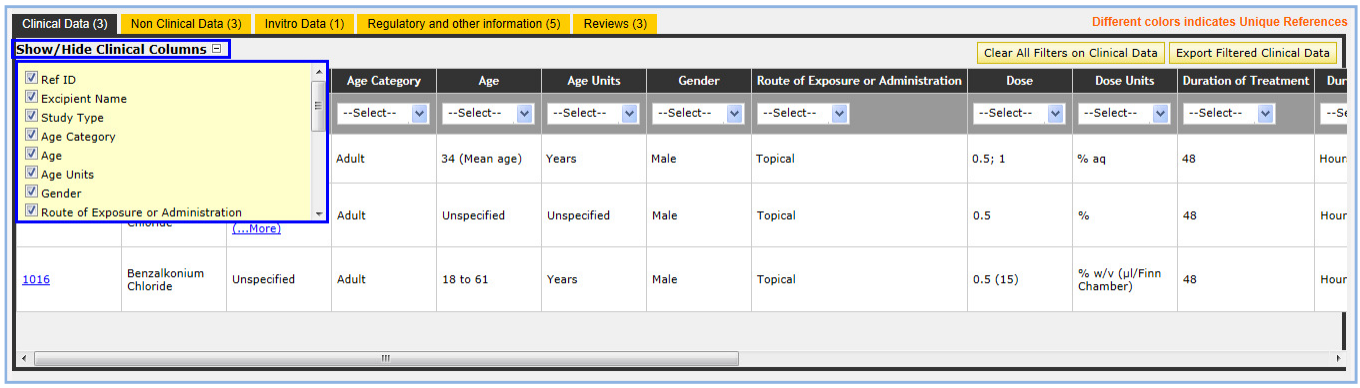
The same filtering functionality will be applicable for Non Clinical Data and Invitro Data tabs in the "Search Results" page.

8.8 Show/Hide Columns

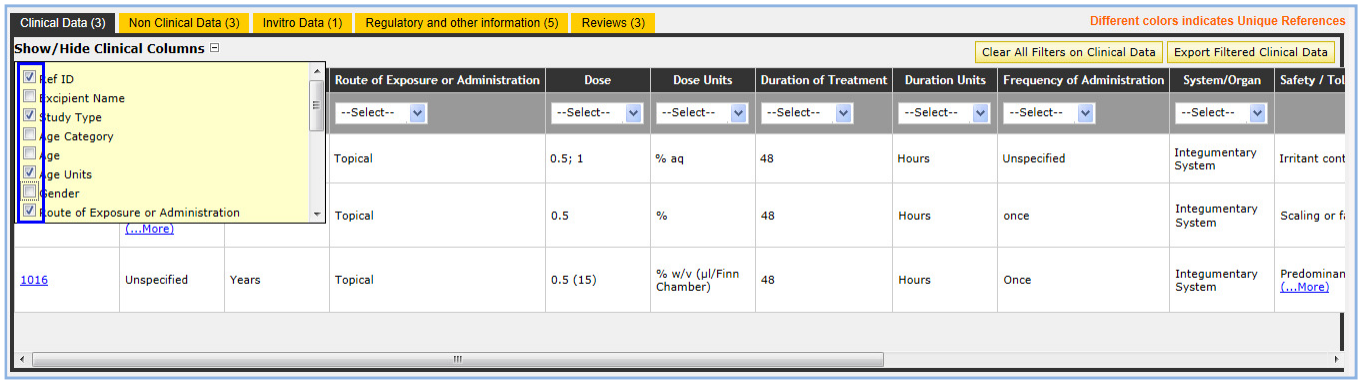
User is also allowed to view or to hide the required columns using the "Show/Hide Columns" as shown below



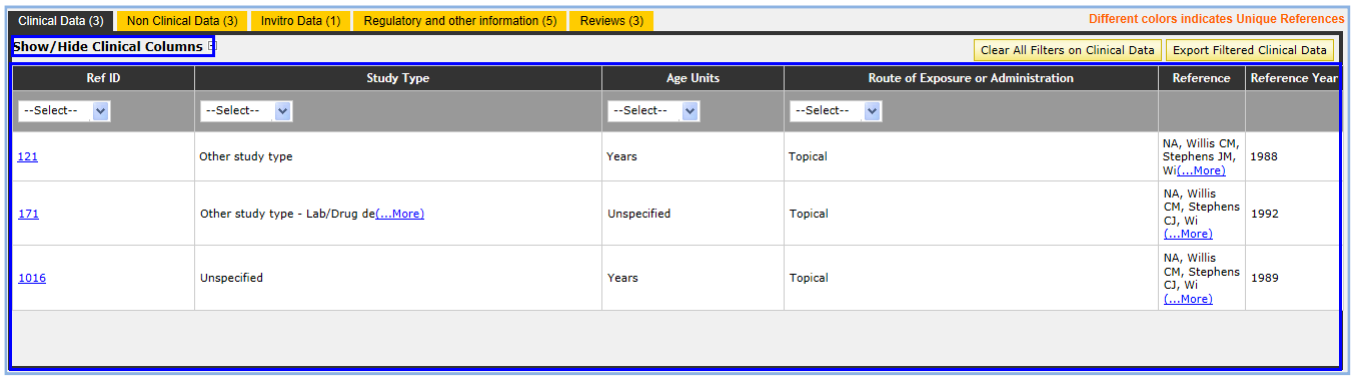
When user clicks "[+]" besides "Show/Hide Columns" then it displays all the columns in the page as shown below. By default all the columns appears in the checked state.



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

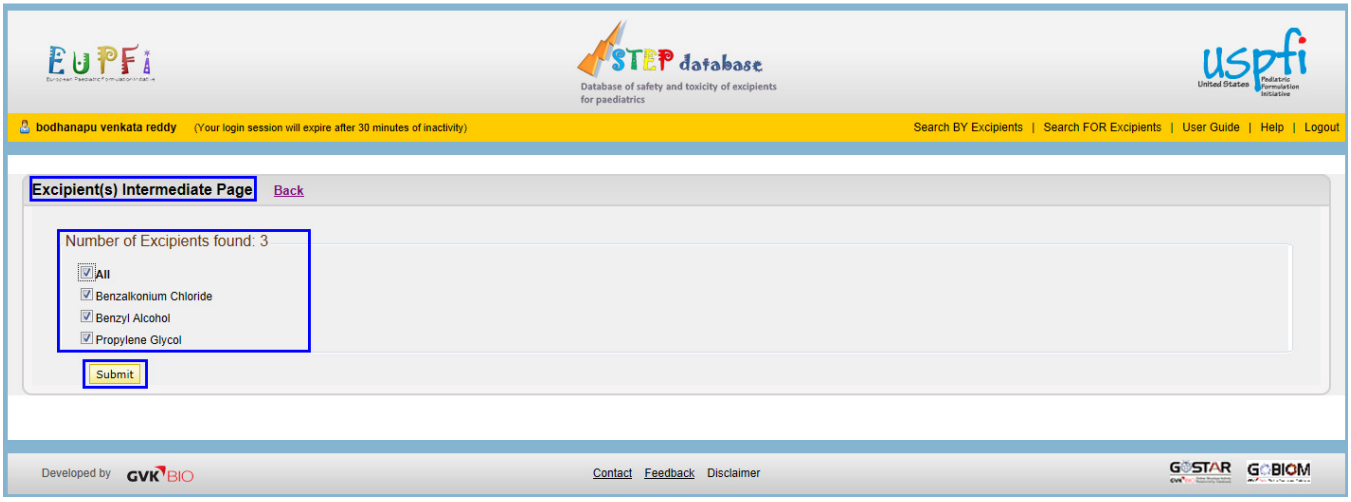


When user selects the required columns then the page gets refreshed and search results page only displays the selected columns as shown below

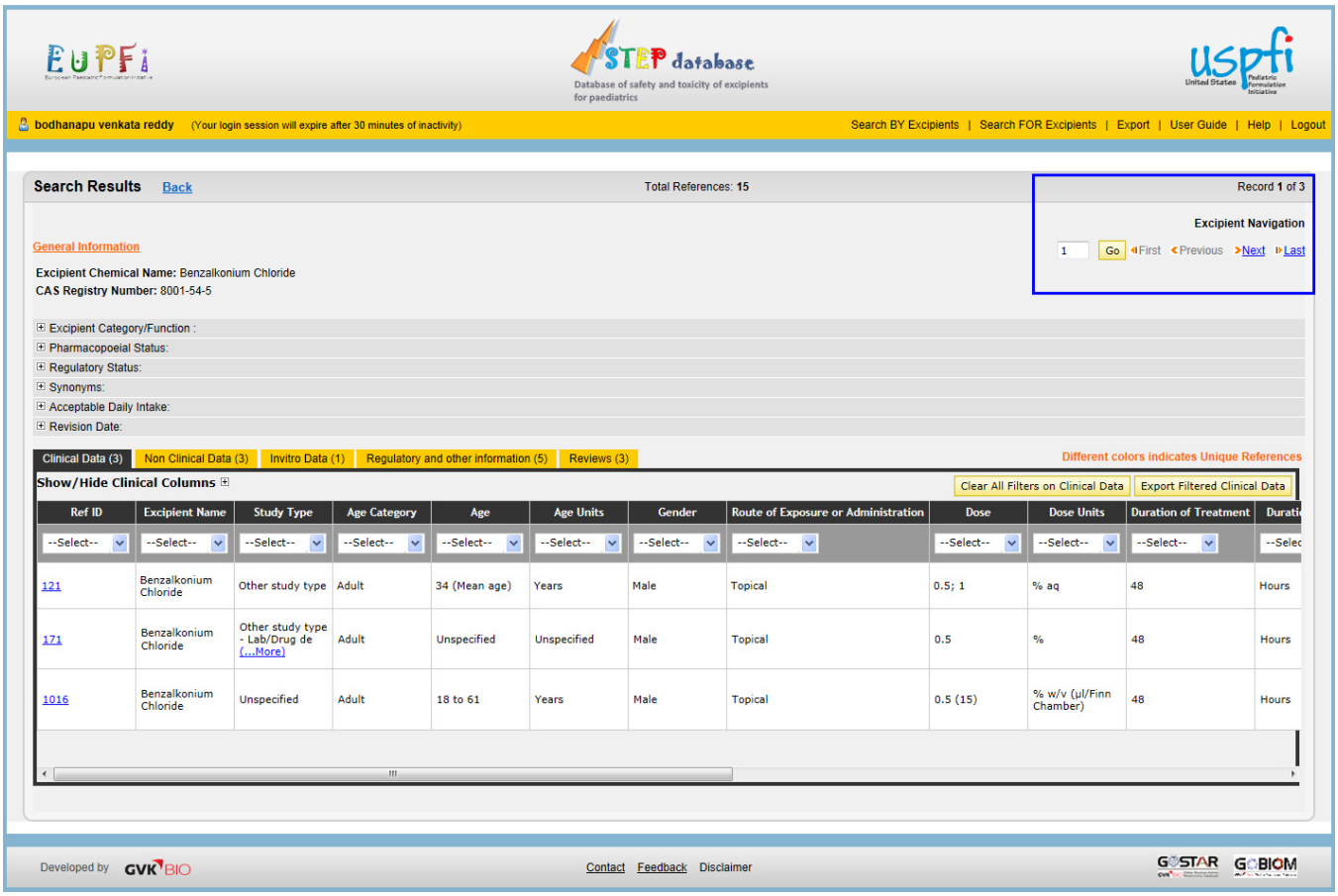


8.9 Navigations in Search Results page

Whenever user selects more than one excipient as shown below



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

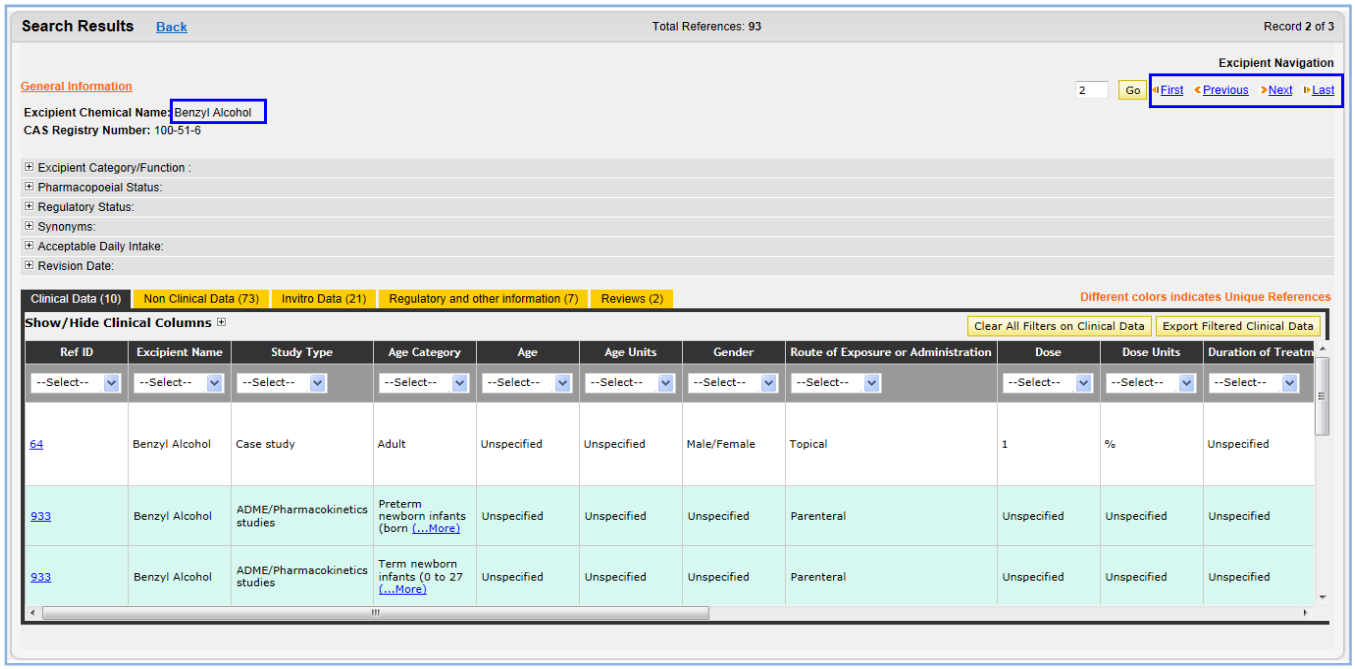


When user selects multiple excipients then only these navigation links appears using which user can view the search results information of the related excipient.

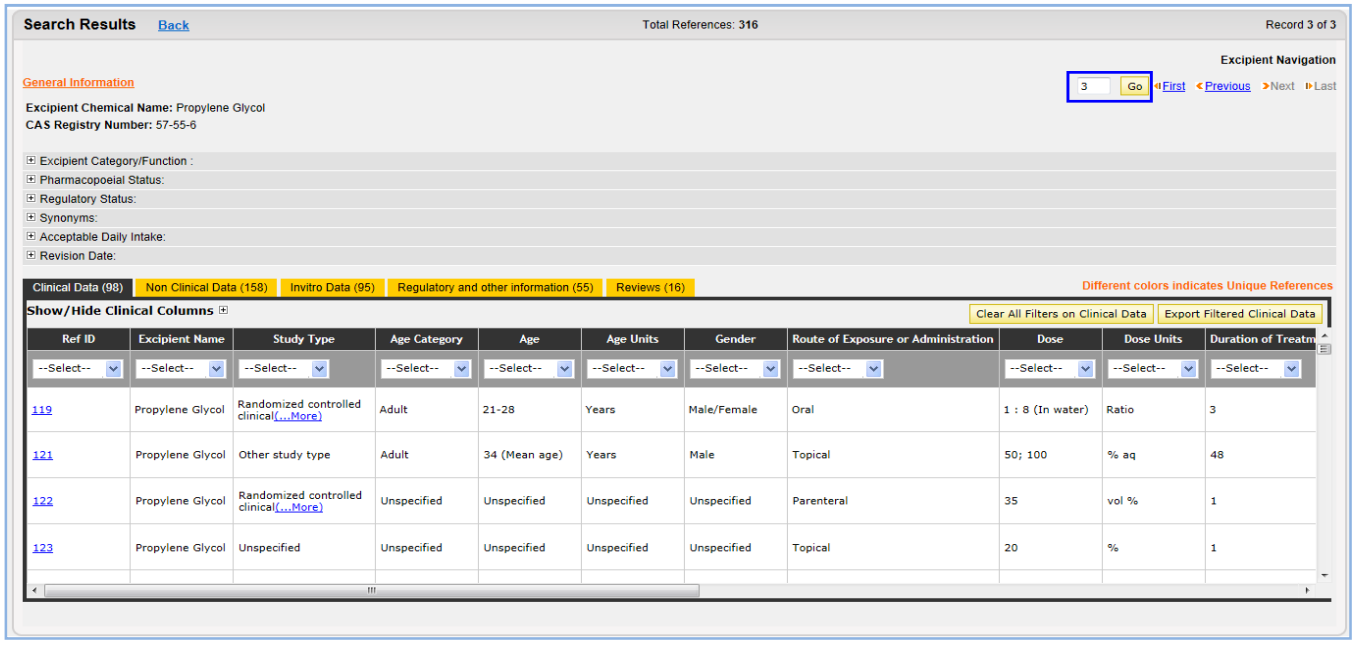
Based on the selection initially “Benzalkonium chloride” information is displaying as shown below.

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,



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



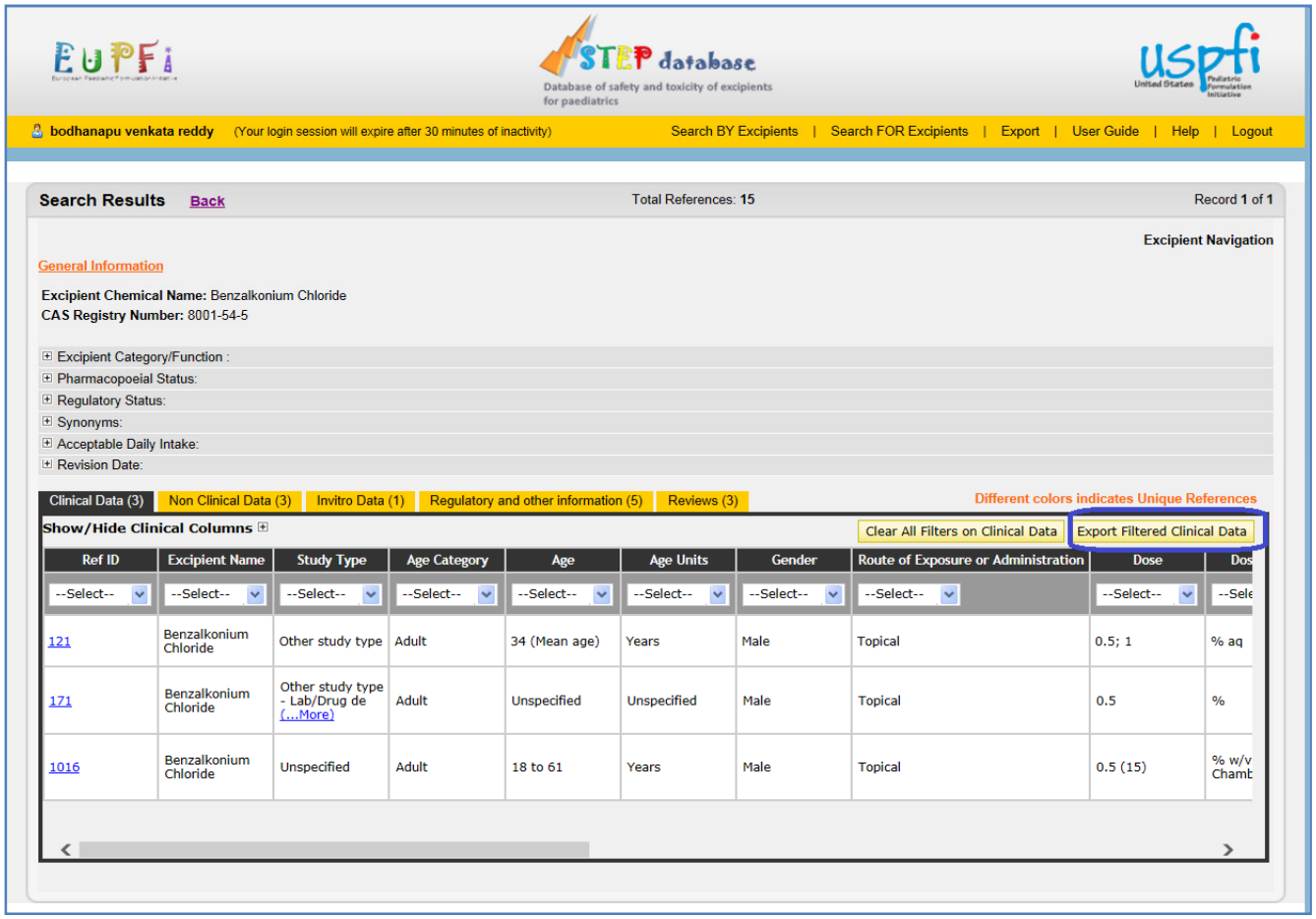
Note:

- 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)

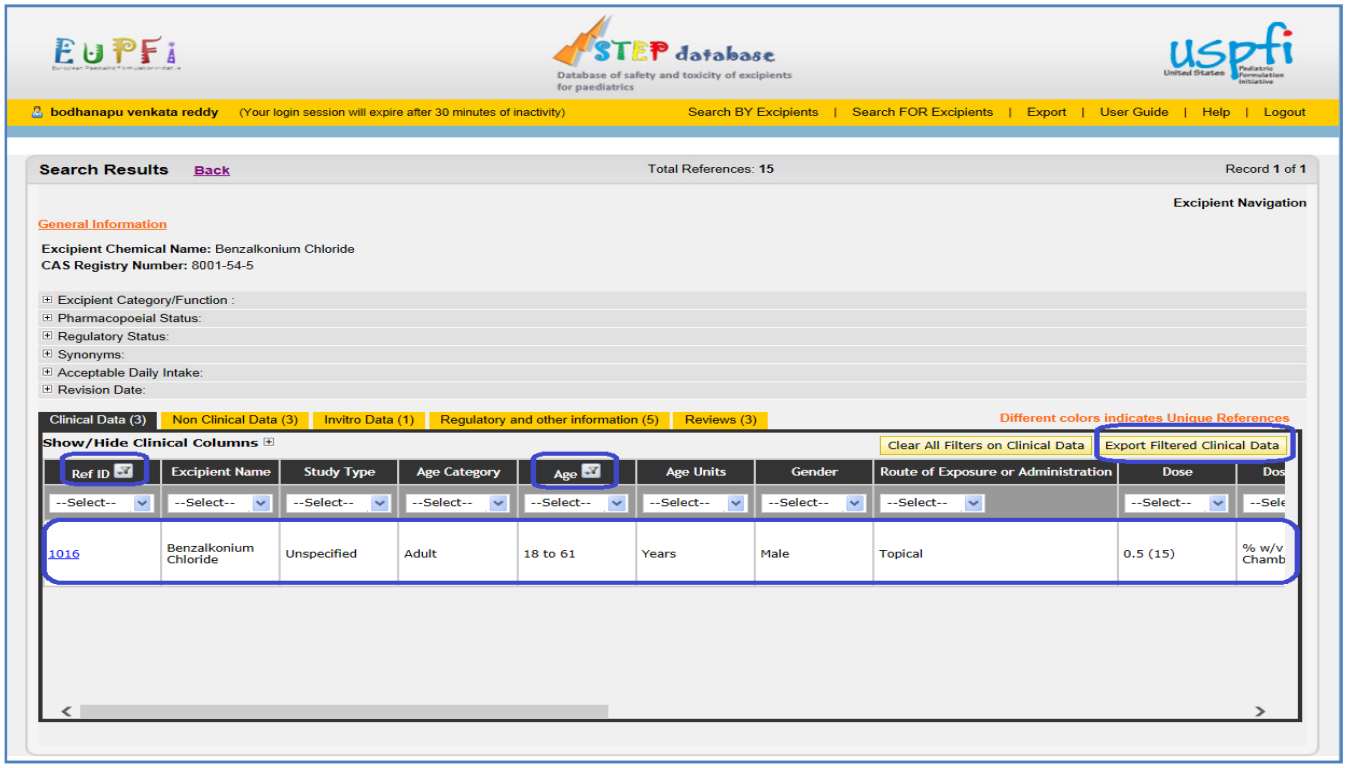
Here user can export the data that has been filtered either horizontally or vertically or combination of both filters. For this user can find the respective button(s) to export the filtered data in the search results page in 4 cases as given below.



Case: 1

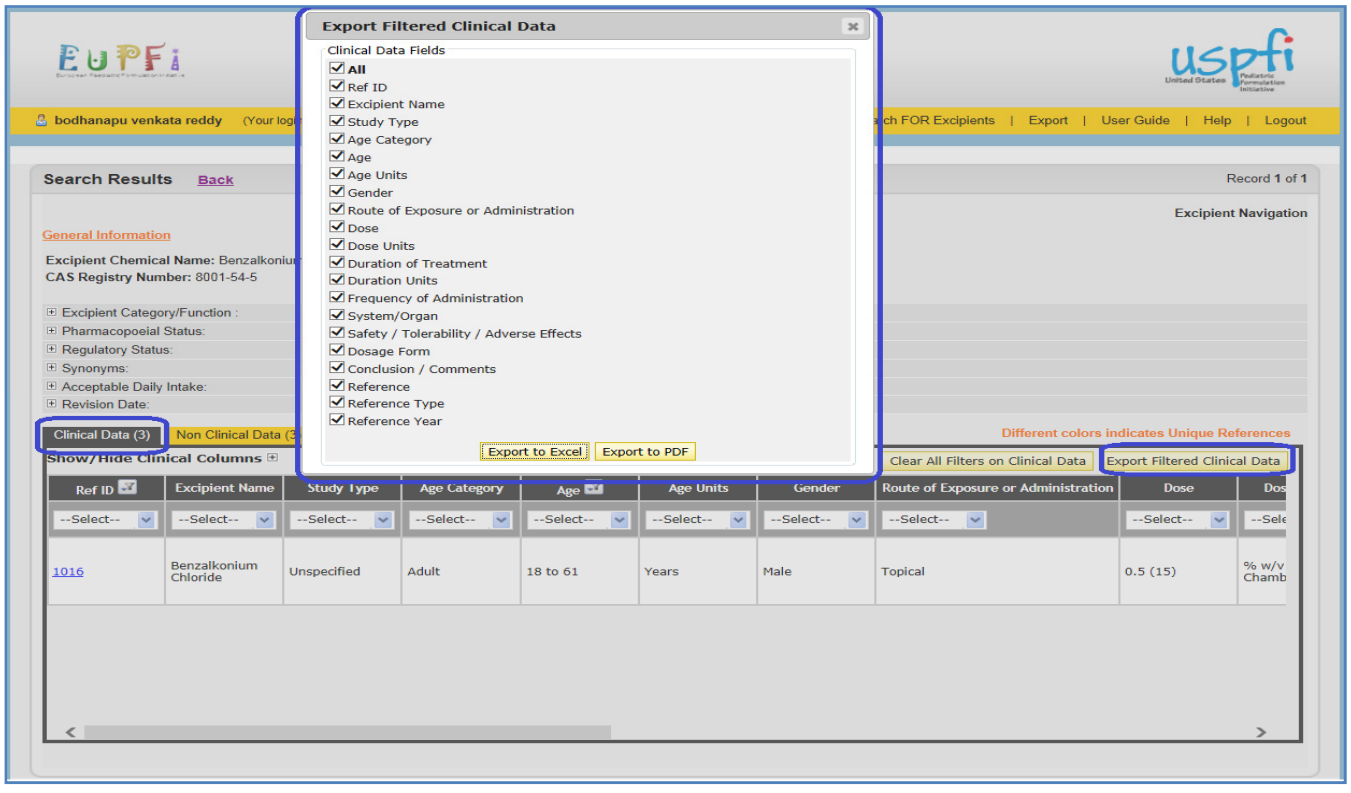
Filtered Data export by applying Horizontal Filters:

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



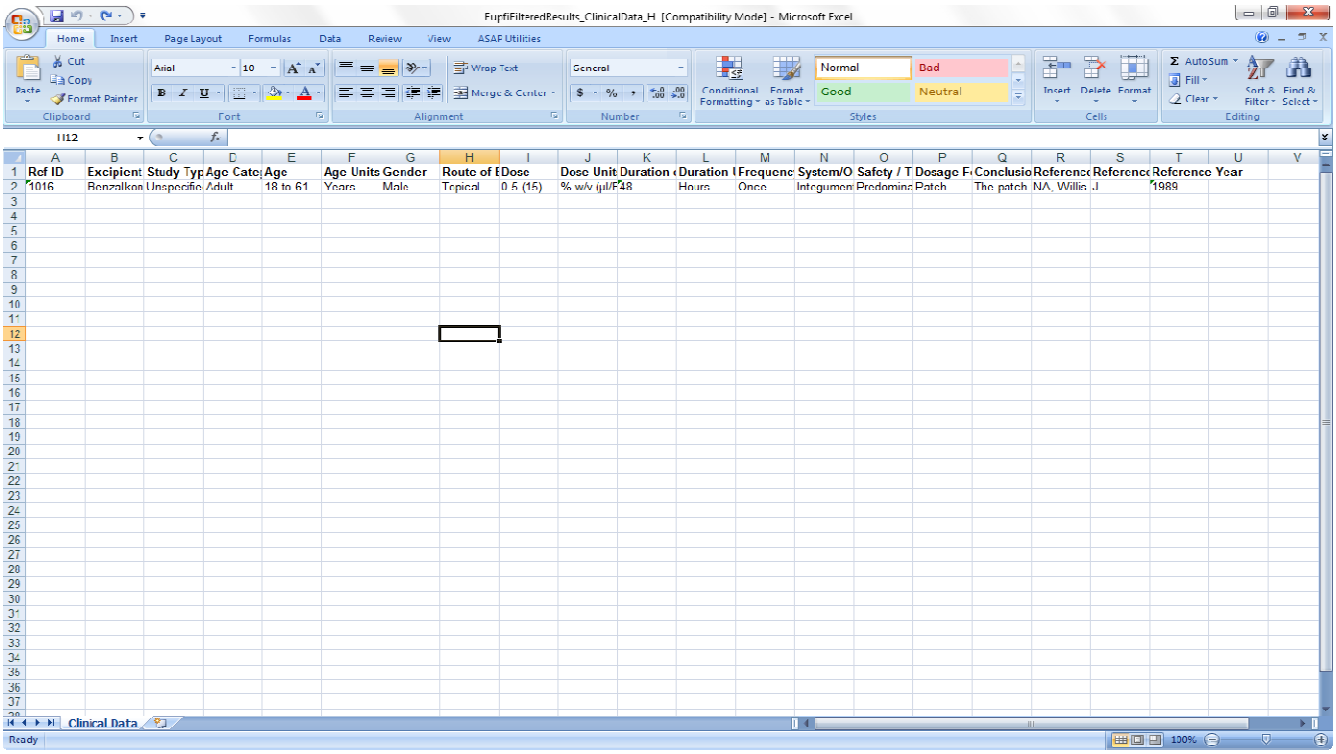
If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

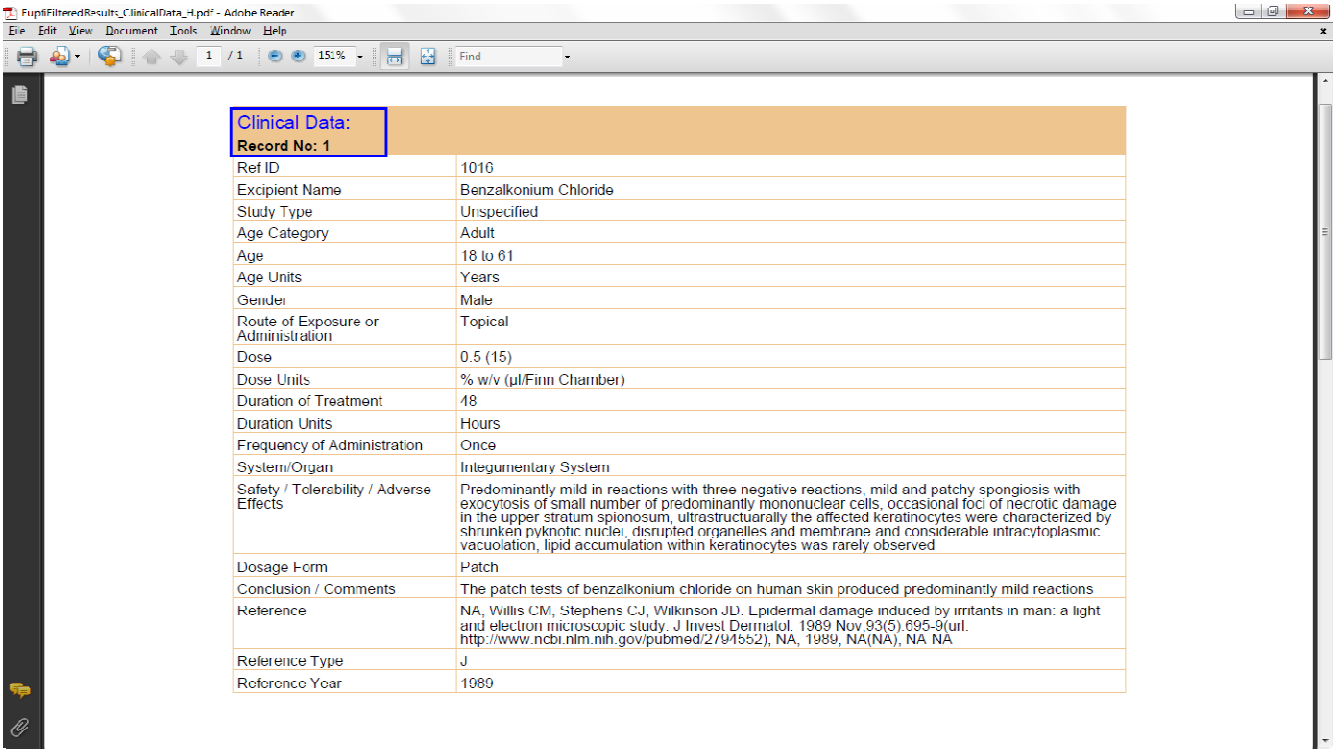
It will display one dialog box, which will contain all the fields available in that respective table like below.



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.





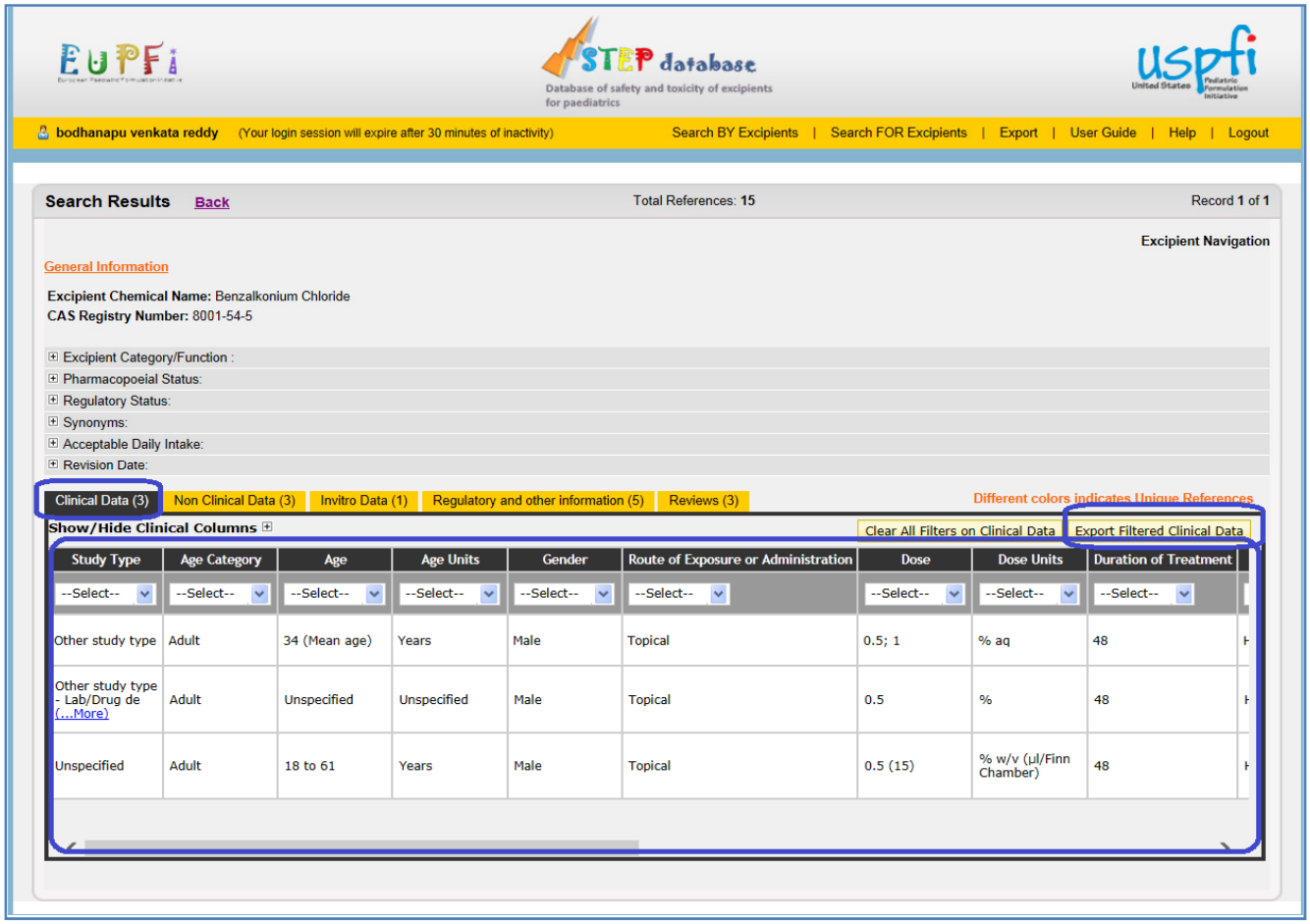
Clinical Data:
Record No: 1

Ref ID	1016
Excipient Name	Benzalkonium Chloride
Study Type	Unspecified
Age Category	Adult
Age	18 to 61
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5 (15)
Dose Units	% w/v (µl/Finn Chamber)
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Once
System/Organ	Integumentary System
Safety / Tolerability / 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 damage 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. 1989 Nov;93(5):695-9(url. http://www.ncbi.nlm.nih.gov/pubmed/2794552), NA, 1989, NA(NA), NA NA
Reference Type	J
Reference Year	1989

Case: 2:

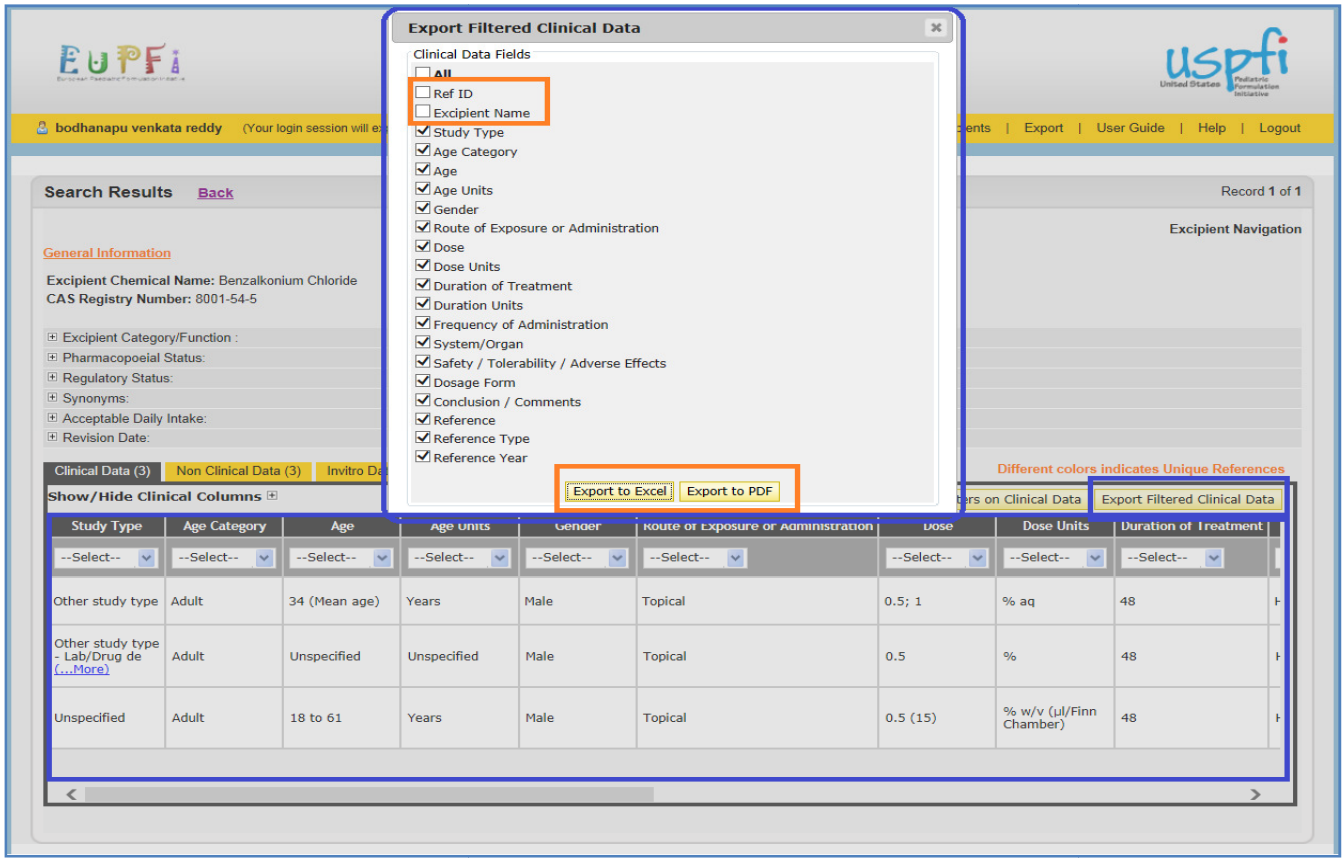
Filtered Data export by applying Vertical Filters:

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



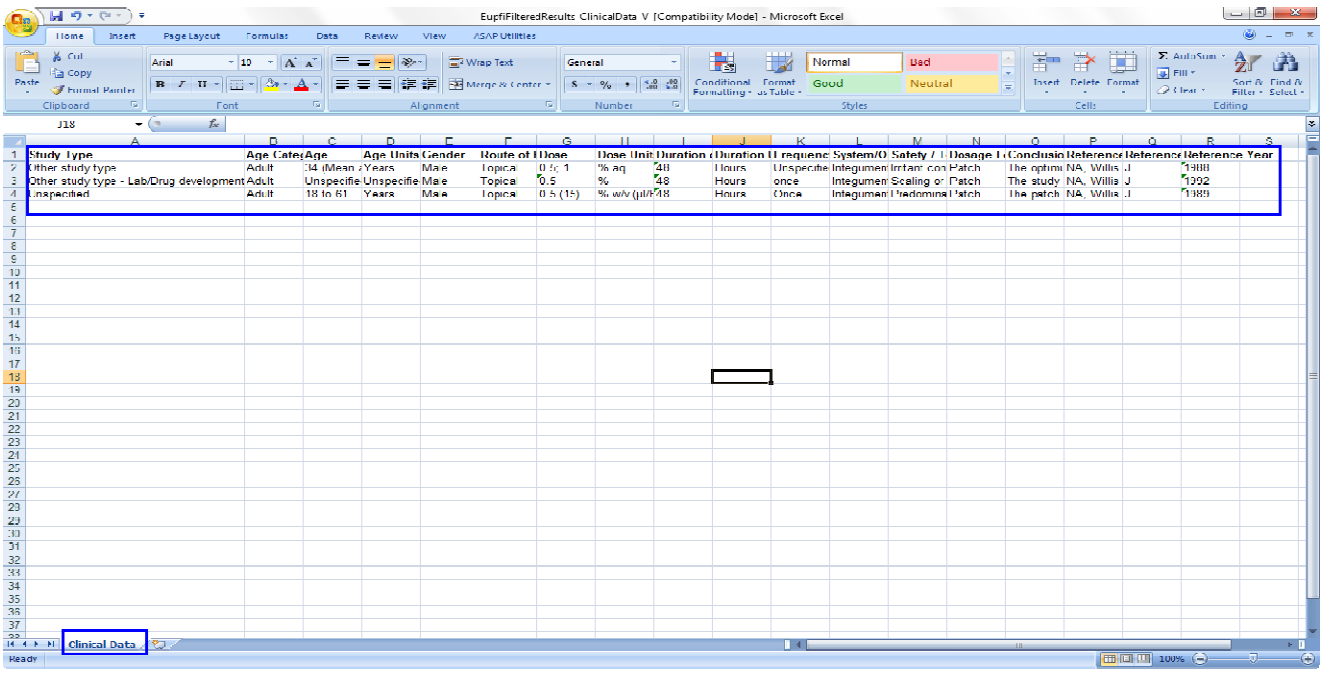
If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

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.



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

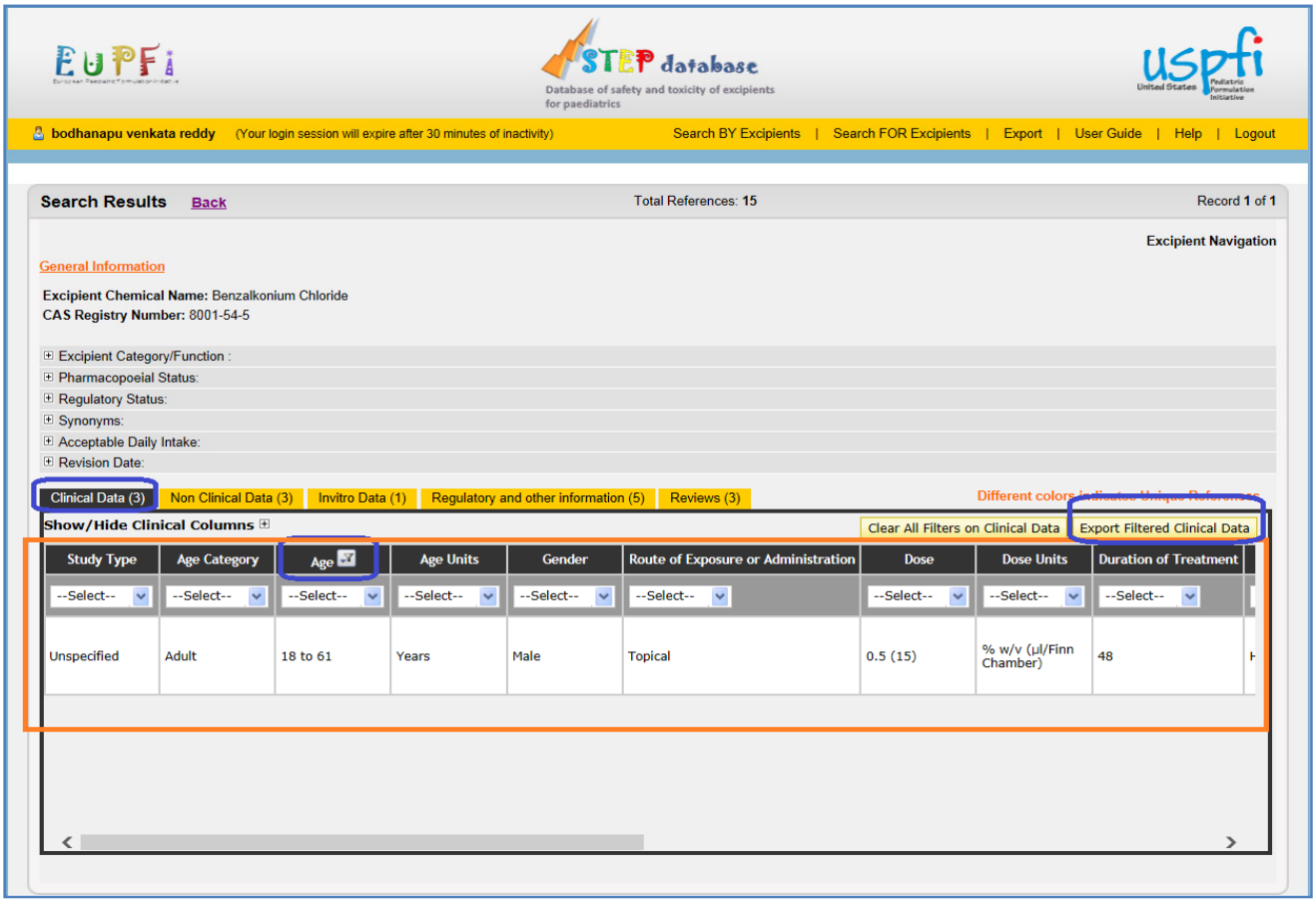
Based on the given export, the filtered data will be exported like below.



Clinical Data:	
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 Effects	Irritant contact dermatitis
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	Patch
Conclusion / Comments	The study in healthy non atopic male subjects indicates that the cellular changes like proliferation in 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 Type	J
Reference Year	1992
Record No: 3	
Study Type	Unspecified
Age Category	Adult
Age	18 to 61
Age Units	Years
Gender	Male
Route of Exposure or Administration	Topical
Dose	0.5 (15)
Dose Units	% w/v (µl/Finn Chamber)
Duration of Treatment	48
Duration Units	Hours
Frequency of Administration	Once
System/Organ	Integumentary System
Safety / Tolerability / 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 damage in the upper stratum spinosum, 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. 1989 Nov;93(5):695-9(url: http://www.ncbi.nlm.nih.gov/pubmed/2794552), NA, 1989, NA(NA), NA-NA
Reference Type	J

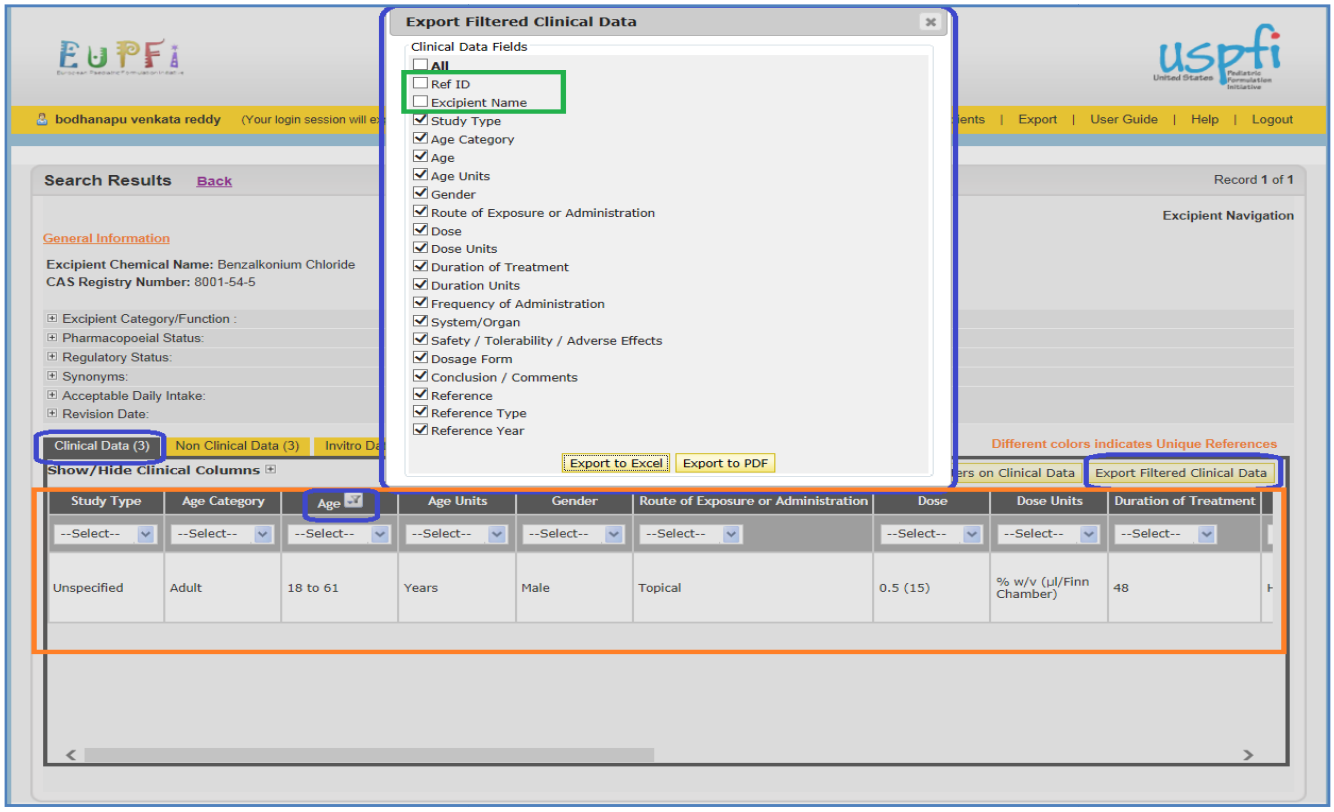
Case: 3:

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



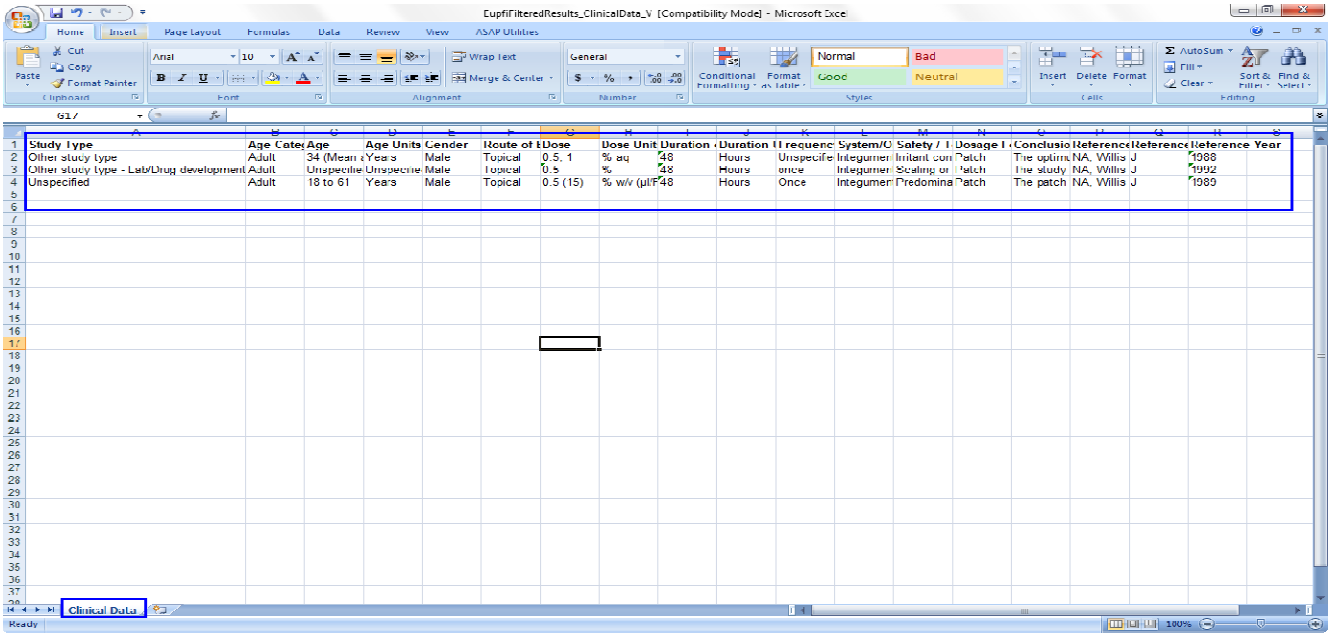
If user wants to export this filtered data, then click on “Export Filtered Clinical Data” button.

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.



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

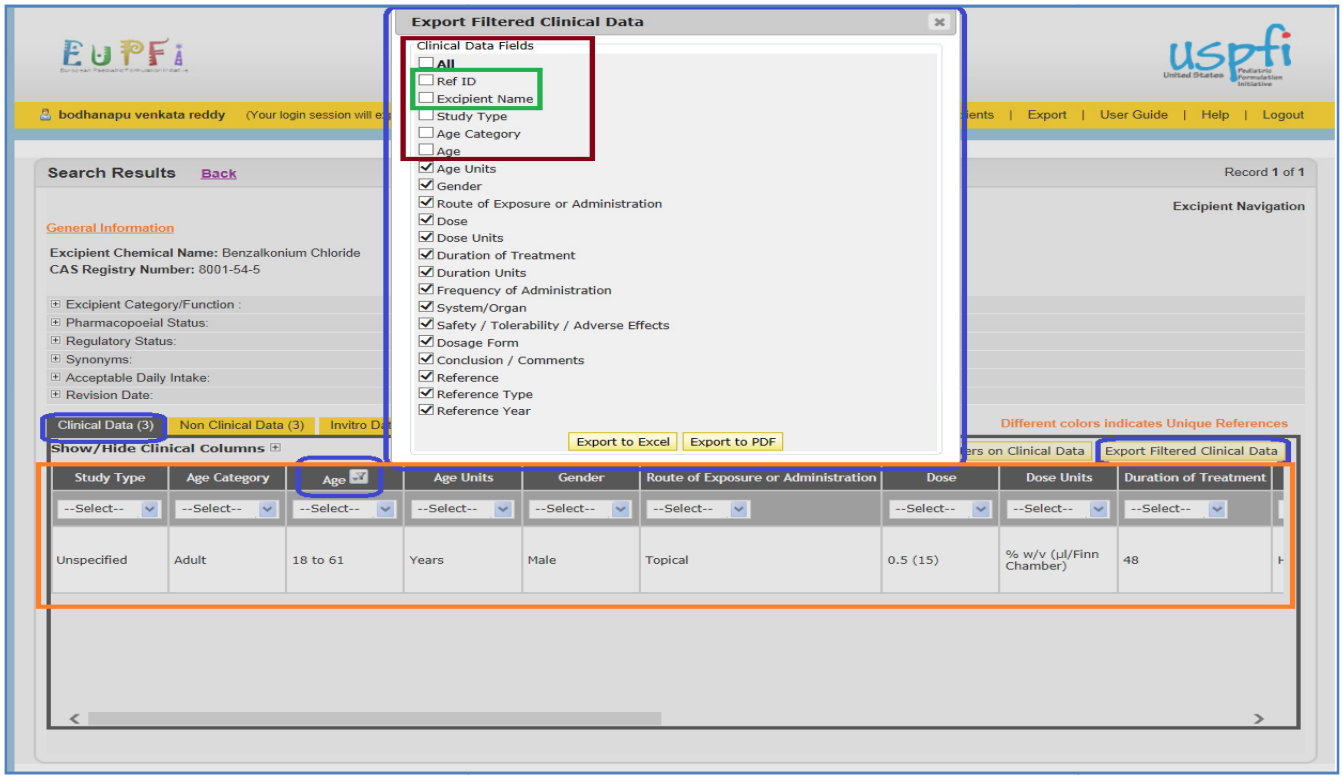
Based on the given export, the filtered data will be exported like below.



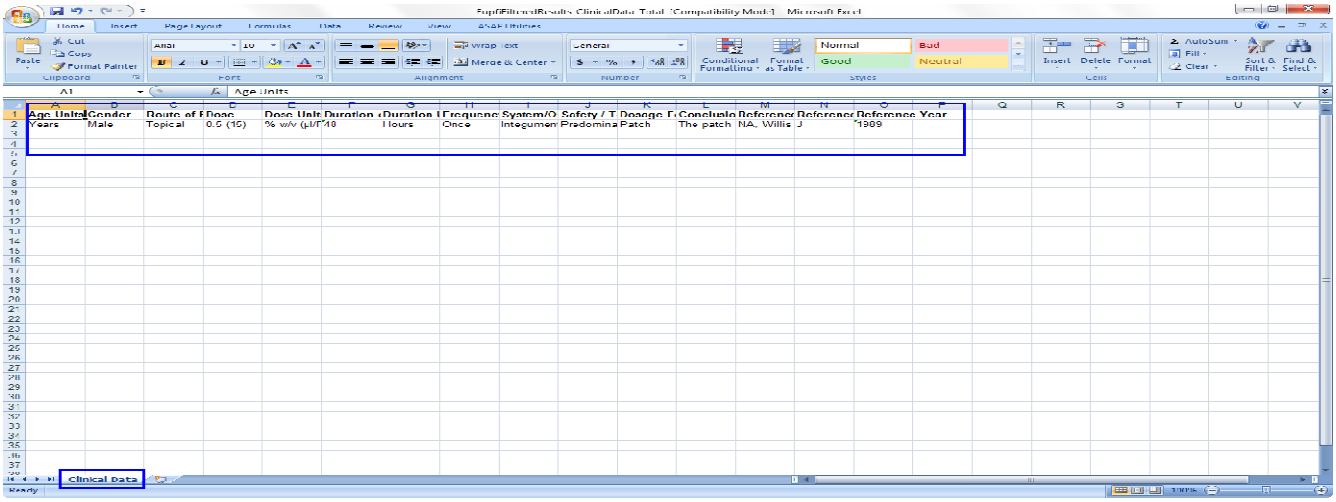
The Same data will be export in PDF format also.

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.



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



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.

Note:

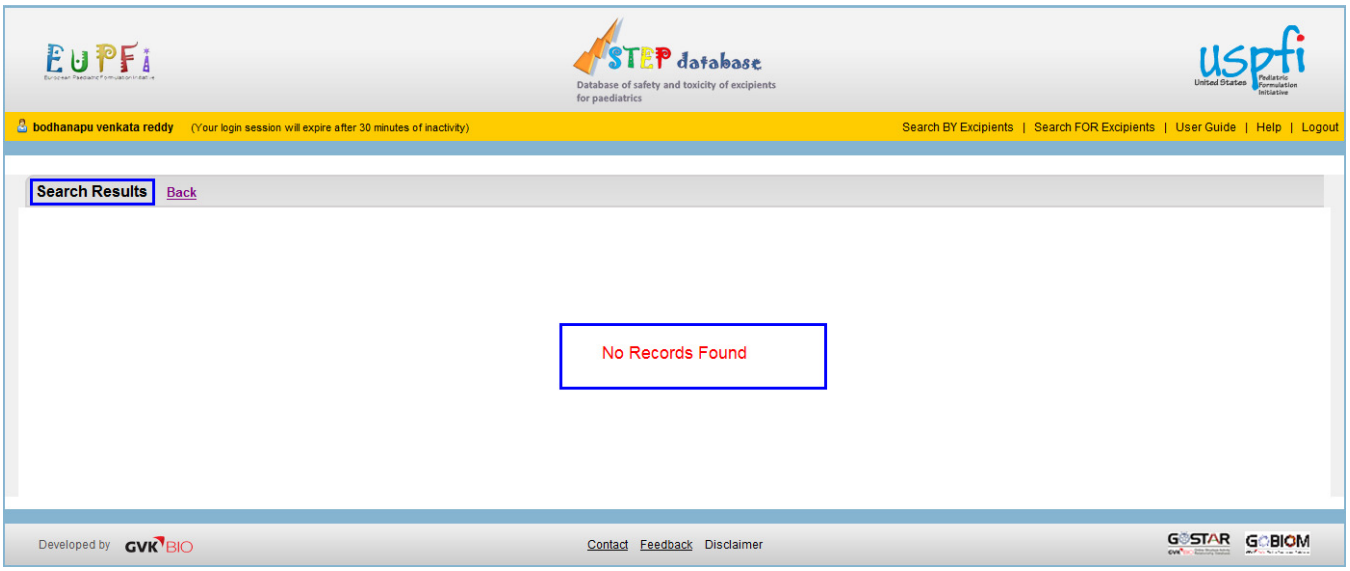
- Filtered data export is applicable for Clinical Data, Non Clinical Data and Invitro Data.
- The file names are

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

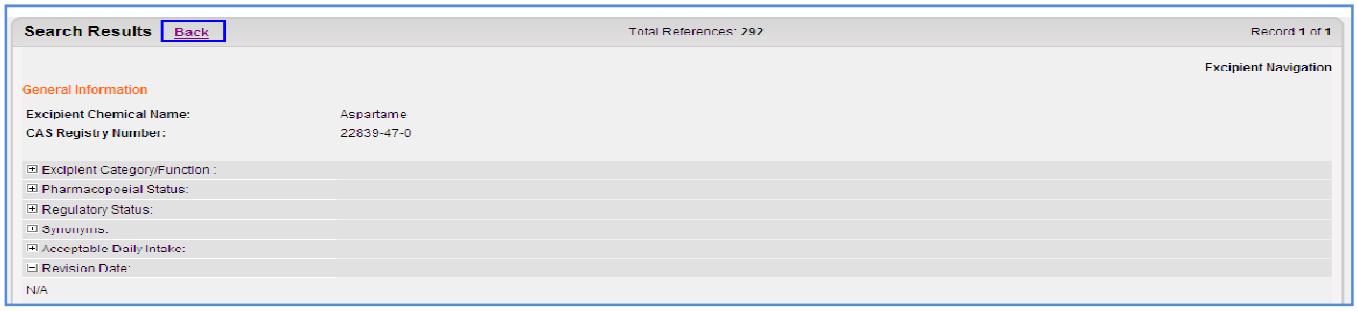
If there is no data available for the given search criteria, then the below failure (No Records Found) page will appears.



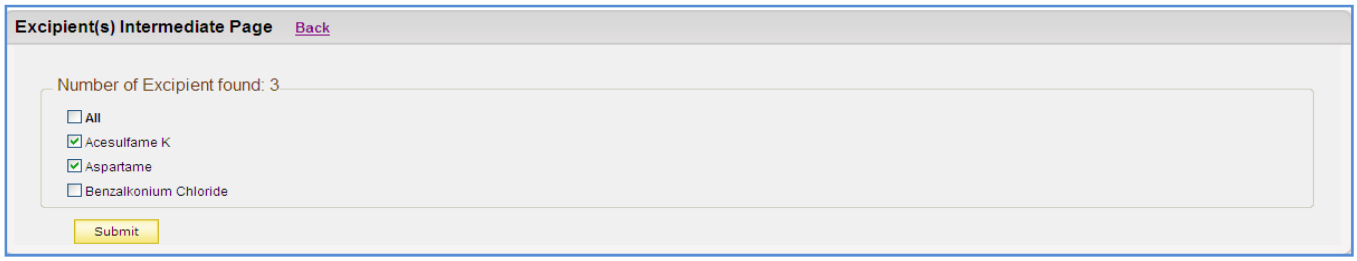
8.12 Back Link Functionality

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.



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



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.

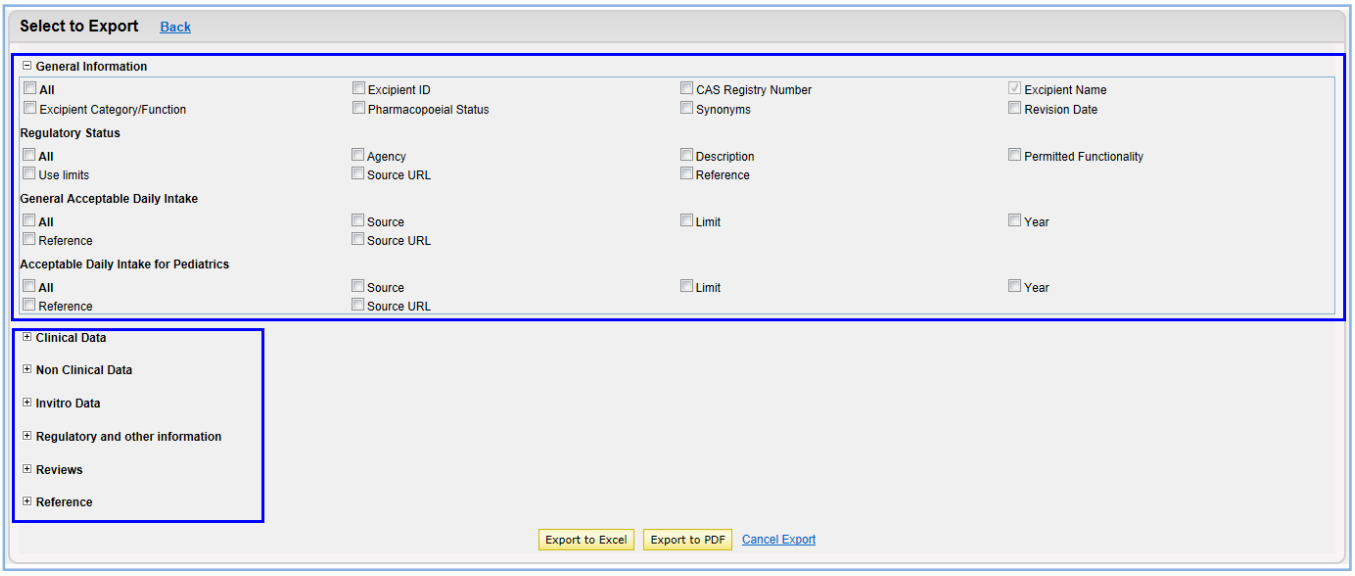
- Color coding is applicable for Clinical Data, Non Clinical Data and Invitro Data sections in the results page.

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

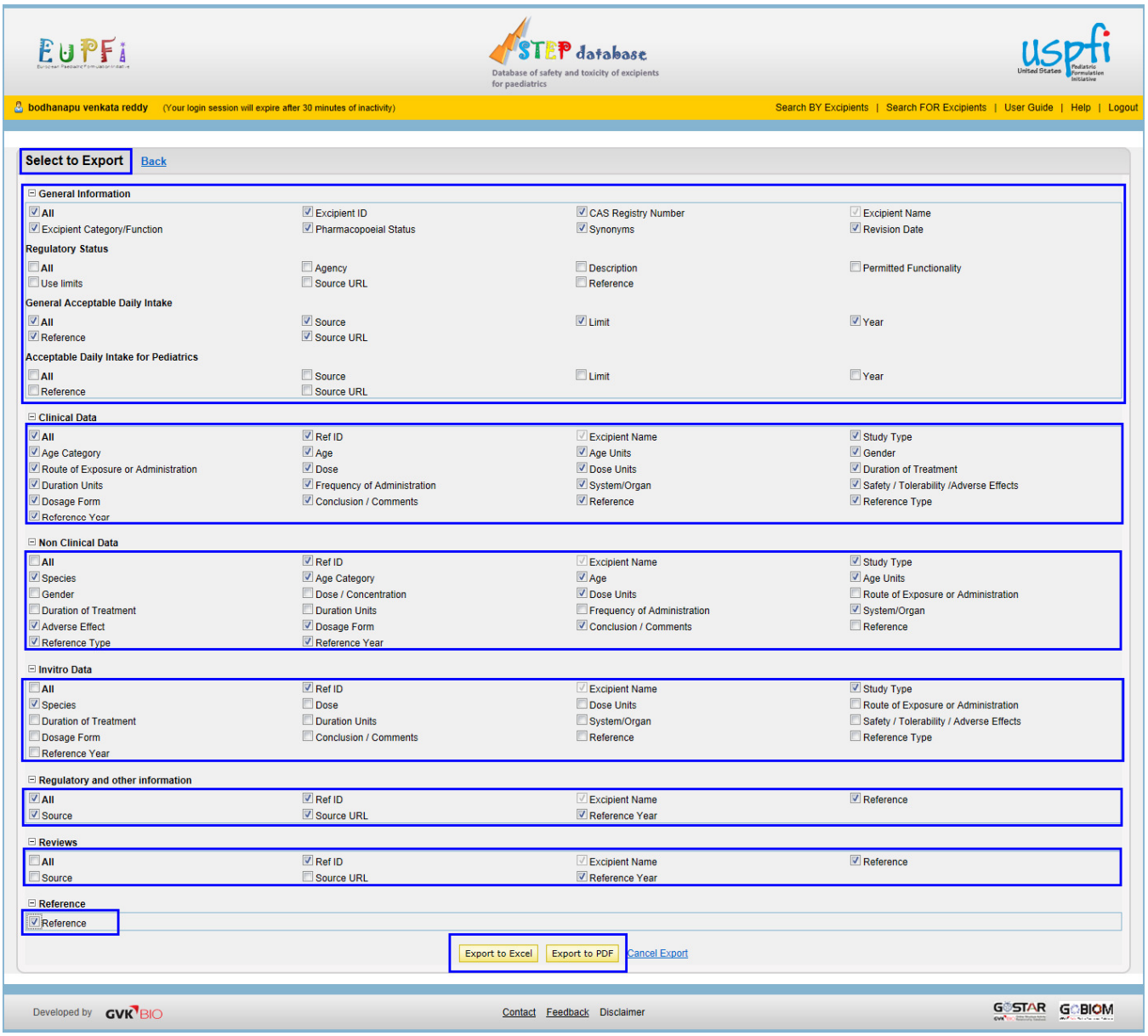
9 Export

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.

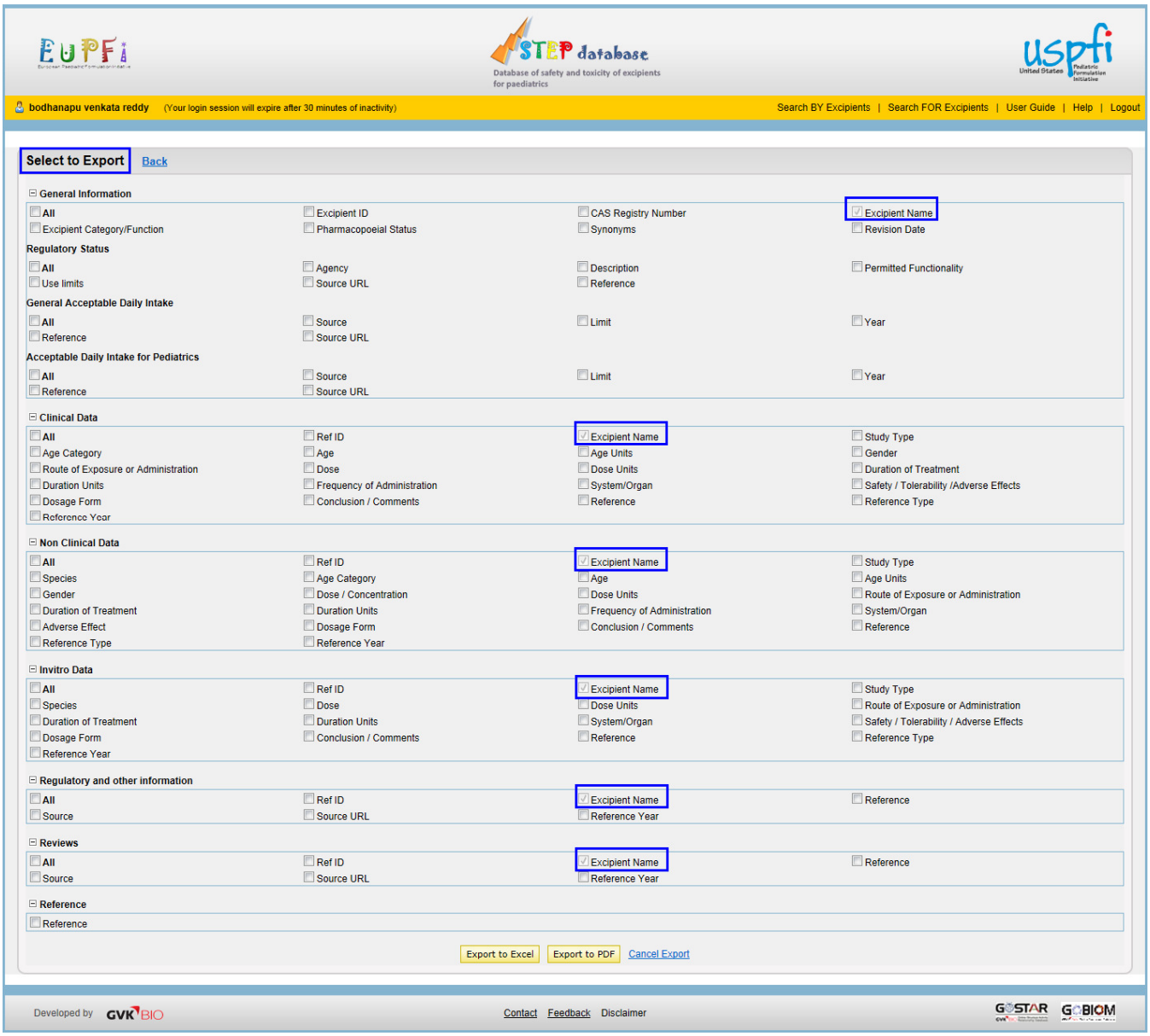
When user clicks “Export” link from the main menu bar “Select to Export” page appears. By default “General Information fields” appears in expanded mode, remaining fields in collapsed mode as shown below.



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.



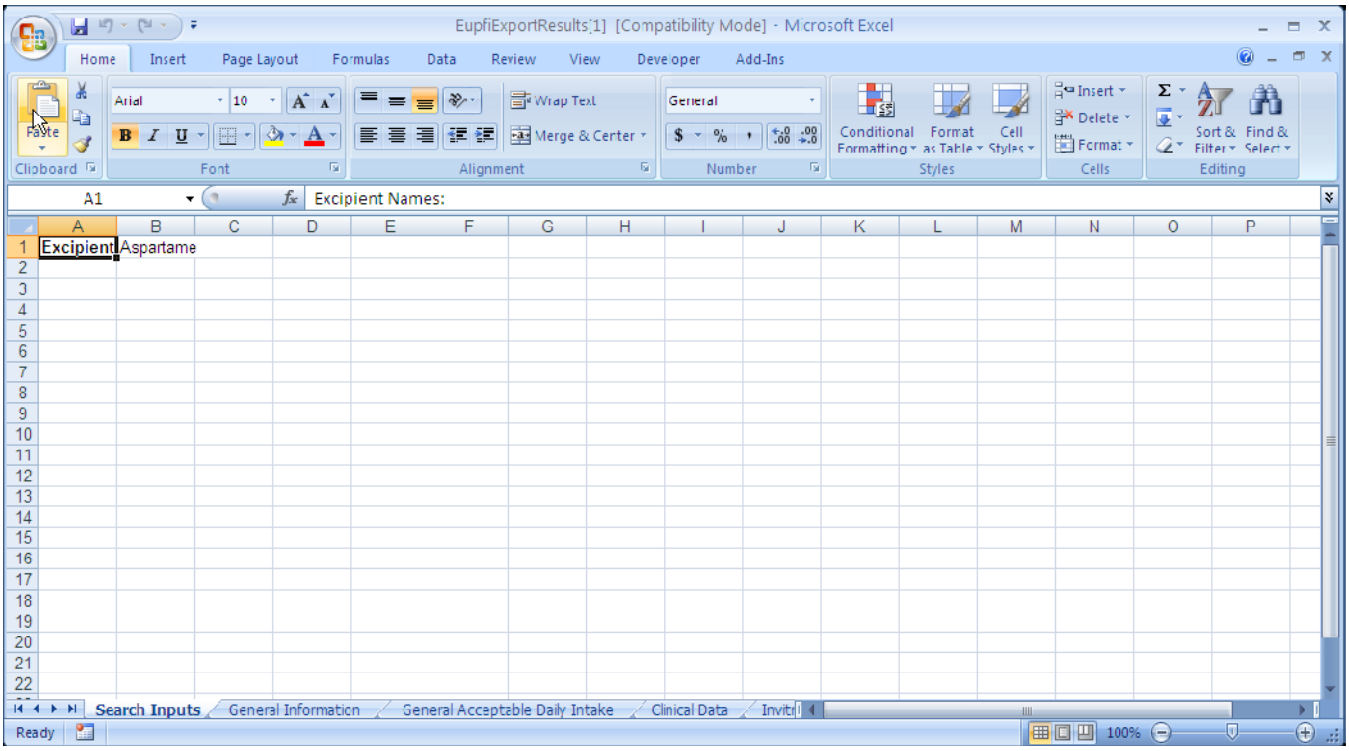
Note: Excipient name appears in selected mode by default and in disable mode as shown below.



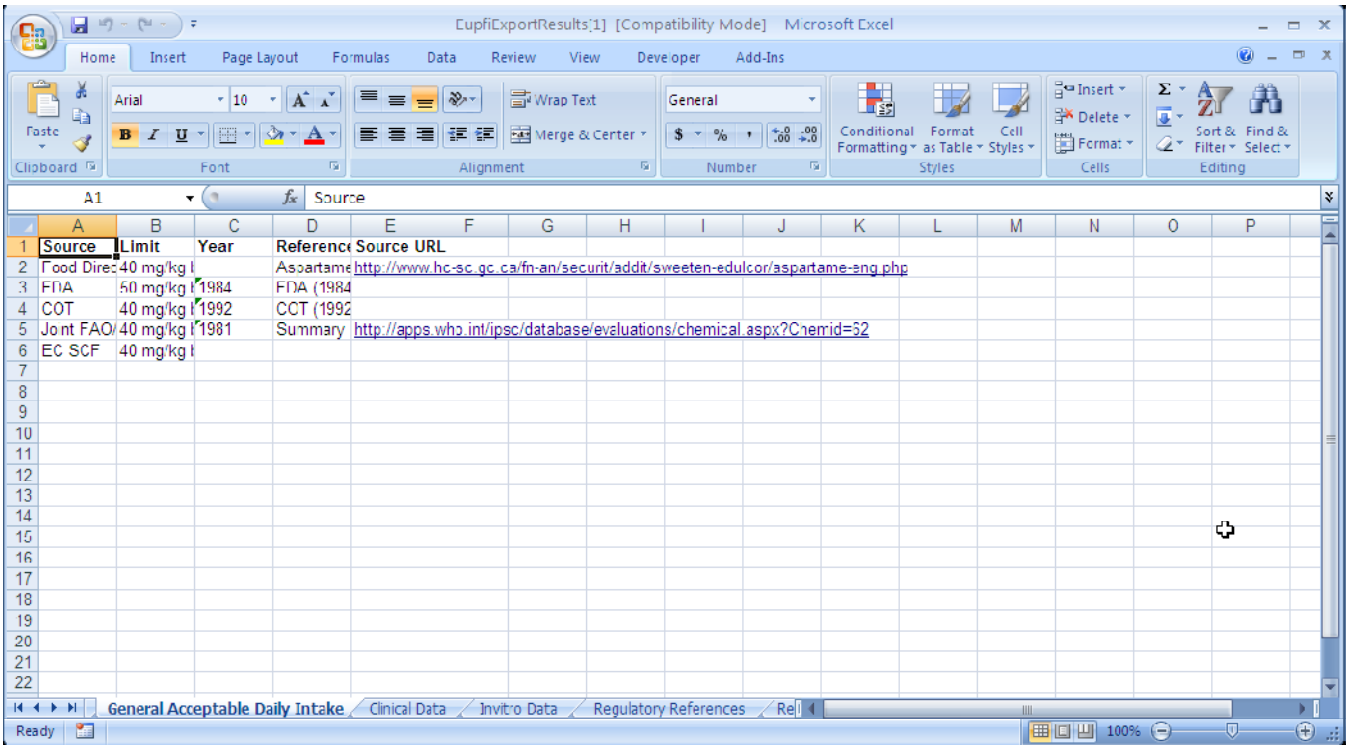
9.1 Export to Excel

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

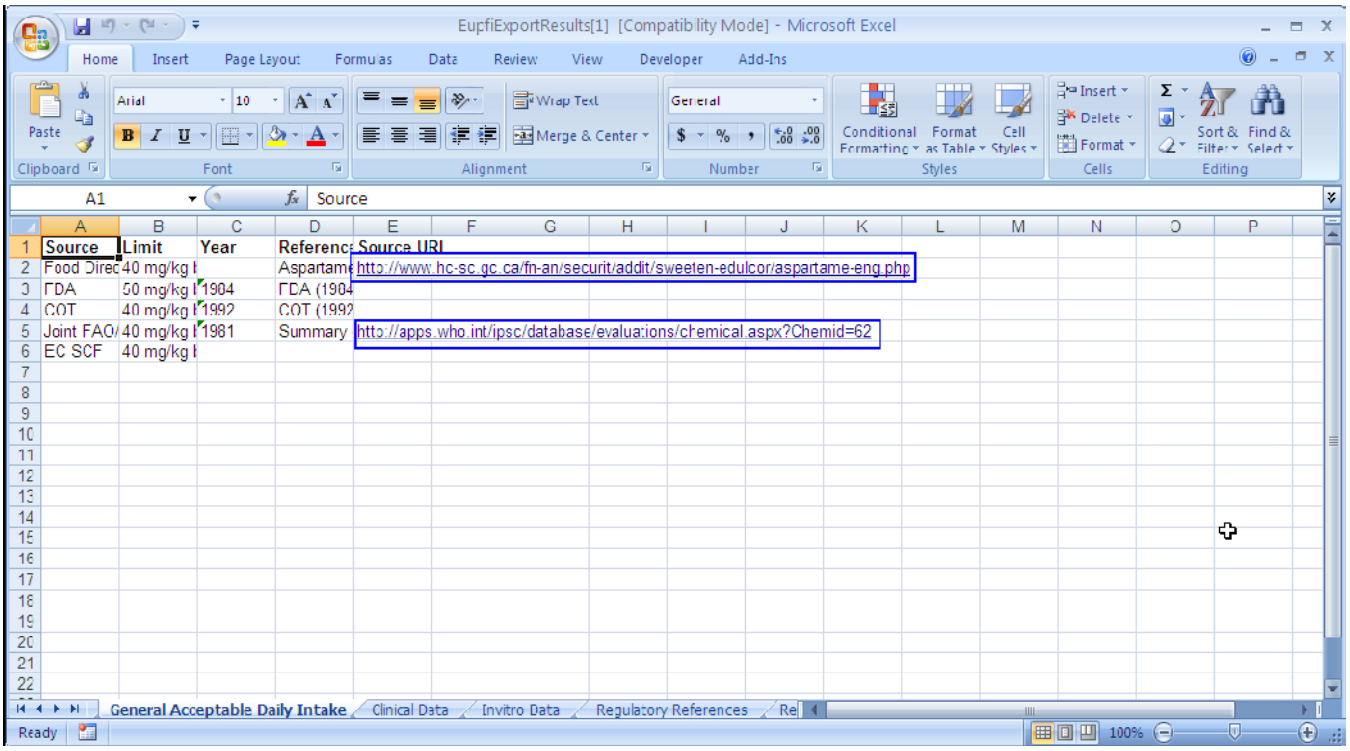
Click “Open” to open the excel file or save it using “Save”. Otherwise cancel the download using “Cancel” on the file download window. First page “Search Inputs” provides the information about the search criteria given by the user.



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.



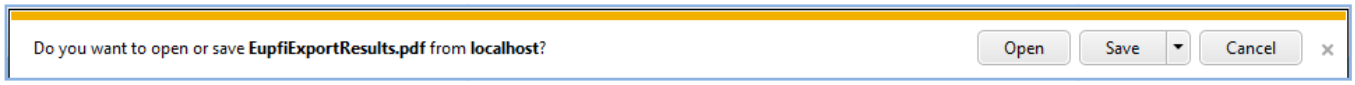
Note: Click "Source URL" from the excel, as shown below corresponding website appears in a new window as shown in the below figures respectively.


EupfiExportResults[1] [Compatibility Mode] - Microsoft Excel
Source
Source
Limit
Year
Reference Source URL
Food Direc 40 mg/kg
Aspartame http://www.hc-sc.gc.ca/fn-an/securit/addit/sweeten-edulcor/aspartame-eng.php
FDA 50 mg/kg 1984 FDA (1984
COT 40 mg/kg 1992 COT (1992
Joint FAO/ 40 mg/kg 1981 Summary http://apps.who.int/ipsc/database/evaluations/chemical.aspx?Chemid=62
EC SCF 40 mg/kg
General Acceptable Daily Intake
Clinical Data
Invitro Data
Regulatory References
Ready


WHO | Evaluations of Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Microsoft I...
http://apps.who.int/ipsc/database/ev
Delta Search
File Edit View Favorites Tools Help
SnagIt
Favorites
Suggested Sites
Get more Add-ons
Zimbra: I...
EUPFI - ...
WHO...
Page
Safety
Tools
The International Programme on Chemical Safety (IPCS)
WHO
ILO
UNEP
All WHO
This site only
Publications | About IPCS | Events
International Programme on Chemical Safety > Chemicals in food > Joint FAO/WHO Expert Committee on Food Additiv
Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JEC
ASPARTAME
General Information
Synonyms: ASPARTYL PHENYLALANINE METHYL ESTER
Internet
100%

9.2 Export to PDF

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



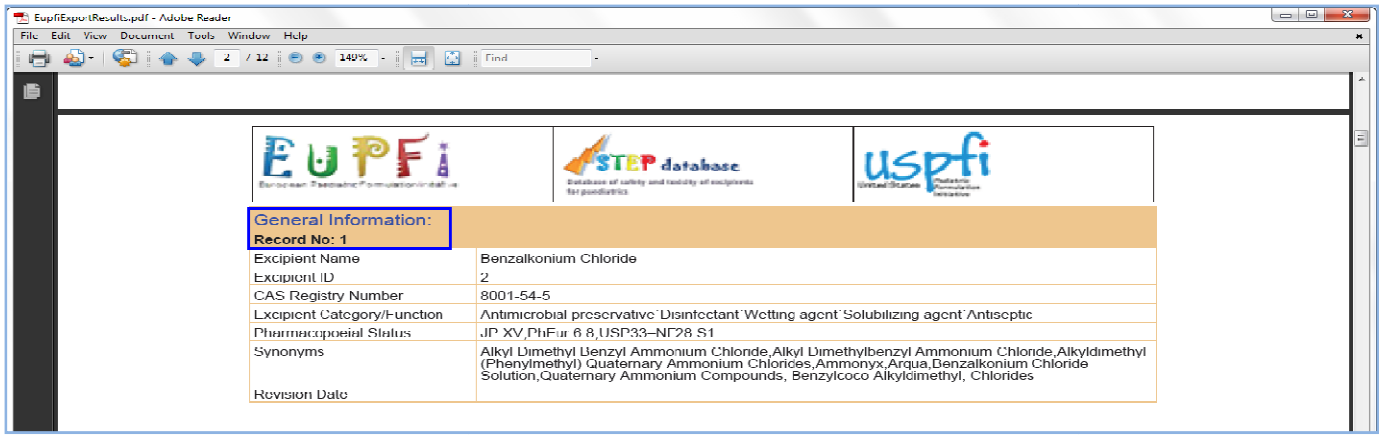
Click “Open” to open the PDF file or save it using “Save”. Otherwise cancel the download using “Cancel” on the file download window.

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

Search Inputs:

Excipient Name	Benzalkonium Chloride

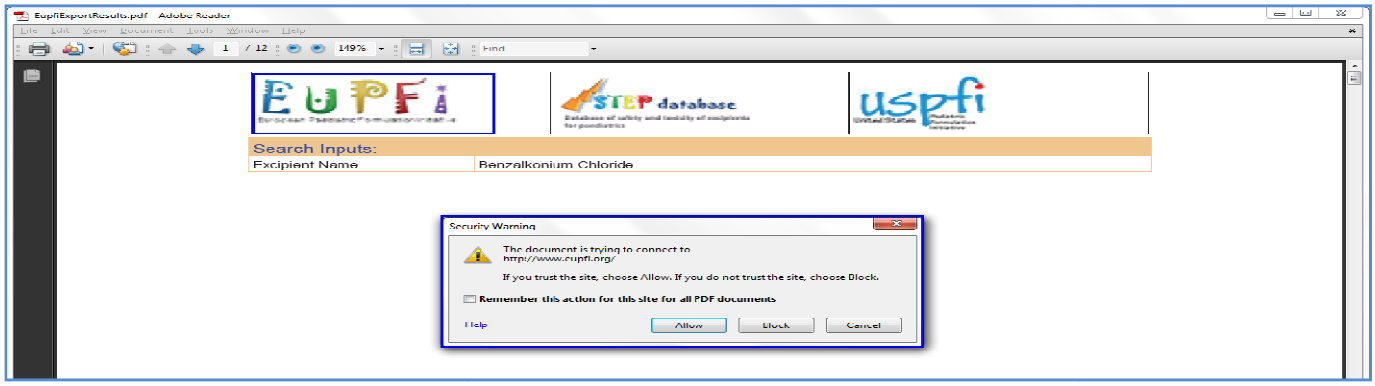
Based on the categorization data in the PDF appears in separate pages as shown below.



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 Benzyl Ammonium Chloride,Alkyl Dimethylbenzyl Ammonium Chloride,Alkyldimethyl (Phenylmethyl) Quaternary Ammonium Chlorides,Ammonyx,Arqua,Benzalkonium Chloride Solution,Quaternary Ammonium Compounds, Benzylcoco Alkyldimethyl, Chlorides
Revision Date	

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



If user clicks on the Allow button then it will display like below.

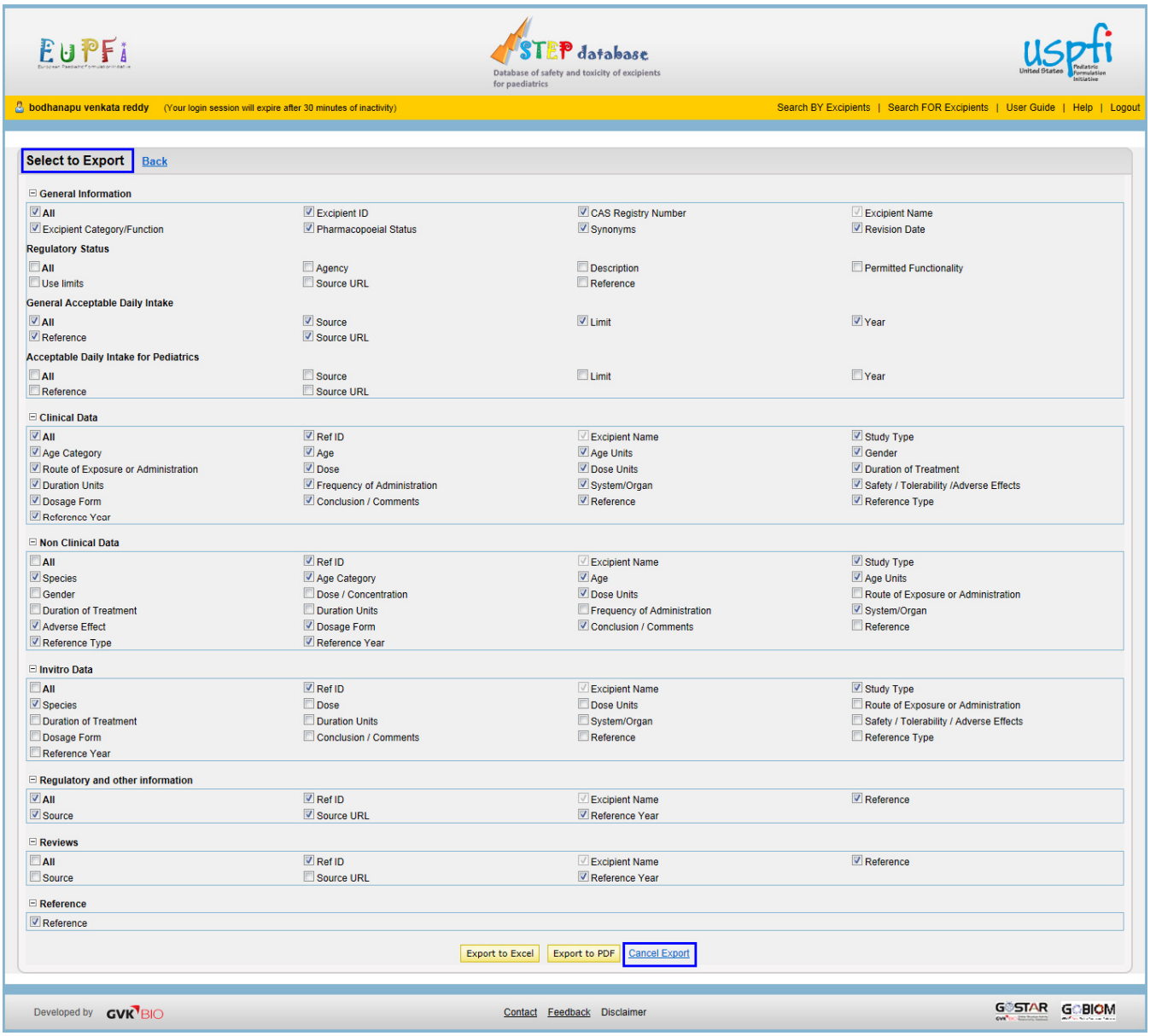
Note:

- 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).

- 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



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

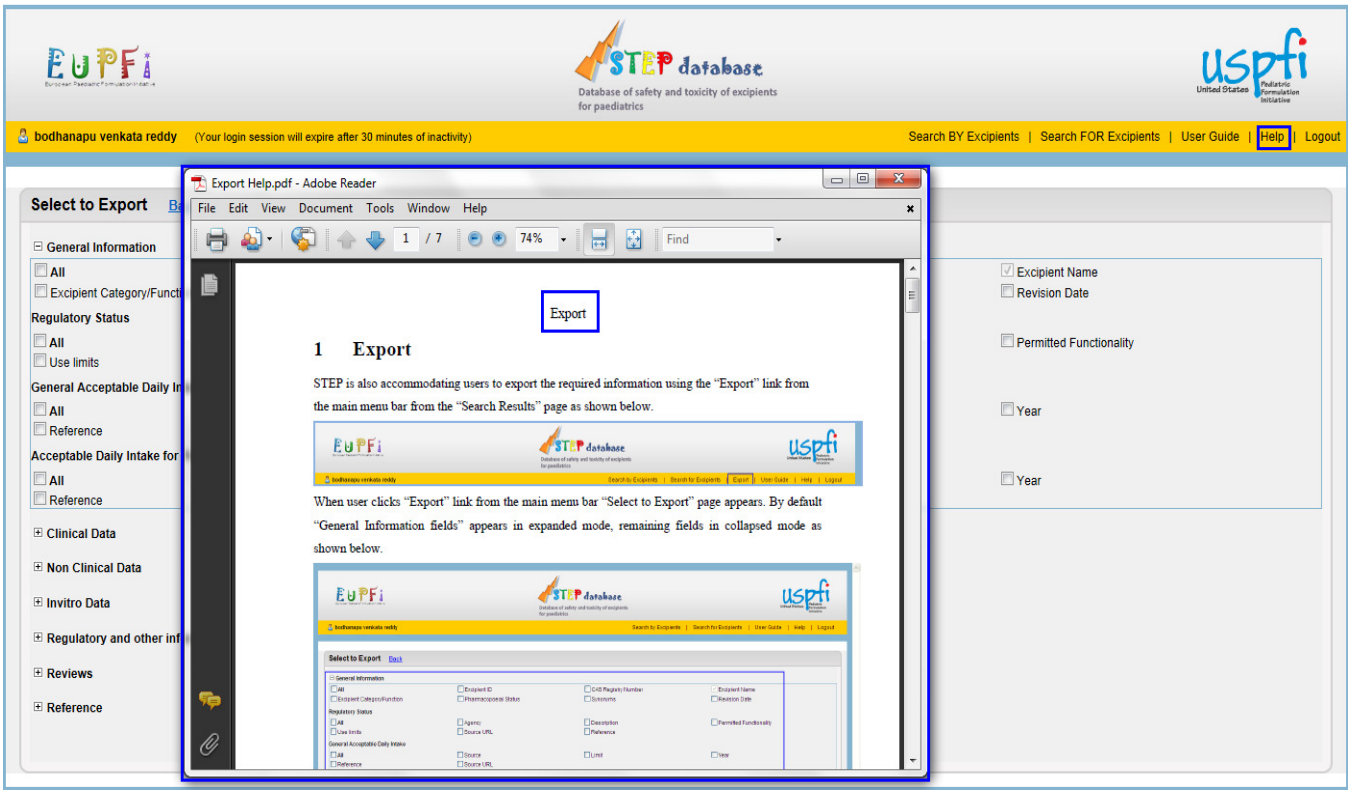
Note:

- 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.



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.

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.