



US PFI

Eu – US PFI

Safety and **T**oxicity of **E**xipients for **P**aediatric [STEP]

User Guide

European Paediatric Formulation Initiative (EuPFI)

UCL School of Pharmacy

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www.eupfi.org

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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

STEP login page appears as shown below

I'm an Existing Eupfi User [User Guide](#)

Login Email [Log In](#) [Forgot Login Email](#)

New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

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☐ I've read the Disclaimer and accepted the Terms & Conditions

User Name * Organization

Email Address * Confirm Email Address *

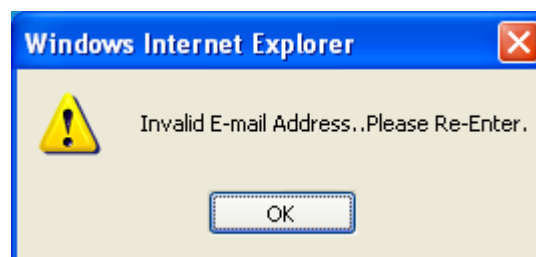
Contact Number Country

[Register](#) [Reset](#) * Indicates mandatory field.

When user clicks “Log in” button without entering “Login Email” then an alert message appears as shown below



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



If user logs in with unregistered Login Email as shown below

I'm an Existing Eupfi User [User Guide](#)

Login Email [Forgot Login Email](#)

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User Name *	<input type="text"/>	Organization	<input type="text"/>
Email Address *	<input type="text"/>	Confirm Email Address *	<input type="text"/>
Contact Number	<input type="text"/>	Country	<input type="text"/>

* Indicates mandatory field.

And clicks “Log in” button then the below message appears

I'm an Existing Eupfi User [User Guide](#)

Email ID not yet registered. Please register before logging in.

Login Email [Log In](#) [Forgot Login Email](#)

New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

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2.2 Why Registration

STEP provides the detailed information about the necessity of registration. To know that information user has to click “Why Registration?” link besides the “New User – Register Now” as shown below

New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

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User Name * Organization

Email Address * Confirm Email Address *

Contact Number Country

[Register](#) [Reset](#) * Indicates mandatory field.

Then the information appears as shown below

New User - Register Now
[\(Why Registration?\)](#)
Revision Date: 06/25/2012

The benefits of becoming a Registered User with Step Database, include access to the Reference Database, collaboration in User Communities, Best Practice and Tutorials. This allows you to build your expertise in areas of particular interest to you, and to create a 'myDBA' Profile which is personalized for you.

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☐ I've read the Disclaimer and accepted the Terms & Conditions

User Name *	<input type="text"/>	Organization	<input type="text"/>
Email Address *	<input type="text"/>	Confirm Email Address *	<input type="text"/>
Contact Number	<input type="text"/>	Country	<input type="text"/>

Register
Reset
* Indicates mandatory field.

When user clicks “Why Registration” link then the data gets collapsed and the page appears as shown below

New User - Register Now
[\(Why Registration?\)](#)
Revision Date: 06/25/2012

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☐ I've read the Disclaimer and accepted the Terms & Conditions

User Name *	<input type="text"/>	Organization	<input type="text"/>
Email Address *	<input type="text"/>	Confirm Email Address *	<input type="text"/>
Contact Number	<input type="text"/>	Country	<input type="text"/>

Register
Reset
* Indicates mandatory field.

2.3 New user registration

STEP facilitates user to create a new user in a simple way by using the “New-User Register Now” process. Here before registering user should check the “I’ve read the disclaimer and accepted the Terms & Conditions” then the new user registration form then only the “Register” button appears in enabled mode as shown below

New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

The benefits of becoming a Registered User with Step Database, include access to the Reference Database, collaboration in User Communities, Best Practice and Tutorials. This allows you to build your expertise in areas of particular interest to you, and to create a 'myDBA' Profile which is personalized for you.

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The School of Pharmacy,
University of London 29-39,
Brunswick Square London ,
WC1N 1AX
Phone: 0044 20 7753 5846
Fax: 0044 20 7753 5942
Email: smita.salunke@pharmacy.ac.uk

☒ I've read the Disclaimer and accepted the Terms & Conditions

User Name * Organization
Email Address * Confirm Email Address *
Contact Number Country
 * Indicates mandatory field

1. In this page user need to specify the required details for registering as a new user. After filling all the details click “Register” button as shown below

New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

The benefits of becoming a Registered User with Step Database, include access to the Reference Database, collaboration in User Communities, Best Practice and Tutorials. This allows you to build your expertise in areas of particular interest to you, and to create a 'myDBA' Profile which is personalized for you.

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The School of Pharmacy,
University of London 29-39,
Brunswick Square London ,
WC1N 1AX
Phone: 0044 20 7753 5846
Fax: 0044 20 7753 5942
Email: smite.salunke@pharmacy.ac.uk

☒ I've read the Disclaimer and accepted the Terms & Conditions

User Name *	Saraswathi	Organization	Gvkbio
Email Address *	saraswathi.nimmaraju@gvkbio.com	Confirm Email Address *	saraswathi.nimmaraju@gvkbio.com
Contact Number	9247363984	Country	India

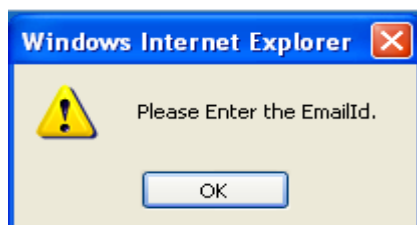
* Indicates mandatory field.

Note:


- User Name and Email Address are the mandatory fields
- If user doesn't enter "User Name" and clicks "Register" button then the below alert message appears



- If user doesn't enter "Email Address" and clicks "Register" button then the below alert message appears



- Then the user gets registered and an acknowledgement message appears as shown below along with all the users information



New User Registered Successfully (Please save the details for future reference.)

The benefits of becoming a Registered User with Step Database, include access to the Reference Database, collaboration in User Communities, Best Practice and Tutorials. This allows you to build your expertise in areas of particular interest to you, and to create a 'myDBA' Profile which is personalized for you

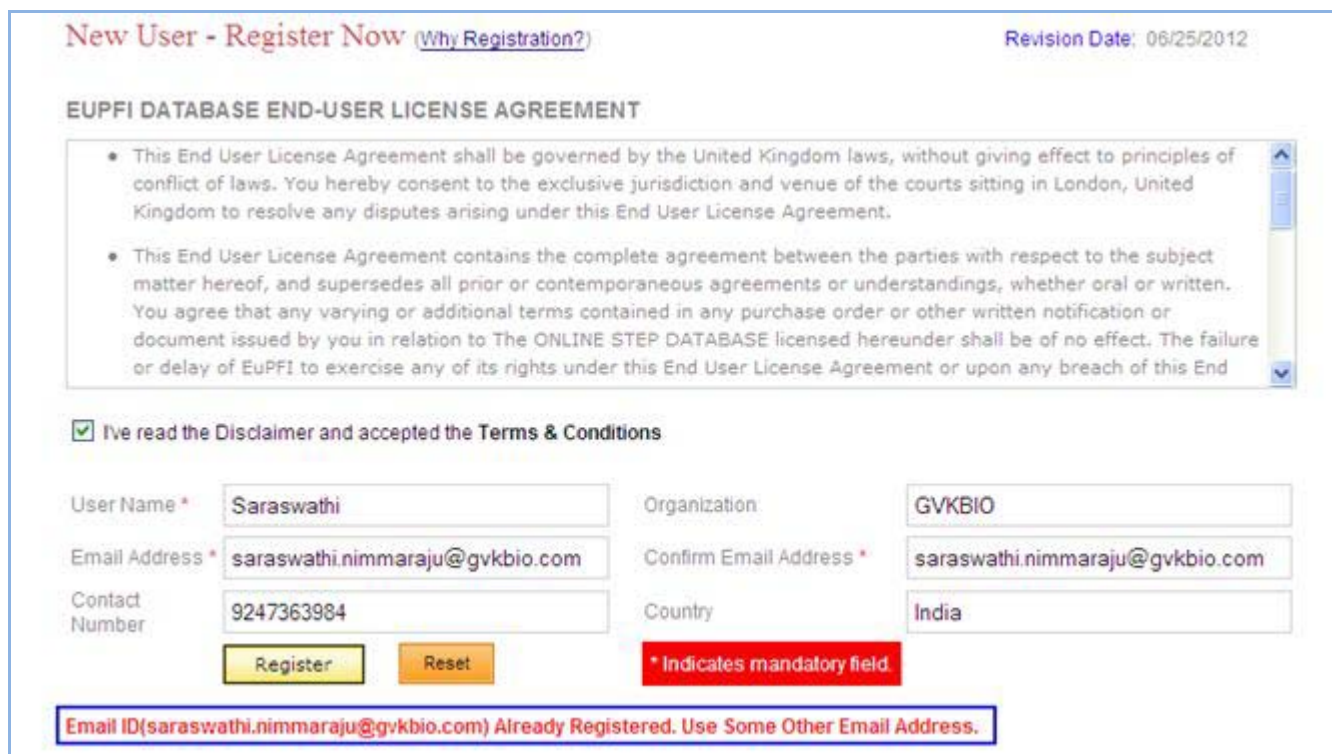
Email Address :	saraswathi.nimmaraju@gvkbio.com
User ID :	140
User Name :	Saraswathi
Organization :	Gvkbio
Country :	India
Contact Number :	9247363984

OK

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GOSTAR **GEBIOM**

- User should save the above information for further reference.
- If user tries to register with the existing Login Email/ User name then an alert message appears as shown below indicating the user has already existed as shown below



New User - Register Now ([Why Registration?](#)) Revision Date: 06/25/2012

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User Name *	Saraswathi	Organization	GVKBIO
Email Address *	saraswathi.nimmaraju@gvkbio.com	Confirm Email Address *	saraswathi.nimmaraju@gvkbio.com
Contact Number	9247363984	Country	India

Register Reset * Indicates mandatory field

Email ID(saraswathi.nimmaraju@gvkbio.com) Already Registered. Use Some Other Email Address.

2.4 Forgot Login Email

STEP database provides access to users using “Login Email” if user forgets the login email can retrieve it very easily using “Forgot Login Email” link

1. Click “Forgot Login Email” link as shown above then the below page appears

2. Enter the User name (Full name of the user with which the earlier user was created) in the “User Name” text box. Then enter the “UserID” provided by the application at the time of registration.
3. After entering the details click “Get Login Mail” button as shown below

Forgot Email : * Indicates mandatory field.

User Name:*
(Full name the user registered with)

User ID:*

[Get Login Mail](#)

Click [Here](#) to Login

4. Then the corresponding login Email Id appears as shown below

Forgot Email : * Indicates mandatory field.

User Name:*
(Full name the user registered with)

User ID:*

[Get Login Mail](#)

Your Login Email id Is: saraswathi.nimmaraju@gvkbio.com

Click [Here](#) to Login

5. User can access the application using the retrieved Login Email

6. If user enters incorrect User ID in the “User ID” text box and clicks “Get Login Mail” button then the application prompts the below message

Forgot Email : * Indicates mandatory field.

User Name:*
(Full name the user registered with)

User ID:*

[Get Login Mail](#)

Your Login Email id Is: Not Found, Please Enter The Correct Data.

Click [Here](#) to Login

Developed by

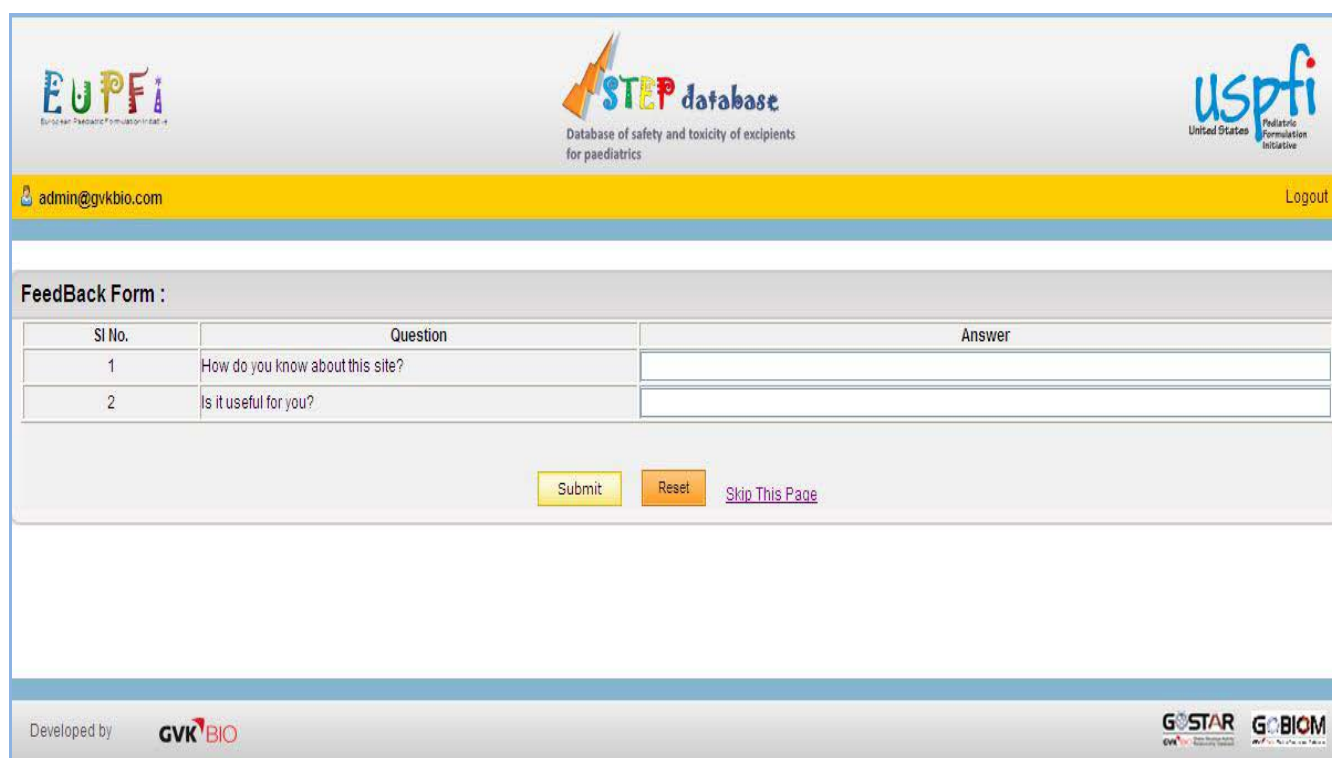
Stating that “Your Login Email id is not Found, Please Enter the Correct Data”.

7. To avoid this message it's recommended to save the “User ID” after registration as a new user.

2.5 Regular User

STEP provides a new option for the regular user who ever are visited more than 25 times can provide Feedback on the application using feedback form

Whenever user logs into the application more than 25times then for the next time feedback appears as shown below



admin@gvkbio.com Logout

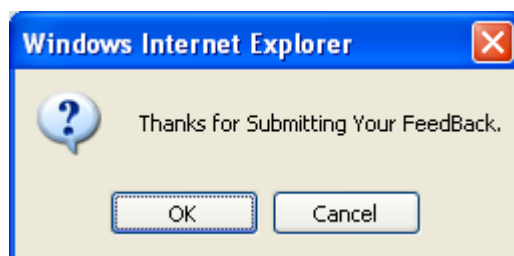
FeedBack Form :

SI No.	Question	Answer
1	How do you know about this site?	
2	Is it useful for you?	

Submit Reset [Skip This Page](#)

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User is recommended to fill the feedback form with the relevant information then a message box appears as an acknowledgement for submitting the feedback as shown below



Eu – US PFI User Guide

Then click “Ok” on the message box then “Basic Search” page appears

If user is not interested in filling the form then can skip this page using “Skip This Page” link as shown below

FeedBack Form :

Sl No.	Question	Answer
1	How do you know about this site?	
2	Is it useful for you?	

[Submit](#) [Reset](#) [Skip This Page](#)

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Then this Feedback Form page gets skipped and “Basic Search Page” appears as shown below

Search by Excipient

Excipient Name: -- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number: -- Select --
100-51-6
131-11-3
1319-77-3
16731-55-8

Synonyms (As per the Handbook of Excipients): -- Select --
1 vinyl 2 pyrrolidinone polymer
1,2-Benzenedicarboxylic acid, dimethyl ester
1,2-Diethyl phthalate
1,2-propanediol

Function: -- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Submit](#) [Reset](#) [Advanced Search](#)

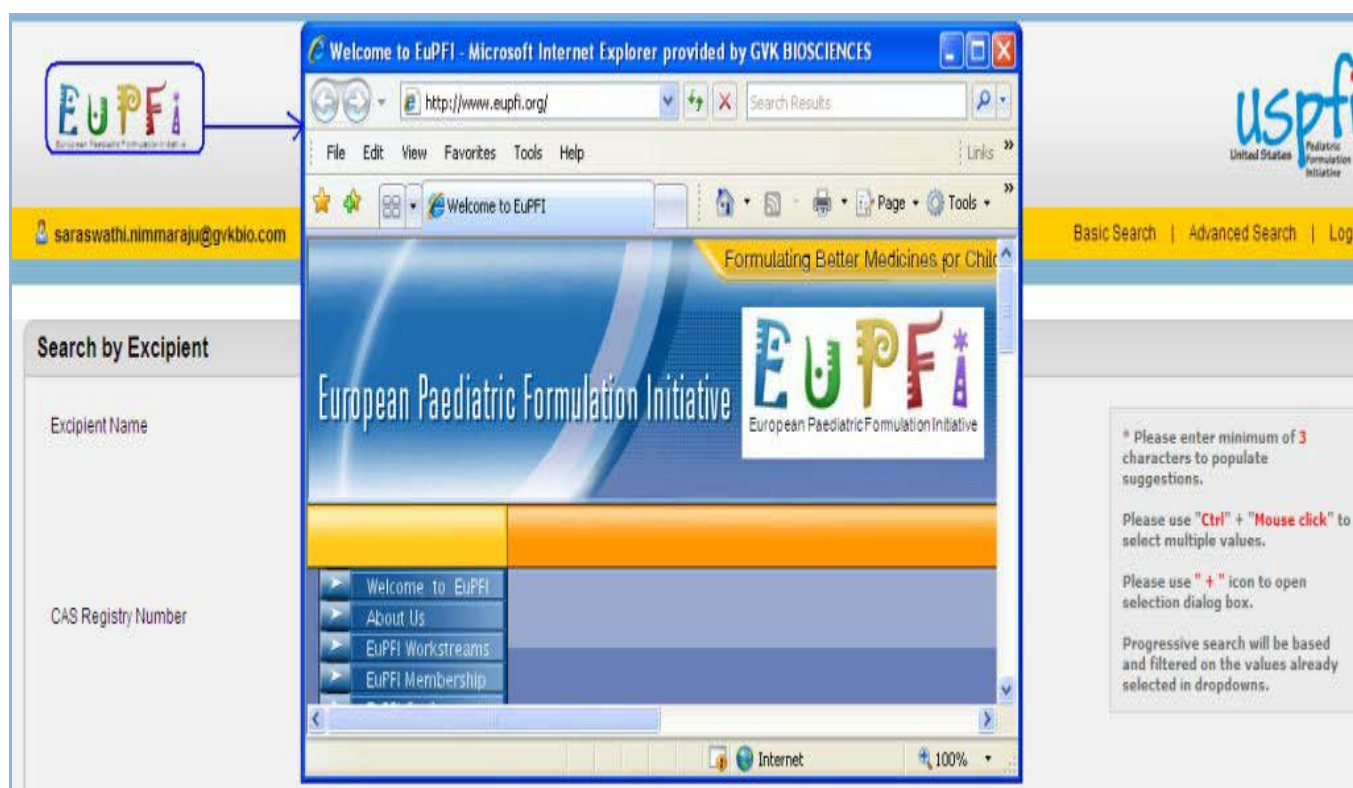
* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

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 appears.
- Until unless user fills the Feedback Form this “Feedback Form” will appear for every login
- It's recommendable to fill the “Feedback Form” to avoid the above circumstances

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 for more than 30minutes then the session automatically gets expired and displays the below message.

The screenshot shows the top header with logos for EUPFI, STEP database, and uspfi. Below the header, a grey bar contains the text "Session Expired:". The main content area is white and contains the text "click [Here](#) to login." at the bottom center. The footer includes "Developed by GVK BIO" and logos for GOSTAR and GBIOM.

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

The screenshot shows the login and registration interface. At the top, it says "I'm an Existing Eupfi User" with a "User Guide" link. Below is a login section with a "Login Email" field, a "Log In" button, and a "Forgot Login Email" link. Underneath is a "New User - Register Now" link with a "Why Registration?" link and a "Revision Date: 06/25/2012". The main section is titled "EUPFI DATABASE END-USER LICENSE AGREEMENT" and contains two bullet points. Below the agreement is a checkbox labeled "I've read the Disclaimer and accepted the Terms & Conditions". At the bottom, there are registration fields for "User Name", "Email Address", "Contact Number", "Organization", "Confirm Email Address", and "Country". There are "Register" and "Forgot" buttons, and a red box indicating "* Indicates mandatory field".

4 LOGOUT

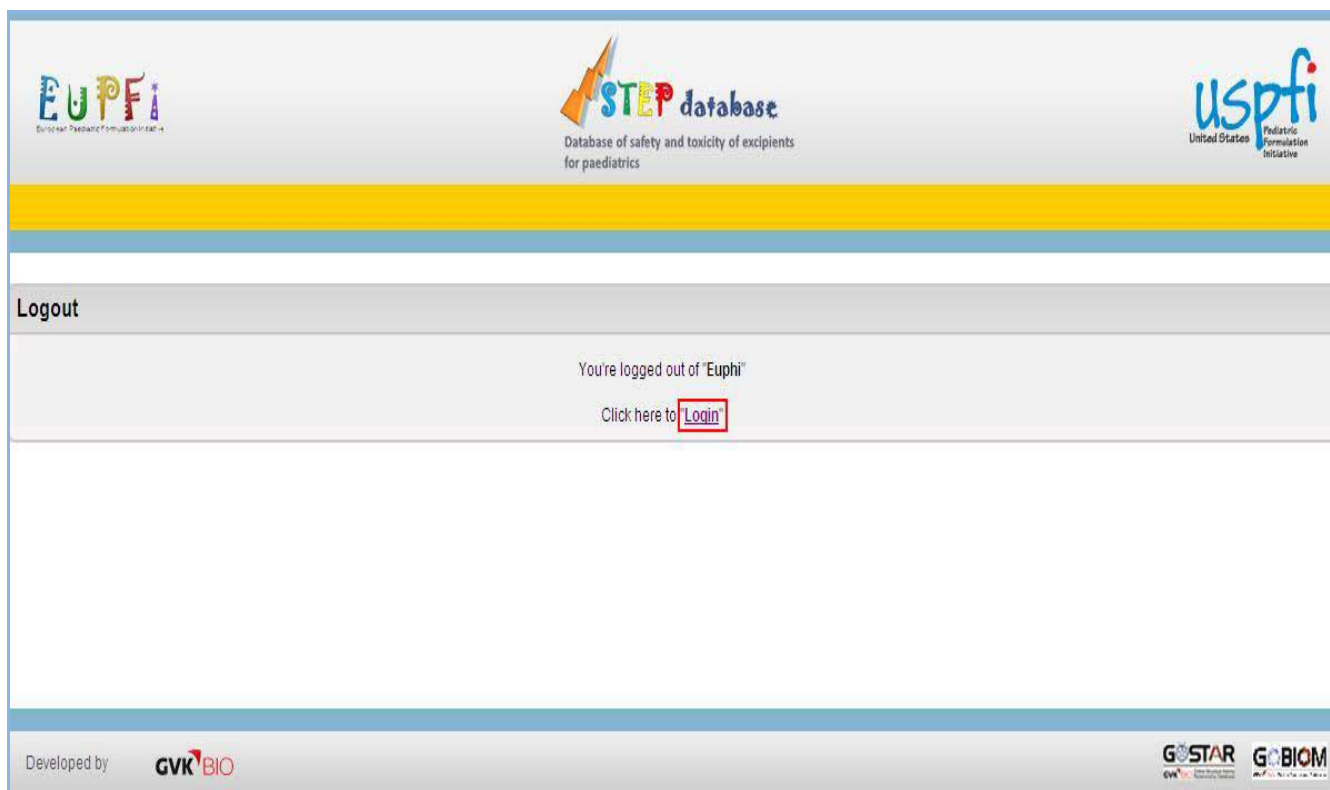
In order to logout of the application user can use Logout link in the right top corner as shown below

The screenshot shows the top navigation bar with logos for EUPFI, STEP database, and uspfi. Below the logos is a yellow bar containing the user email 'saraswathi.nimmaraju@gvkbio.com', links for 'Basic Search' and 'Advanced Search', and a 'Logout' button. The main content area is titled 'Search by Excipient' and contains two dropdown menus for 'Excipient Name' and 'CAS Registry Number'. The 'Excipient Name' dropdown shows options: '-- Select --', 'Aspartame', 'Benzalkonium chloride', 'Benzoic acid', and 'Benzyl alcohol'. The 'CAS Registry Number' dropdown shows options: '-- Select --', '100-51-6', '131-11-3', '1319-77-3', and '16731-55-8'. To the right of the dropdowns is a text box with instructions: '* Please enter minimum of 3 characters to populate suggestions.', 'Please use "Ctrl" + "Mouse click" to select multiple values.', 'Please use "+" icon to open selection dialog box.', and 'Progressive search will be based and filtered on the values already selected in dropdowns.'

Then the application logs out and navigates to the below page

The screenshot shows the top navigation bar with logos for EUPFI, STEP database, and uspfi. Below the logos is a yellow bar. The main content area is titled 'Logout' and contains the text 'You're logged out of "Euphi"' and 'Click here to "Login"'. At the bottom of the page is a footer with the text 'Developed by' and logos for GVK BIO, GOSTAR, and GBIOM.

If user desires to login to the application can click “Login” link as shown below



Then the login page appears as shown below

I'm an Existing Eupfi User

User Guide

Login Email

Log In

Forgot Login Email

New User - Register Now

Why Registration?

Revision Date: 06/25/2012

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User Name *

Organization

Email Address *

Confirm Email Address *

Contact Number

Country

Register

Forgot

* Indicates mandatory field.

5 BASIC SEARCH

Login to the application with valid user credentials as shown below

I'm an Existing Eupfi User [User Guide](#)

Login Email [Log In](#) [Forgot Login Email](#)

[New User - Register Now](#) ([Why Registration?](#)) Revision Date: 06/25/2012

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

Search by Excipient

Excipient Name +
 -- Select --
 Aspartame
 Benzalkonium chloride
 Benzoic acid
 Benzyl alcohol

CAS Registry Number +
 -- Select --
 100-51-6
 131-11-3
 1319-77-3
 16731-55-8

Synonyms
 (As per the Handbook of Excipients) +
 -- Select --
 1-vinyl-2-pyrrolidinone polymer
 1,2-Benzenedicarboxylic acid, dimethyl ester
 1,2-Diethyl phthalate
 1,2-propanediol

Function +
 -- Select --
 Adsorbent
 Antimicrobial preservative
 Coating agent
 Confectionery base

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
 Please use "Ctrl" + "Mouse click" to select multiple values.
 Please use "+" icon to open selection dialog box.
 Progressive search will be based and filtered on the values already selected in dropdowns.

In the STEP application by default “Basic Search” page appears wherein user is allowed to select the required data and can view the results.

Search page provides results based on “Excipient Name, CAS Registry Number, Synonyms and Function.”

5.1 Search by Excipient

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 “Basic Search” page user can select the required excipient name from the “Excipient Name” drop down as shown below

Search by Excipient

Excipient Name:

CAS Registry Number:

Synonyms (As per the Handbook of Excipients):

Function:

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.

Please use "Ctrl" + "Mouse click" to select multiple values.

Please use "+" icon to open selection dialog box.

Progressive search will be based and filtered on the values already selected in dropdowns.

5.1.1.1 Multiple Excipient selection

To add more than one excipient user can use “CTRL” button and then select the excipients from the drop down either continuously or randomly as shown below

Search by Excipient

Excipient Name: Benzalkonium chloride|Benzoic acid|Benzyl alcohol +

-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number: 100-51-6
65-85-0
8001-54-5 +

Synonyms (As per the Handbook of Excipients): Alkyldimethylbenzylammonium chloride
Benzalkonii chloridum
Benzalkonium
alpha hydroxytoluene
benzenecarboxylic acid +

Function: -- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base +

Submit Reset [Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Search by Excipient

Excipient Name: Aspartame|Benzoic acid +

-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number: 65-85-0 +

Synonyms (As per the Handbook of Excipients): benzenecarboxylic acid
benzoate
benzoylate
carboxybenzene +

Function: -- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base +

Submit Reset [Advanced Search](#)

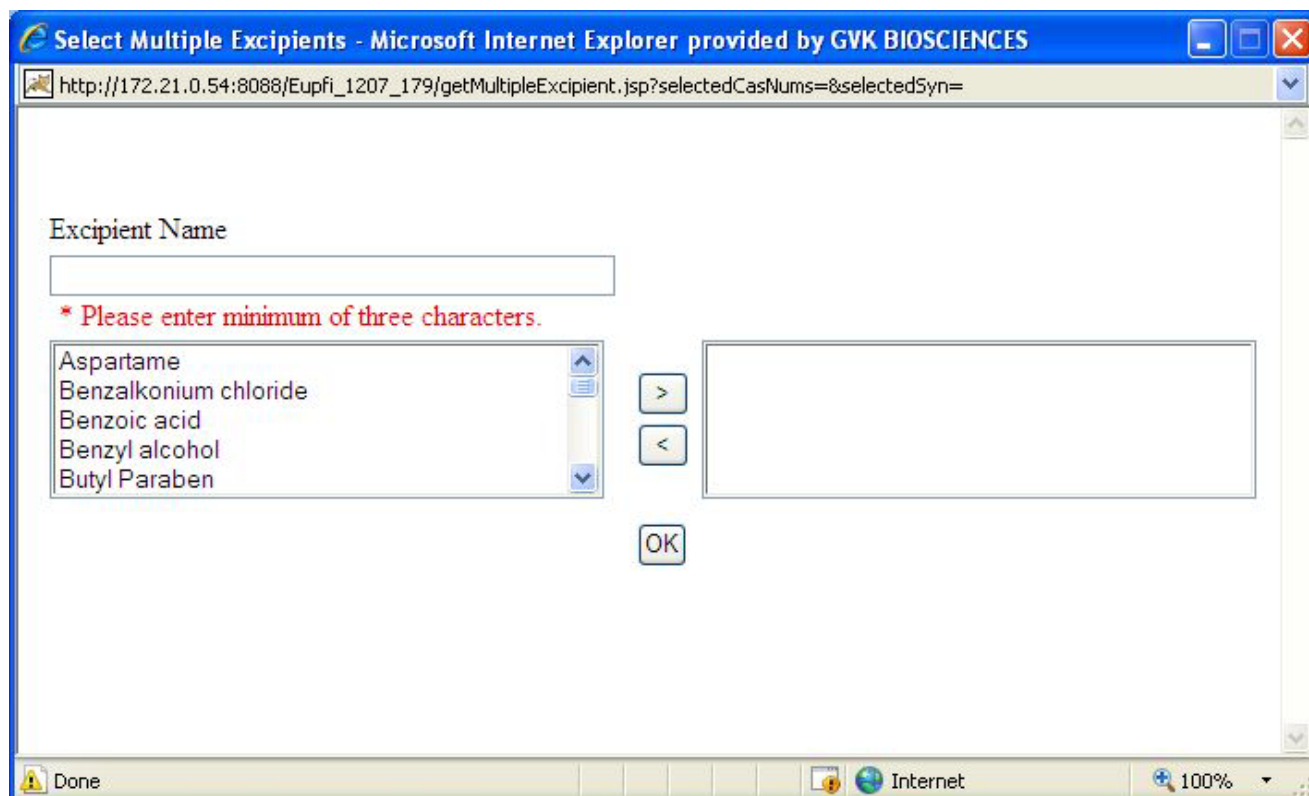
* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Based on the selected “Excipient Name” data in the “CAS Registry Number, Synonyms and Function” appears. User can use the “+” symbol placed besides the “Excipient Name” textbox to select multiple excipients randomly.

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



In the Basic Search if user enters required excipient name in the “Excipient Name” text box

Example: “Ben” then only the relevant excipient appears in the drop down as shown below

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES

http://172.21.0.54:8088/Eupfi_1207_179/getMultipleExcipient.jsp?selectedCasNums=&selectedSyn=

Excipient Name

benz

* Please enter minimum of three characters.

Benzalkonium chloride
Benzoic acid
Benzyl alcohol
Sodium benzoate

>
<
OK

Done Internet 100%

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

Select Multiple Excipients - Microsoft Internet Explorer provided by GVK BIOSCIENCES

http://172.21.0.54:8088/Eupfi_1207_179/getMultipleExcipient.jsp?selectedCasNums=&selectedSyn=

Excipient Name

benz

* Please enter minimum of three characters.

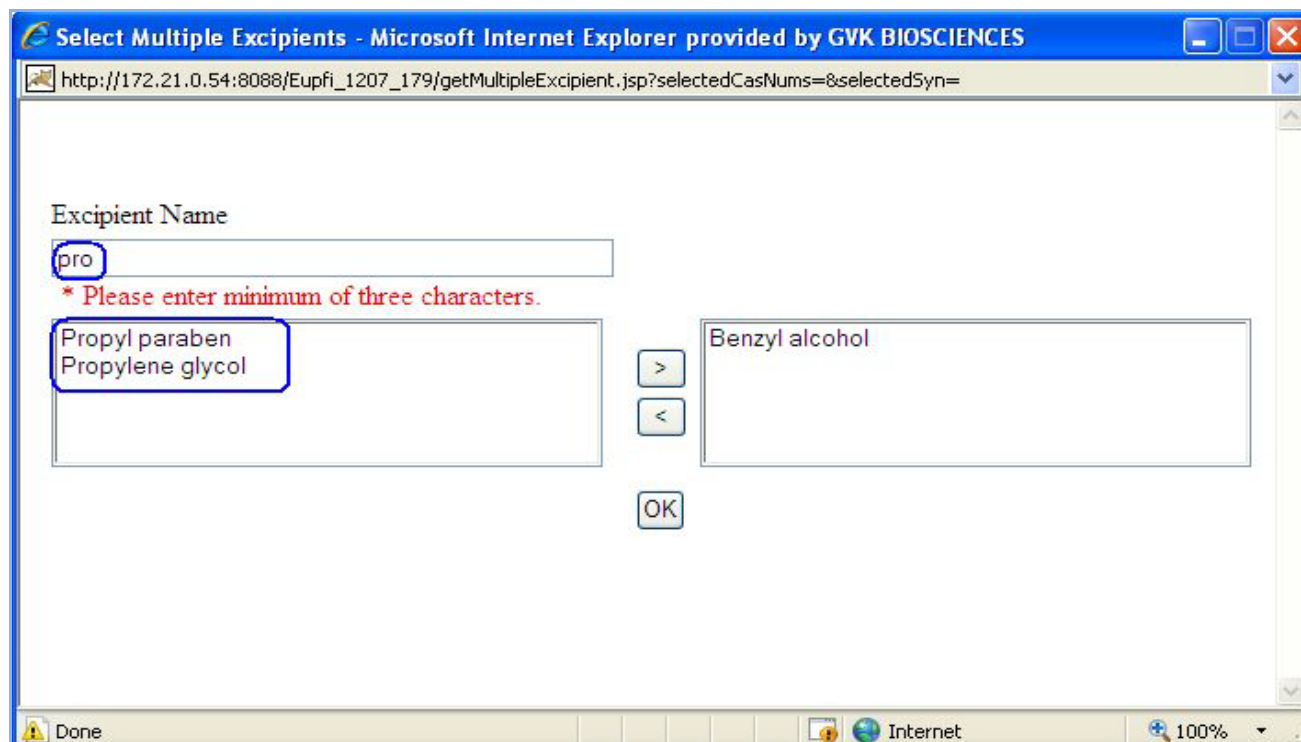
Benzalkonium chloride
Benzoic acid
Sodium benzoate

Benzyl alcohol

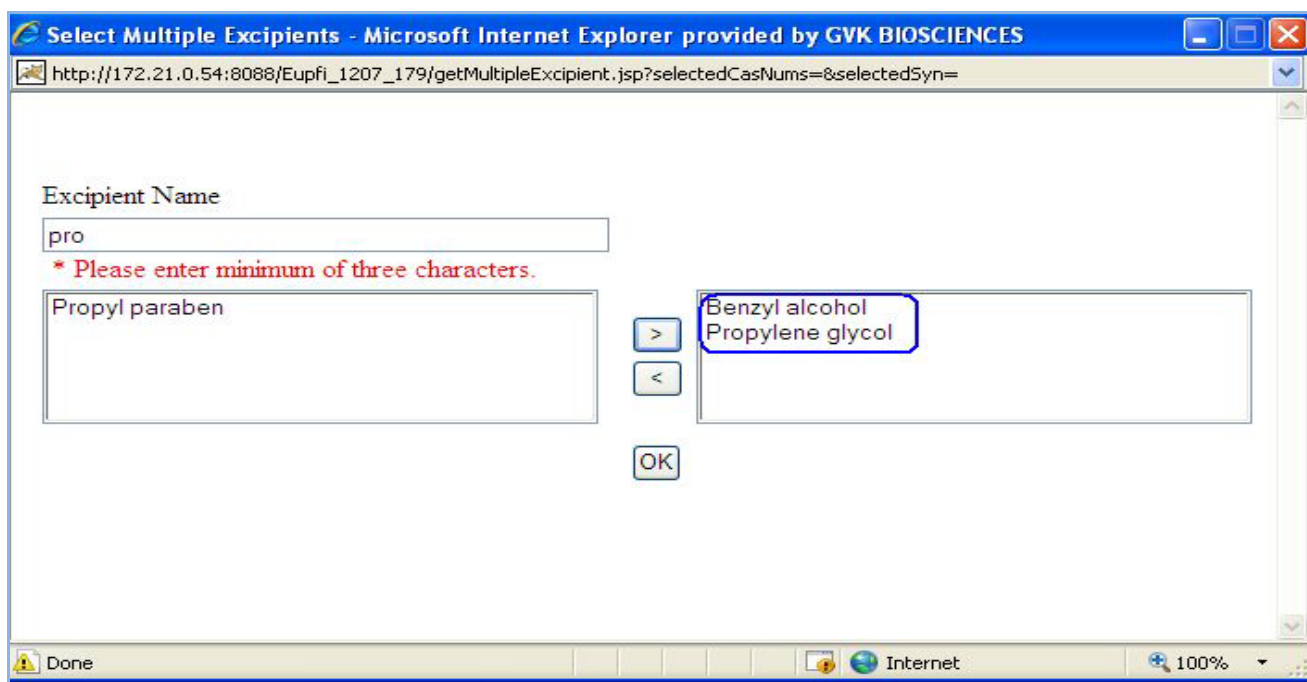
>
<
OK

Done Internet 100%

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 “Basic Search” page as shown below

Search by Excipient

Excipient Name: +
Polyethylene glycol
Polyvinylpyrrolidone
Potassium metabisulphite
Propyl paraben
Propylene glycol

CAS Registry Number: +
100-51-6

Synonyms (As per the Handbook of Excipients): +
alpha hydroxytoluene
benzylic alcohol
hydroxymethylbenzene
phenmethylol
phenylcarbinol

Function: +
-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

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

Search by Excipient

Excipient Name: +
Polyethylene glycol
Polyvinylpyrrolidone
Potassium metabisulphite
Propyl paraben
Propylene glycol

CAS Registry Number: +
100-51-6

Synonyms (As per the Handbook of Excipients): +
alpha hydroxytoluene
benzylic alcohol
hydroxymethylbenzene
phenmethylol
phenylcarbinol

Function: +
-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

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

Search Results Total References: 25 Record 1 of 1

Excipient Navigation

General Information Excipient Chem ID

Excipient Chemical Name: Benzyl alcohol
CAS Registry Number: 100-51-6

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data | Non Clinical Data | In vitro Data | Regulatory Reference | Reviews

Show/Hide Clinical Columns ⊕

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
25	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34

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”.

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 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 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

Basic Search before selecting the CAS Registry Number

Search by Excipient

Excipient Name

-- Select --

Aspartame

Benzalkonium chloride

Benzoic acid

Benzyl alcohol

CAS Registry Number

-- Select --

100-51-6

131-11-3

1319-77-3

16731-55-8

Synonyms
(As per the Handbook of Excipients)

-- Select --

1 vinyl 2 pyrrolidinone polymer

1,2-Benzenedicarboxylic acid, dimethyl ester

1,2-Diethyl phthalate

1,2-propanediol

Function

-- Select --

Adsorbent

Antimicrobial preservative

Coating agent

Confectionery base

Submit

Reset

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.

Please use "Ctrl" + "Mouse click" to select multiple values.

Please use "+" icon to open selection dialog box.

Progressive search will be based and filtered on the values already selected in dropdowns.

Basic Search after selecting the CAS Registry Number

Search by Excipient

Excipient Name

CAS Registry Number

Synonyms (As per the Handbook of Excipients)

Function

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Note: Although user selects required CAS Registry Number value after selecting the Excipient Name but the data in the search results appears considering not only with the selected CAS Registry Number but also with all the other CAS Registry Numbers that are related to the selected Excipient Name

Search by Excipient

Excipient Name

CAS Registry Number

Synonyms (As per the Handbook of Excipients)

Function

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Example: In the above scenario user selected Excipient Names as “Benzyl alcohol” and CAS Registry Number as “100-51-6” and clicks submit. Search Results page displays the results that are related to “Benzyl alcohol” along with CAS Registry Number “100-51-6” as shown below

Search Results Total References: 25 Record 1 of 1

Excipient Navigation

General Information Excipient Chem ID

Excipient Chemical Name: Benzyl alcohol

CAS Registry Number: 100-51-6

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data
Non Clinical Data
Invitro Data
Regulatory Reference
Reviews

Show/Hide Clinical Columns ☐

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Do
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50

5.1.3 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: Chem ID Plus

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

Basic Search page before selecting the Synonyms

Search by Excipient

Excipient Name +

-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number +

-- Select --
100-51-6
131-11-3
1319-77-3
16731-55-8

Synonyms
(As per the Handbook of Excipients) +

-- Select --
1 vinyl 2 pyrrolidinone polymer
1,2-Benzenedicarboxylic acid, dimethyl ester
1,2-Diethyl phthalate
1,2-propanediol

Function +

-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Advanced Search](#)

* Please enter minimum of **3** characters to populate suggestions.
Please use "**Ctrl**" + "**Mouse click**" to select multiple values.
Please use "**+**" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Basic Search page after selecting the Synonyms

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

Example: Excipient Name “Benzyl alcohol”, CAS Registry Number “100-51-6”, Synonyms “Benzylic alcohol” then click “Submit” as shown below

Search by Excipient

Excipient Name:

-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number:

-- Select --
100-51-6
131-11-3
1319-77-3
16731-55-8

Synonyms
(As per the Handbook of Excipients):

-- Select --
1-vinyl-2-pyrrolidinone polymer
1,2-Benzenedicarboxylic acid, dimethyl ester
1,2-Diethyl phthalate
1,2-propanediol

Function:

-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.

Please use "Ctrl" + "Mouse click" to select multiple values.

Please use "+" icon to open selection dialog box.

Progressive search will be based and filtered on the values already selected in dropdowns.

Search Results page appears considering the search criteria as shown below

Search Results

Total References: 25

Record 1 of 1

Excipient Navigation

General Information

Excipient Chem ID

Excipient Chemical Name:

Benzyl alcohol

CAS Registry Number:

100-51-6

Excipient Category/Function :

Pharmacopoeial Status:

Regulatory Status:

Synonyms:

Acceptable Daily Intake:

Revision Date:

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Doc
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34

6 ADVANCED SEARCH

Advanced Search supports user in selecting the search criteria in an easy manner. User can access the “Advanced Search” page either from the “Advanced Search” link in the main menu bar or from the “Advanced Search” link in the “Basic Search” page at the bottom as shown below

The screenshot displays the "Advanced Search" interface. At the top, there is a navigation bar with "Basic Search" and "Advanced Search" (highlighted) and a "Logout" link. The main heading is "Search by Excipient". Below this, there are four search criteria, each with a text input field and a dropdown menu:

- Excipient Name:** The dropdown menu is open, showing options: "-- Select --", Aspartame, Benzalkonium chloride, Benzoic acid, and Benzyl alcohol.
- CAS Registry Number:** The dropdown menu is open, showing options: "-- Select --", 100-51-6, 131-11-3, 1319-77-3, and 16731-55-8.
- Synonyms (As per the Handbook of Excipients):** The dropdown menu is open, showing options: "-- Select --", 1 vinyl 2 pyrrolidinone polymer, 1,2-Benzenedicarboxylic acid, dimethyl ester, 1,2-Diethyl phthalate, and 1,2-propanediol.
- Function:** The dropdown menu is open, showing options: "-- Select --", Adsorbent, Antimicrobial preservative, Coating agent, and Confectionery base.

At the bottom of the form, there are three buttons: "Submit", "Reset", and "Advanced Search" (highlighted). On the right side of the form, there is a text box with instructions:

- * Please enter minimum of 3 characters to populate suggestions.
- Please use "Ctrl" + "Mouse click" to select multiple values.
- Please use "+" icon to open selection dialog box.
- Progressive search will be based and filtered on the values already selected in dropdowns.

On clicking “Advanced Search” link either from main menu bar or from the basic search page the below “Advanced Search” page appears

Advanced Search

Clinical Data **Non Clinical Data**

Search For Excipients

Study Types

-- Select --
Acute exposure
Acute toxicity
Chronic toxicity
Dermal toxicity

Age Category

-- Select --
Adolescent
Adolescents, adults
Adult
Adults

Route of Exposure / Administration

-- Select --
Cutaneous
Dermal (Closed patch)
IV
Inhalation

Function

-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

Search by Effect

Organ / System

-- Select --
Immune System
Nasal mucosa
Oral cavity
Respiratory

Submit

Reset

[Basic Search](#)

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GVK BIO
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Advanced Search 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 “Advanced Search” are

1. Search for Excipients
 - ✓ Study Types
 - ✓ Age Category
 - ✓ Route of Exposure/Administration
 - ✓ Function
2. Search by Effect
 - ✓ Organ/System

6.1.1 Search for Excipients

Search for Excipients includes all the data related to the excipient related to the Study Types, 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 Types

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

Clinical Data **Non Clinical Data**

Search For Excipients

Study Types

-- Select --
 Acute exposure
 Acute toxicity
 Chronic toxicity
 Dermal toxicity

Age Category

-- Select --
 Adolescent
 Adolescents, adults
 Adult
 Adults

Route of Exposure / Administration

Oral
 intranasal
 intraocular
 ocular
 oral

Function

-- Select --
 Adsorbent
 Antimicrobial preservative
 Coating agent
 Confectionery base

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.

Clinical Data **Non Clinical Data**

Search For Excipients

Study Types

Age Category

Route of Exposure / Administration

Function

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

Clinical Data **Non Clinical Data**

Search For Excipients

Study Types: -- Select --, Acute exposure, Acute toxicity, Chronic toxicity, Dermal toxicity

Age Category: Adolescent, Adolescents, adults, Adult, Adults, Children

Route of Exposure / Administration: -- Select --, Cutaneous, Dermal (Closed patch), IV, Inhalation

Function: Dispersing agent, Dry powder inhaler carrier, Emulsifying agent, Film-forming agent, Ointment base

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

Clinical Data **Non Clinical Data**

Search For Excipients

Study Types: -- Select --, Acute exposure, Acute toxicity, Chronic toxicity, Dermal toxicity

Age Category: Adolescent, Adolescents, adults, Adult, Adults, Children

Route of Exposure / Administration: -- Select --, Cutaneous, Dermal (Closed patch), IV, Inhalation

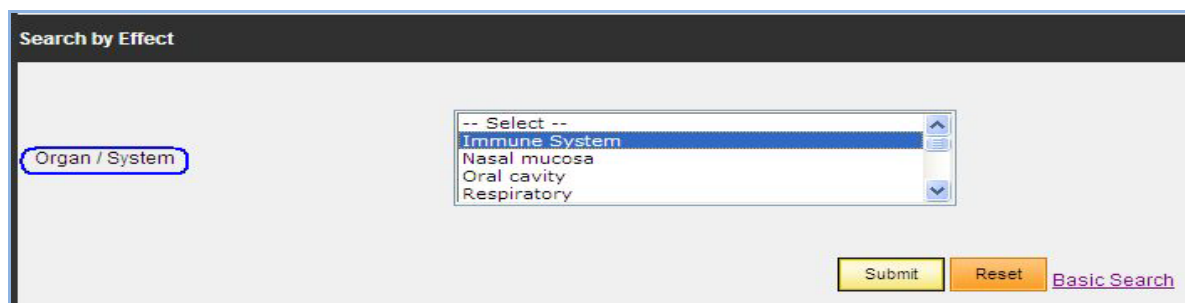
Function: -- Select --, Adsorbent, Antimicrobial preservative, Coating agent, Confectionery base

6.1.2 Search by Effect

“Effect” is any undesired action or effect of an excipient it includes the “System/Organ” information on which the effect occurred.

6.1.2.1 Organ/System

Indicates on which organ or system the effects are observed



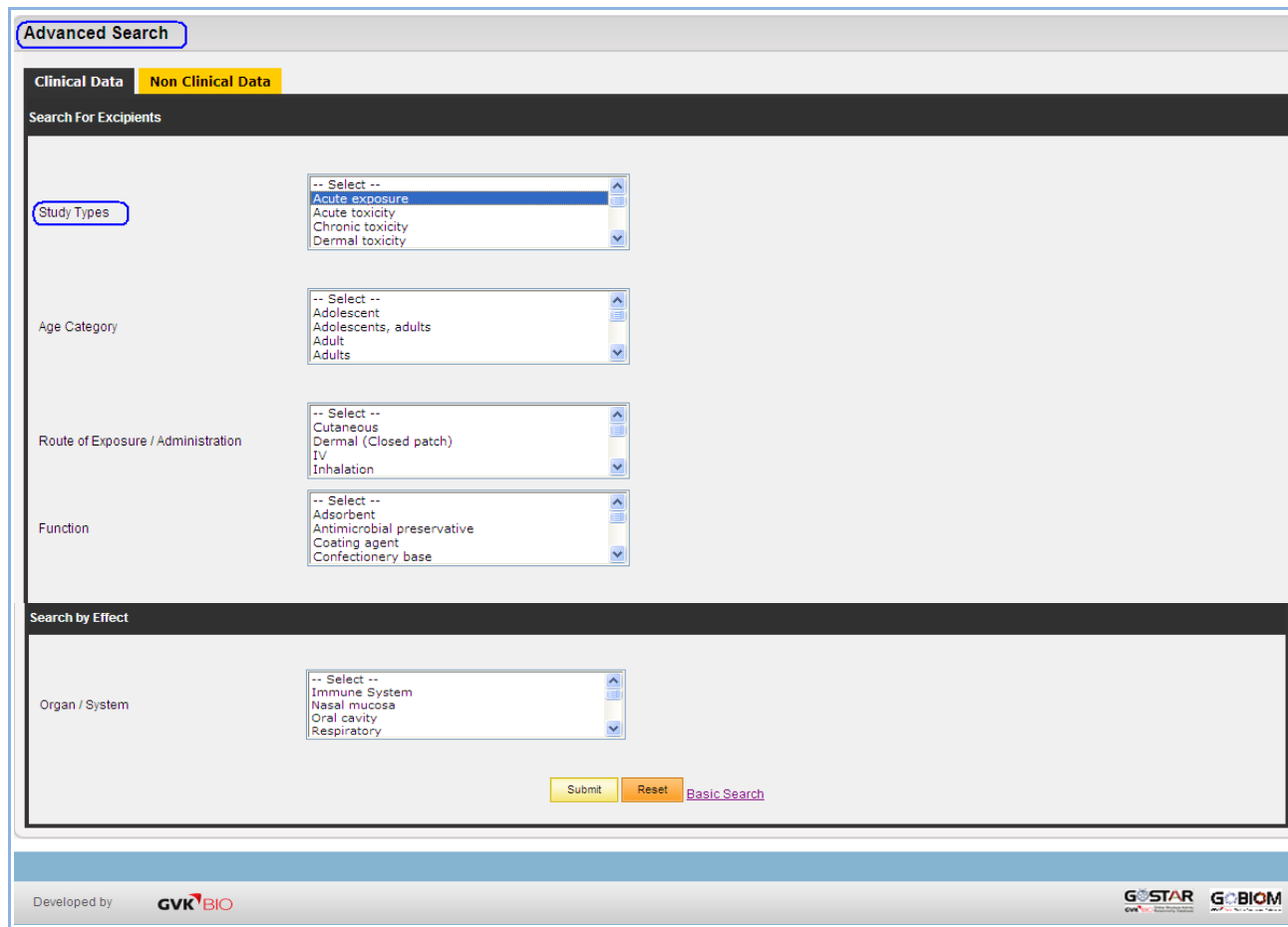
Search by Effect

Organ / System

-- Select --
Immune System
Nasal mucosa
Oral cavity
Respiratory

Submit Reset Basic Search

Based on the selected data under “Search by Excipients” and “Search by Effect” the search results appears



Advanced Search

Clinical Data Non Clinical Data

Search For Excipients

Study Types

-- Select --
Acute exposure
Acute toxicity
Chronic toxicity
Dermal toxicity

Age Category

-- Select --
Adolescent
Adolescents, adults
Adult
Adults

Route of Exposure / Administration

-- Select --
Cutaneous
Dermal (Closed patch)
IV
Inhalation

Function

-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

Search by Effect

Organ / System

-- Select --
Immune System
Nasal mucosa
Oral cavity
Respiratory

Submit Reset Basic Search

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Then the total number of excipients existing for the given search criteria are more than one then it appears as shown below

The screenshot shows the EUPFI website interface. At the top, there are logos for EUPFI, STEP database, and uspfi. Below the logos, a yellow navigation bar contains the text 'Basic Search | Advanced Search | Logout'. The main content area is titled 'Excipient(s) Intermediate Page :'. It displays 'Number of Excipient found: 2' and a list of three checkboxes: 'All', 'Benzalkonium chloride', and 'Benzoic acid'. A yellow 'Submit' button is located below the list. The footer of the page includes 'Developed by GVK BIO' and logos for G-STAR and G-BIOM.

User can select more than one excipient using the check boxes and click “Submit” button as shown below

This is a close-up of the selection form. It shows the text 'Number of Excipient found: 2' at the top. Below it, there are three checkboxes, each with a green checkmark: 'All', 'Benzalkonium chloride', and 'Benzoic acid'. A yellow 'Submit' button is positioned at the bottom of the form. The entire form is enclosed in a light blue border.

Then the Search Results page appears displaying the relevant excipient data as shown below

Search Results Total References: 34 Record 1 of 2

Excipient Navigation

General Information Excipient Chem ID

Excipient Chemical Name: Benzalkonium chloride
CAS Registry Number: 8001-54-5

1 Go First Previous Next Last

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data Non Clinical Data **In vitro Data** Regulatory Reference Reviews

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Do
88	Benzalkonium Chloride	Acute Exposure	Unspecified	Unspecified	Unspecified	Unspecified	Intranasal	0.

User can navigate in between the excipients to view the resultant data using “<First <Previous> Next >Last” navigation links

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

1. Search by Excipients

- Study Type
- Species
- Age Category

- Route of Exposure/Administration
- Function

2. Search by Effect

- ✓ Organ/System

6.2.1 Search by Excipient

Search by Excipients includes all the data related to the excipient related to the Study Types, Species, Age and Route of Exposure/Administration. 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;

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type

- Chronic toxicity
- Experimental animal study
- Eye irritation
- Immunotoxicity
- Imunotoxicity

Species

- Select --
- Dogs
- Mice
- Rabbit
- Rabit

Age Category

- Select --
- Adult
- Adults
- Juvenile
- Juvinille

Route of Exposure / Administration

- Select --
- Inhalation
- Intravenous
- Intravenous infusion
- Oral

Function

- Film-forming agent
- Ointment base
- Sweetening agent
- Tablet and capsule lubricant
- antimicrobial agent

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;

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: Eye irritation, Immunotoxicity, Immunotoxicity, Neurotoxicity, Ocular toxicity

Species: Rabbit, Rat, Rats, Zebrafish, chicks

Age Category: -- Select --, Adult, Adults, Juvenile, Juvenile

Route of Exposure / Administration: -- Select --, Inhalation, Intravenous, Intravenous infusion, Oral

Function: Film-forming agent, Ointment base, Sweetening agent, Tablet and capsule lubricant, antimicrobial agent

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.

Route of Exposure / Administration: -- Select --, Inhalation, Intravenous, Intravenous infusion, Oral

Function: tablet and capsule filler, tablet and capsule lubricant, tablet binder, tablet disintegrant, tablet disintegrant.

Search by Effect

Organ / System: -- Select --, kidney, Brain, Cellular system, Central Nervous System

Submit Reset [Basic Search](#)

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

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
 Acute toxicity
 Acute toxicity
 Carcinogenicity
 Chronic toxicity

Species: -- Select --
 Dogs
 Mice
 Rabbit
 Rabbit

Age Category: -- Select --
 Adult
 Adults
 Juvenile
 Juvenile

Route of Exposure / Administration: -- Select --
 Inhalation
 Intravenous
 Intravenous infusion
 Oral

Function: -- Select --
 Adsorbent
 Antimicrobial preservative
 Coating agent
 Confectionery base

6.2.2 Search by Effect

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

6.2.2.1 Organ/System

Indicates on which organ or system the effects are observed

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

Search by Effect

Organ / System: -- Select --
 kidney
 Brain
 Cellular system
 Central Nervous System

Submit Reset [Basic Search](#)

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

Clinical Data **Non Clinical Data**

Search For Excipients

Study Type: -- Select --
Acute toxicity
Acute toxicity
Carcinogenicity
Chronic toxicity

Species: -- Select --
Dogs
Mice
Rabbit
Rabit

Age Category: -- Select --
Adult
Adults
Juvenile
Juvinille

Route of Exposure / Administration: -- Select --
Inhalation
Intravenous
Intravenous infusion
Oral

Function: -- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

Search by Effect

Organ / System: -- Select --
kidney
Brain
Cellular system
Central Nervous System

Submit Reset [Basic Search](#)

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

saraswathi.nimmaraju@gvkbio.com Basic Search | Advanced Search | Logout

Number of Excipient found:2

☐ All
☐ Propyl paraben
☐ polysorbate 80

Developed by: **GVK¹BIO** **GOSTAR** **GOBIOM**

And in the above page user is allowed to select the required excipient using the check boxes and then click “Submit” button as shown below

Number of Excipient found:2

☐ All
☐ Propyl paraben
☒ polysorbate 80

Then the “Search Results” page appears considering the selected excipient as shown below

Search Results Total References: 35

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: polysorbate 80
 CAS Registry Number: 9005-65-6

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data](#) [Non Clinical Data](#) [Invitro Data](#) [Regulatory Reference](#) [Reviews](#)

Show/Hide Clinical Columns ☐

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Do
15	Polysorbate 80		Infants	1 -12;	Weeks	Unspecified	IV	9
17	Polysorbate 80	Sensitization	Adolescents, Adults	0 - >60	Years	F,M	Dermal (Closed Patch)	Ur

7 SEARCH RESULTS

Based on the search criteria given in the basic search page search results page appears. 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 “Basic Search” or from “Advanced Search”

Example: If user selects Excipient Name as “Benzyl alcohol”, CAS Registry Number as “100-51-6”, and Synonyms as “Benzylic alcohol” and clicks “Submit” button as shown below

Search by Excipient

Excipient Name: +
-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number: +
-- Select --
100-51-6
131-11-3
1319-77-3
16731-55-8

Synonyms (As per the Handbook of Excipients): +
-- Select --
1 vinyl 2 pyrrolidinone polymer
1,2-Benzenedicarboxylic acid, dimethyl ester
1,2-Diethyl phthalate
1,2-propanediol

Function: +
-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

[Advanced Search](#)

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Then the Search Results page appears displaying the corresponding information as shown below

Search Results Total References: 25 Record 1 of 1

Excipient Navigation

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: Benzyl alcohol

CAS Registry Number: 100-51-6

☐ Excipient Category/Function:
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data](#) [Non Clinical Data](#) [Invitro Data](#) [Regulatory Reference](#) [Reviews](#)

Show/Hide Clinical Columns ☐

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	D
35	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

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 Reference
- ✓ Reviews

Among those “General Information” and “Clinical Data” information appears by default as shown below

Search Results Total References: 25 Record 1 of 1

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: Benzyl alcohol
CAS Registry Number: 100-51-6

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data](#) [Non Clinical Data](#) [Invitro Data](#) [Regulatory Reference](#) [Reviews](#)

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	D
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34

7.1 General Information

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

Search Results Total References: 25 Record 1 of 1

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: Benzyl alcohol
CAS Registry Number: 100-51-6

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

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

Search Results Total References: 25

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: Benzyl alcohol
CAS Registry Number: 100-51-6

+ Excipient Category/Function :

+ Pharmacopoeial Status:

+ Regulatory Status:

+ Synonyms:

+ Acceptable Daily Intake:

+ Revision Date:

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

Search Results Total References: 27 Record 1 of 1

Excipient Navigation

[General Information](#) [Excipient Chem ID](#)

Excipient Chemical Name: Benzyl alcohol
CAS Registry Number: 100-51-6

- Excipient Category/Function :
Antimicrobial preservative;disinfectant;solvent.

- Pharmacopoeial Status:
JP XV; USP32?NF27 PhEur 6.5;

- Regulatory Status:
Included in the FDA Inactive Ingredients Database (dental injections, oral capsules, solutions and tablets, topical, and vaginal preparations). Included in parenteral and nonparenteral medicines licensed in the UK.
Included in the Canadian List of Acceptable Non-medicinal Ingredients.

- Synonyms:

alpha hydroxytoluene	benzylic alcohol	hydroxymethylbenzene	phenmethylol
phenylcarbinol	phenylmethanol		

- Acceptable Daily Intake:

General Acceptable Daily Intake 0-5 mg/kg bw (1996)	Acceptable Daily Intake for Pediatrics N/A
---	--

- Revision Date:
N/A

Note: Acceptable Daily Intake provides information of both “General Acceptable Daily Intake and Acceptable Daily Intake for Pediatrics”

- ✓ Frequency of Administration
- ✓ System/Organ
- ✓ Safety/Tolerability/Adverse Effects
- ✓ Dosage Form
- ✓ Conclusion/Comments
- ✓ Reference
- ✓ Reference Type

7.2.1 Ref ID

Ref ID accommodates the reference ID information of the selected excipient. If there is only one record there will be no color differentiation and the page appears as shown below

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	De
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

When user clicks “Ref ID” value then the complete reference information appears in a separated tabular format as shown below

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Details
35	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

REF ID	REFERENCE	TITLE	AUTHOR	REFERENCE TYPE	YEAR
36		Flier LJ Jr, Baker GL, Stegink LD. Effect Of Aspartame Loading On Plasma And Erythrocyte Free Amino Acid Concentrations In One-Year-Old Infants. J Nutr. 1983 Aug;113(8):1591-9. PubMed PMID: 6135765.			

The Reference information tabular format includes complete information about the related “Reference ID”, “Reference” information, “Title”, “Author”, “Reference Type” and “Year” as shown above.

7.2.2 Excipient Name

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews									
Show/Hide Clinical Columns									
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Details	
35	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34	
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50	
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34	
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15	

7.2.3 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.

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	De
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
95	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.4 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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	De
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
95	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.5 Age

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

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.6 Age Units

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

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.7 Gender

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.8 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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
36	Benzyl Alcohol	Toxicokinetics	Infant	1	Year	F,M	Oral	34
41	Benzyl Alcohol	Toxicokinetics	Unspecified	Unspecified	Unspecified	Unspecified	Oral	50
81	Benzyl Alcohol	Acute Toxicity	Adolescent,Children	5-13;	Years	F,M	Oral	34
85	Benzyl Alcohol	Acute Toxicity	Adult	18-25	Years	F,M	Oral	15

7.2.9 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

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Clinical Columns

Dose	Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
50; 300; 600	Mg	Unspecified	Unspecified	3 Times/Day For 2 Days		NA
34	Mg/Kg	2	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)
15;45	Mg/Kg Bw/Day	20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect
NA	Multiple Doses: 10%	Unspecified	Unspecified	Unspecified		Effects Unknown

7.2.10 Dose Units

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

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews		
Show/Hide Clinical Columns						
Dose	Dose Units	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
50; 300; 600	Mg	Unspecified	Unspecified	3 Times/Day For 2 Days		NA
34	Mg/Kg	2	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)
15;45	Mg/Kg Bw/Day	20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect
NA	Multiple Doses: 10%	Unspecified	Unspecified	Unspecified		Effects Unknown

7.2.11 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below in days, weeks or months

Clinical Data	Non Clinical Data	In vitro Data	Regulatory Reference	Reviews
Show/Hide Clinical Columns ⓘ				
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
▼	▼	▼	▼	▼
Unspecified	NA	Unspecified		Unspecified
Unspecified	Unspecified	3 Times/Day For 2 Days		NA
2	Weeks	Single	Neurophysiologic,Neuropsycholo ...More	No Effect On Cognitive And Beh ...More
20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo ...More	No Effect

7.2.12 Duration Units

Displays duration of the dose in units

Clinical Data	Non Clinical Data	In vitro Data	Regulatory Reference	Reviews
Show/Hide Clinical Columns ⓘ				
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
▼	▼	▼	▼	▼
Unspecified	NA	Unspecified		Unspecified
Unspecified	Unspecified	3 Times/Day For 2 Days		NA
2	Weeks	Single	Neurophysiologic,Neuropsycholo ...More	No Effect On Cognitive And Beh ...More
20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo ...More	No Effect

7.2.13 Frequency of Administration

This indicates the administration of doses to the test species (example: 2 doses per day, 5 days per week) as shown below

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews
Show/Hide Clinical Columns				
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
Unspecified	NA	Unspecified		Unspecified
Unspecified	Unspecified	3 Times/Day For 2 Days		NA
2	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)
20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect

7.2.14 System/Organ

Indicates on which organ or system the effects were observed

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews
Show/Hide Clinical Columns				
Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects
Unspecified	NA	Unspecified		Unspecified
Unspecified	Unspecified	3 Times/Day For 2 Days		NA
2	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)
20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect

7.2.15 Safety/Tolerability/adverse effects

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

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews						
Show/Hide Clinical Columns ⓘ						
	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Re
▼	▼	▼	▼	▼	▼	
	Unspecified	NA	Unspecified		Unspecified	As Di Si (...More)
	Unspecified	Unspecified	3 Times/Day For 2 Days		NA	
	2	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)	N C B
	20	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect	N R

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

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews						
Show/Hide Clinical Columns ⓘ						
Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments
▼	▼	▼	▼	▼		
	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)	No Effect On Cognitive And Beh (...More)	Conversion P(...More) Aspartame At Greater Than 10 T(...More)
	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect	Neuropsychologic Results; Adve (...More)	Large Daily Doses (20 Times T(...More)
ied	Unspecified	Unspecified		Slight Nausea	Administration Of Aspartame At (...More)	No Effect Of Aspartame Loading (...More)
	Weeks	Unspecified		Neurologic, Behavioral, Gastro (...More)	A-L-Aspartyl-L-Phenylalanine Con (...More)	No Biochemical Evidence Of Tox (...More)

Mouse hover on “more” link also displays the complete information of the “Adverse Effects” in a tooltip as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews						
Show/Hide Clinical Columns ⓘ						
Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments
▼	▼	▼	▼	▼		
	Weeks	Single	Neurophysiologic,Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)	No Effect On Cognitive And Beh (...More)	Conversion P(...More) Aspartame At Greater Than 10 T(...More)
	Days	3 Times Daily	Neurophysiologic,Neuropsycholo (...More)	No Effect on cognitive and behavioral status ; mild stomachache, mood swings, headaches	Neuropsychologic Results; Adve (...More)	Large Daily Doses (20 Times T(...More)
ied	Unspecified	Unspecified		Slight Nausea	Administration Of Aspartame At (...More)	No Effect Of Aspartame Loading (...More)
	Weeks	Unspecified		Neurologic, Behavioral, Gastro (...More)	A-L-Aspartyl-L-Phenylalanine Con (...More)	No Biochemical Evidence Of Tox (...More)

7.2.16 Dosage Form

Describe the results of examinations based on free text template (delete/add elements as appropriate) as shown below

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
ent	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						Conversion P[...More]		
	Weeks	Single	Neurophysiologic,Neuropsycholo [...More]	No Effect On Cognitive And Beh [...More]	No Effect On Cognitive And Beh [...More]	Aspartame At Greater Than 10 T[...More]		
	Days	3 Times Daily	Neurophysiologic,Neuropsycholo [...More]	No Effect	Neuropsychologic Results; Adve [...More]	Large Daily Doses (20 Times T[...More]		
	Unspecified	Unspecified		Slight Nausea	Administration Of Aspartame At [...More]	No Effect Of Aspartame Loading [...More]		
	Weeks	Unspecified		Neurologic, Behavioral, Gastro [...More]	A-L-Aspartyl-L-Phenylalanine Con [...More]	No Biochemical Evidence Of Tox [...More]		

When user clicks “more” link the complete information about the “Dosage Form” appears in an expanded mode as shown below

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
ent	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						Conversion P[...More]		
	Weeks	Single	Neurophysiologic,Neuropsycholo [...More]	No Effect On Cognitive And Beh [...More]	No Effect On Cognitive And Behavioral Status And Urinary Excretion Rates Of Monoamines And Metabolites In Children With ADD. [...Less]	Aspartame At Greater Than 10 T[...More]		
	Days	3 Times Daily	Neurophysiologic,Neuropsycholo [...More]	No Effect	Neuropsychologic Results; Adve [...More]	Large Daily Doses (20 Times T[...More]		

User can click “Less” link to close the expanded mode as shown below

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
ent	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						Conversion P[...More]		
	Weeks	Single	Neurophysiologic,Neuropsycholo [...More]	No Effect On Cognitive And Beh [...More]	No Effect On Cognitive And Behavioral Status And Urinary Excretion Rates Of Monoamines And Metabolites In Children With ADD. [...Less]	Aspartame At Greater Than 10 T[...More]		
	Days	3 Times Daily	Neurophysiologic,Neuropsycholo [...More]	No Effect	Neuropsychologic Results; Adve [...More]	Large Daily Doses (20 Times T[...More]		

Mouse hover on “more” link also displays the complete information of the “Dosage Form” in a tool tip as shown below

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns ⓘ								
ent	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						Conversion P (...More)		
Weeks	Single		Neurophysiologic, Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)	No Effect On Cognitive And Beh (...More)	Aspartame At Greater Than 10 T (...More)		
Days	3 Times Daily		Neurophysiologic, Neuropsycholo (...More)	No Effect	Neurophysiologic Results: A (...More)	no effect on cognitive and behavioral status and urinary excretion rates of monoamines and metabolites in children with ADD.		
Unspecified	Unspecified			Slight Nausea	Administration Of Aspartame At (...More)	No Effect Of Aspartame Loading (...More)		
Weeks	Unspecified			Neurologic, Behavioral, Gastro (...More)	A-L-Aspartyl-L-Phenylalanine Con (...More)	No Biochemical Evidence Of Tox (...More)		

7.2.17 Conclusion/Comments

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.

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns ⓘ								
ent	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
						Conversion P (...More)		
Weeks	Single		Neurophysiologic, Neuropsycholo (...More)	No Effect On Cognitive And Beh (...More)	No Effect On Cognitive And Beh (...More)	Aspartame At Greater Than 10 T (...More)		
Days	3 Times Daily		Neurophysiologic, Neuropsycholo (...More)	No Effect	Neurophysiologic Results: Adve (...More)	Large Daily Doses (20 Times T (...More)		
Unspecified	Unspecified			Slight Nausea	Administration Of Aspartame At (...More)	No Effect Of Aspartame Loading (...More)		
Weeks	Unspecified			Neurologic, Behavioral, Gastro (...More)	A-L-Aspartyl-L-Phenylalanine Con (...More)	No Biochemical Evidence Of Tox (...More)		

7.2.18 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.

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide Clinical Columns ⓘ									
Its	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
All ▾			All ▾	All ▾	All ▾				All ▾
12 Days			Daily	Renal			Conversion P (...More)	Regina Scherlie (Se), The MTT A (...More)	J
						No Effect On Cognitive And Beh (...More)	Aspartame At Greater Than 10 T (...More)		

7.2.19 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;

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide Clinical Columns ⓘ									
Its	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type
All ▾			All ▾	All ▾	All ▾				All ▾
12 Days			Daily	Renal			Conversion P (...More)	Regina Scherlie (Se), The MTT A (...More)	J
						No Effect On Cognitive And Beh (...More)	Aspartame At Greater Than 10 T (...More)		

7.3 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.

- ✓ Ref ID
- ✓ Excipient Name
- ✓ Study Type
- ✓ Species
- ✓ Age Category
- ✓ Age
- ✓ Age Units
- ✓ Gender

- ✓ Dose/Concentration
- ✓ Dose Units
- ✓ Route of Exposure/Administration
- ✓ Duration Of Treatment
- ✓ Duration Units
- ✓ Frequency Of Administration
- ✓ System/Organ
- ✓ Adverse Effect
- ✓ Dosage Form
- ✓ Conclusion/Comments
- ✓ Reference
- ✓ Reference Type

7.3.1 Ref ID

Ref ID accommodates the reference ID information of the selected excipient. If there is only one record there will be no color differentiation and the page appears as shown below

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
52	Ethanol	Tolerance	Mice	Juvenile	8	Weeks	F,M	3; 5; 13
53	Ethanol	Tolerance	Rat	Juvenile	8	Weeks	F,M	2; 4; 10
73	Ethanol	Chronic Toxicity	Rat	Juvenile	23	Days	F,M	9 (24-7)
74	Ethanol	Developmental Toxicity	Rat	Adult	100	Days	F,M	2000; 4000

If there are multiple excipients (records) then the navigation links appears in the search results page. And all the references of first record appears as and the color differentiation is also included to provide the variation in reference data as shown below

Search Results Total References: 57 Record 1 of 4

Excipient Navigation

General Information [Excipient Chem ID](#)

Excipient Chemical Name: Ethanol
CAS Registry Number: 64-17-5

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

[Clinical Data](#) [Non Clinical Data](#) [Invitro Data](#) [Regulatory Reference](#) [Reviews](#)

Show/Hide Non Clinical Columns

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Rat	Adult	Unspecified	Unspecified	M	100
27	Ethanol	Pharmacology	Rat	Adult	Unspecified	Unspecified	M	5; 10; 30; 200
38	Ethanol	Neurotoxicity	Rat	Unspecified	Unspecified	Unspecified	Unspecified	0.75-1.0

When user clicks “Ref ID” value then the complete reference information appears in a separated tabular format as shown below

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Rat	Adult	Unspecified	Unspecified	M	100
27	Ethanol	Pharmacology	Rat	Adult	Unspecified	Unspecified	M	5; 10; 30; 200
38	Ethanol	Neurotoxicity	Rat	Unspecified	Unspecified	Unspecified	Unspecified	0.75-1.0
32	Ethanol	Tolerance	Mice	Juvenile	8	Weeks	F,M	3; 5; 13
33	Ethanol	Tolerance	Rat	Juvenile	8	Weeks	F,M	2; 4; 10

REF ID	REFERENCE	TITLE	AUTHOR	REFERENCE TYPE	YEAR
38		G. Guiso, S. Caccia, A. Vezzani, M.A. Stasi, M. Salmona, M. Romano, S. Garattini. Effect Of Aspartame On Seizures In Various Models Of Experimental Epilepsy. Toxicol. Appl. Pharmacol., 96 (1988), Pp. 4857493			

The Reference information tabular format includes complete information about the related “Reference ID”, “Reference” information, “Title”, “Author”, “Reference Type” and “Year” as shown above.

7.3.2 Excipient Name

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	250; 500 1000
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100 200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100

7.3.3 Study Type

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	250; 500 1000
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100 200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100

7.3.4 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 as shown below

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	250; 500 1000
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100 200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100

7.3.5 Age Category

Age Category provides category in which the age has to be considered on the search criteria

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns ⓘ								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	250; 500 1000
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100 200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	200
27	Ethanol	Pharmacology	Mice	Adult	Unspecified	Unspecified	M	50; 100

7.3.6 Age

Age column provides the numerical entry of the age

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
38	Ethanol	Neurotoxicity	Rat	Unspecified	Unspecified	Unspecified	Unspecified	0.75-1.0
52	Ethanol	Tolerance	Mice	Juvenile	8	Weeks	F,M	3; 5; 13
53	Ethanol	Tolerance	Rat	Juvenile	8	Weeks	F,M	2; 4; 10
73	Ethanol	Chronic Toxicity	Rat	Juvenile	23	Days	F,M	9 (24-7)
74	Ethanol	Developmental	Rat	Adult	100	Days	F,M	2000; 4000

7.3.7 Age Units

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Non Clinical Columns								
Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
38	Ethanol	Neurotoxicity	Rat	Unspecified	Unspecified	Unspecified	Unspecified	0.75-1.0
52	Ethanol	Tolerance	Mice	Juvenile	8	Weeks	F,M	3; 5; 13
53	Ethanol	Tolerance	Rat	Juvenile	8	Weeks	F,M	2; 4; 10
73	Ethanol	Chronic Toxicity	Rat	Juvenile	23	Days	F,M	9 (24-7)
74	Ethanol	Developmental	Rat	Adult	100	Days	F,M	2000; 4000

7.3.8 Gender

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

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Non Clinical Columns

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
38	Ethanol	Neurotoxicity	Rat	Unspecified	Unspecified	Unspecified	Unspecified	0.75-1.0
52	Ethanol	Tolerance	Mice	Juvenile	8	Weeks	F,M	3; 5; 13
53	Ethanol	Tolerance	Rat	Juvenile	8	Weeks	F,M	2; 4; 10
73	Ethanol	Chronic Toxicity	Rat	Juvenile	23	Days	F,M	9 (24-7)
74	Ethanol	Developmental	Rat	Adult	100	Days	F,M	2000; 4000

7.3.9 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

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Non Clinical Columns

Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.10 Dose Units

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

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.11 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 will be displayed as shown below

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns ⓘ							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
<div>▼</div>	<div>▼</div>	<div>▼</div>	<div>▼</div>	<div>▼</div>	<div>▼</div>	<div>▼</div>	
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.12 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below in days, weeks or months

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.13 Duration Units

Displays duration of the dose in units (Weeks, Days)

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In B Weight
2000; 4000	Mg/Kg	Oral					

7.3.14 Frequency of Administration

This indicates the administration of doses to the test species (example: 2 doses per day, 5 days per week) as shown below

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.15 System/Organ

Indicates on which organ or system the effects were observed like Renal, Liver, Cardiovascular etc

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Non Clinical Columns							
Dose / Concentration	Dose Units	Route Of Exposure / Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect
0.75-1.0	G/Kg	Oral	Unspecified	Unspecified	Unspecified	Plasma, Brain	Convulsions
3; 5; 13	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
2; 4; 10	G/Kg/Day	Oral	4	Weeks	Continuous		No Effect
9 (24-7)	% (Gm/Kg)	Oral	9	Weeks	Continuous	Multi Organ	Reduction In Br Weight
2000; 4000	Mg/Kg	Oral					

7.3.16 Adverse Effect

It displays the adverse effects that are in the excipient appears in the above column

Clinical Data Non Clinical Data Intro Data Regulatory Reference Reviews									
Show/Hide Non Clinical Columns									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
90		Days	Unspecified	Kidney/Liver	Histopathological Changes In L [...More]	NOAEL - 4% ; LD50 - 2100-3450m [...More]			
6		Days	Every 24 H	Dopaminergic Neurons	Sodium Benzoate Exposure Can C [...More]	Was Able To Induce Neurotoxic [...More]			
2		Days	1g On First Day And 4g On Seco [...More]		Muscular, Weakness And Nausea. [...More]	A Dosage Of 1430 Mg, Of Sodium [...More]			
1		Month	Once A Day	Skin	Erythema And Edema	Daily Application			

7.3.17 Dosage Form

Describe the results of examinations based on free text template (delete/add elements as appropriate).







Describe the results of examinations based on free text template (delete/add elements as appropriate) as shown below

Clinical Data Non Clinical Data Intro Data Regulatory Reference Reviews									
Show/Hide Non Clinical Columns									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
90		Days	Unspecified	Kidney/Liver	Histopathological Changes In L [...More]	NOAEL - 4% ; LD50 - 2100-3450m [...More]			
6		Days	Every 24 H	Dopaminergic Neurons	Sodium Benzoate Exposure Can C [...More]	Was Able To Induce Neurotoxic [...More]			
2		Days	1g On First Day And 4g On Seco [...More]		Muscular, Weakness And Nausea. [...More]	A Dosage Of 1430 Mg, Of Sodium [...More]			
1		Month	Once A Day	Skin	Erythema And Edema	Daily Application			

When user clicks “More” link then the complete information appears in expanded mode as below

Clinical Data	Non Clinical Data	In Vitro Data	Regulatory Reference	Reviews					
Show/Hide Non Clinical Columns ⓘ									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
	2	Days	1g On First Day And 4g On Seco[...More]		Muscular, Weakness And Nausea, [...More]	A Dosage Of 1430 Mg, Of Sodium Benzoate/Kg Over A 2 Day Period Resulted I N The Death Of Thedog [...Less]			
	1	Month	Once A Day	Skin	Erythema And Edema	Daily Application For 1 Month [...More]			
	30	Days	Unspecified	Adrenal,Liver,Upper		LD50 -			

User can click “Less” link to close the expanded mode. When user places mouse hover on “More” link then the detailed information appears in a tool tip as shown below

Clinical Data	Non Clinical Data	In Vitro Data	Regulatory Reference	Reviews					
Show/Hide Non Clinical Columns ⓘ									
Administration	Duration Of Treatment	Duration Units	Frequency Of Administration	System/Organ	Adverse Effect	Dosage Form	Conclusion / Comments	Reference	Reference Type
									
2		Days	1g On First Day And 4g On Seco(More)		Muscular, Weakness And Nausea, (More)	A Dosage Of 1430 Mg. Of Sodium Benzoate/Kg Over A 2 Day Period Resulted In The Death Of The dog (More)			
1		Month	Once A Day	Skin	Erythema And Edema	Daily Application For 1 Month (More)	a dosage of 1430 mg, of sodium benzoate/kg over a 2 day period resulted in the death of the dog (More)		
30		Days	Unspecified	Adrenal,Liver,Upper Intestine, (More)		LD50 - 4070mg/Kg			
18-24		Days	Daily	Unspecified	Hemorrhagic Pneumonia With Edema (More)	In The 8 % Dose Level (Approx. (More))			

7.3.18 Conclusion/Comments

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.

7.3.19 Reference

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.

7.3.20 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;

7.4 *Invitro data*

Invitro Data provides the complete information about the

- ✓ Ref ID
- ✓ Excipient Name
- ✓ Study Type
- ✓ Species
- ✓ Dose
- ✓ Dose Units
- ✓ Route of Exposure or Administration
- ✓ Duration of Treatment
- ✓ Duration Units
- ✓ System/Organ
- ✓ Safety/Tolerability/Adverse Effects
- ✓ Dosage Form
- ✓ Conclusion/Comments
- ✓ Reference
- ✓ Reference Type

7.4.1 Ref ID

Ref ID accommodates the reference ID information of the selected excipient. If there is only one record there will be no color differentiation and the page appears as shown below

Clinical DataNon Clinical DataInvitro DataRegulatory ReferenceReviews

Show/Hide Invitro Columns

Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre-Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

When user clicks “Ref ID” value then the complete reference information appears in a separated tabular format as shown below

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews					
Show/Hide Invitro Columns (0)									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre-Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

The Reference information tabular format includes complete information about the related “Reference ID”, “Reference” information, “Title”, “Author” , “Reference Type” and “Year” as shown above.

7.4.2 Excipient Name

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews									
Show/Hide Invitro Columns									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre. Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

7.4.3 Study Type

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

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews									
Show/Hide Invitro Columns									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre. Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

7.4.4 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 as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre- Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

7.4.5 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

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre- Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

7.4.6 Dose Units

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

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns									
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System
22	Benzyl Alcohol	Pharmacology	Bovine	143	µG/MI	Incubation	2	Hr	Bovine
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre- Lipase
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood

7.4.7 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

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews										
Show/Hide In vitro Columns ⓘ										
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System	
22	Benzyl Alcohol	Pharmacology	Bovine	143	µg/MI	Incubation	2	Hr	Bovine	
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre. Lipase	
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate	
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood	

7.4.8 Duration of Treatment

Based on the excipient the complete duration of the treatment will appear in the corresponding column as shown below in days, weeks or months

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews										
Show/Hide In vitro Columns ⓘ										
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of Treatment	Duration Units	System	
22	Benzyl Alcohol	Pharmacology	Bovine	143	µg/MI	Incubation	2	Hr	Bovine	
22	Benzyl Alcohol	Pharmacology	-	1.25	Mg/MI	Incubation	2	Hr	Pancre. Lipase	
22	Benzyl Alcohol	Pharmacology	Rabbit	10; 20; 40	Mg/L				Isolate	
22	Benzyl Alcohol	Pharmacology	Rabbit	-	-	Incubation	-	-	Blood	

7.4.9 Duration Units

Displays duration of the dose in units

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip [...More]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	*	*	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

7.4.10 System/Organ

Indicates on which organ or system the effects were observed

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip [...More]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	*	*	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

7.4.11 Safety/Tolerability/adverse effects

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

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip [...More]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	*	*	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

7.4.12 Dosage Form

Describe the results of examinations based on free text template (delete/add elements as appropriate) as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip [...More]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	-	-	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

When user clicks “more” link the complete information about the “Dosage Form appears in an expanded mode as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lipase Activity. [...Less]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	-	-	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

User can click “Less” link to close the expanded mode as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns ⓘ									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of [...More]			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip [...More]				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve [...More]	The Ability Of Aspartame To Af [...More]			
	-	-	Blood	No Effect	The Average Coagulation Time O [...More]	Effect On Blood Coagulation Wa [...More]			

Mouse hover on “more” link also displays the complete information of the “Dosage Form” in a tool tip as shown below

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of More			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip More				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve More	no significant decrease in lipase activity. Aspartame To Af More			
			Blood	No Effect	The Average Coagulation Time O More	Effect On Blood Coagulation Wa More			

7.4.13 Conclusion/Comments

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.

Clinical Data Non Clinical Data In Vitro Data Regulatory Reference Reviews									
Show/Hide In Vitro Columns									
Exposure Or Administration	Duration Of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Dosage Form	Conclusion / Comments	Reference	Reference Type	
	2	Hr	Bovine Pepsin	No Effect	Did Not Inhibit Pepsin	In Vitro Antipepsin Activity Of More			
	2	Hr	Pancreatic Lipase	No Effect On Lipase Activity	No Significant Decrease In Lip More				
			Isolated Heart	No Effect	Aspartame Was Inactive In Reve More	The Ability Of Aspartame To Af More			
			Blood	No Effect	The Average Coagulation Time O More	Effect On Blood Coagulation Wa More			

7.4.14 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.

7.4.15 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;

7.5 Regulatory Reference

Regulatory Reference includes the references to the regulations, and regulatory requirements for a specific substance.

7.5.1 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.

7.5.2 Reference 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.

Clinical Data Non Clinical Data In vitro Data Regulatory Reference Reviews	
Ref ID	Reference
49	
67	
68	
69	
77	
79	

When user clicks “Ref ID” link in the “Regulatory References” table as shown below the 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	Non Clinical Data	In vitro Data	Regulatory Reference	Reviews		
Ref ID		Reference				
49						
57						
98						
59						
77						
79						
REF ID	REFERENCE	TITLE		AUTHOR	REFERENCE TYPE	YEAR
49		JECFA Toxicological Evaluation Of Some Food Additives Including Anticaking Agents, Antimicrobials, Antioxidants, Emulsifiers And Thickening Agents. WHO Food Additives Series, (5), (1974).				

7.6 Reviews

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

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

Clinical Data	Non Clinical Data	In vitro Data	Regulatory Reference	Reviews
Ref ID	Reference			
40				
59				
77				
91				
99				

7.6.1 References

Indicates 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.

7.6.2 Reference 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 as shown below

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews					
Ref ID			Reference		
40					
59					
72					
81					
99					
...					

REF ID	REFERENCE	TITLE			AUTHOR	REFERENCE TYPE	YEAR
59		Maher TJ, Wurtman RJ. Possible Neurologic Effects Of Aspartame, A Widely Used Food Additive. Environ Health Perspect. 1987 Nov;75:53-7. Review. PubMed PMID:3319565; PubMed Central PMCID: PMC1474447.					

Then the entire information of the reference appears as a tabular separate with the “Ref ID, Reference, Title, Author, Reference Type and Year information as shown above

7.7 Customization

In the STEP application user is allowed to customize the excipient selection by selecting more than one excipient using “Basic Search” as shown below using CTRL key

Search by Excipient

Excipient Name

Aspartame||Benzalkonium chloride||Benzoic acid

-- Select --
Aspartame
Benzalkonium chloride
Benzoic acid
Benzyl alcohol

CAS Registry Number

-- Select --
100-51-6
131-11-3
1319-77-3
16731-55-8

Synonyms
(As per the Handbook of Excipients)

-- Select --
1-vinyl 2-pyrrolidinone polymer
1,2-Benzenedicarboxylic acid, dimethyl ester
1,2-Diethyl phthalate
1,2-propanediol

Function

-- Select --
Adsorbent
Antimicrobial preservative
Coating agent
Confectionery base

Submit

Reset

Advanced Search

* Please enter minimum of 3 characters to populate suggestions.
Please use "Ctrl" + "Mouse click" to select multiple values.
Please use "+" icon to open selection dialog box.
Progressive search will be based and filtered on the values already selected in dropdowns.

Then click “Submit” button then below page appears

Excipient(s) Intermediate Page

Number of Excipient found: 2

☐ All
☐ Benzalkonium chloride
☐ Benzyl alcohol

Submit

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

saraswathi.nimmaraju@gvkbio.com Basic Search | Advanced Search | Logout

Excipient(s) Intermediate Page

Number of Excipient found: 2

☒ All
☒ Benzalkonium chloride
☒ Benzyl alcohol

Submit

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

Search Results Total References: 34 Record 1 of 2

Excipient Navigation

General Information [Excipient Chem ID](#)

Excipient Chemical Name: Benzalkonium chloride
CAS Registry Number: 8001-54-5

Go
[First](#) [Previous](#) [Next](#) [Last](#)

☐ Excipient Category/Function:
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data | **Non Clinical Data** | **In vitro Data** | **Regulatory Reference** | **Reviews**

Show/Hide Clinical Columns ☐

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
3a	Benzalkonium Chloride	Chronic Toxicity	Adults	64-98	Years	F,M	Intraocular	0.1
4a	Benzalkonium Chloride	Long Term	Adults	Unspecified	Unspecified	F,M	Intranasal	0.1




In the search results page user can customize the columns by using the drop down option in all the columns as shown below

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Do
3	Benzalkonium Chloride	<input checked="" type="checkbox"/> Select All <input checked="" type="checkbox"/> Acute Exposure <input checked="" type="checkbox"/> Chronic Toxicity <input checked="" type="checkbox"/> Immunotoxicity <input checked="" type="checkbox"/> Long Term		64-98	Years	F,M	Intraocular	0.1
4	Benzalkonium Chloride			Unspecified	Unspecified	F,M	Intranasal	0.1
56	Benzalkonium Chloride	Immunotoxicity	Adults	42-45;	Year	M	Inhalation	60
88	Benzalkonium Chloride	Acute Exposure	Unspecified	Unspecified	Unspecified	Unspecified	Intranasal	0.1

In the drop downs of all columns all the values that are in the drop downs appears as shown above along with check boxes and user can select/deselect the required value (Study Type) using the checkboxes as shown below

When user selects the required checkboxes then only those values appears in the results as shown below

Clinical Data Non Clinical Data Invitro Data Regulatory Reference Reviews								
Show/Hide Clinical Columns								
Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Do
4	Benzalkonium Chloride	<input type="checkbox"/> Select All <input type="checkbox"/> Acute Exposure <input type="checkbox"/> Chronic Toxicity <input checked="" type="checkbox"/> Immunotoxicity <input checked="" type="checkbox"/> Long Term		Unspecified	Unspecified	F,M	Intranasal	0.1
56	Benzalkonium Chloride			42-45;	Year	M	Inhalation	60

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews				
Show/Hide Clinical Columns 								
Ref ID	Excipient Name	Study Type 	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
								
4	Benzalkonium Chloride	Long Term	Adults	Unspecified	Unspecified	F,M	Intranasal	0.
55	Benzalkonium Chloride	Immunotoxicity	Adults	42-45;	Year	M	Inhalation	60

Note:

As the data columns in all the tabs among the “Clinical, Non-Clinical, Regulatory Reference, Invitro, Regulatory References and Reviews” are different the customization selection applicable to that particular tab only if user selects any other tab among “Clinical, Non-Clinical, Invitro, Regulatory Reference, and Reviews” then the complete data appears irrespective of selected customized value from the drop down as shown below

Clinical Data

Non Clinical Data

Invitro Data

Regulatory Reference

Reviews

Show/Hide Non Clinical Columns

Ref ID	Excipient Name	Study Type	Species	Age Category	Age	Age Units	Gender	Dose / Concentrat
5	Benzalkonium Chloride	Ocular Toxicity	Rabit	Unspecified	Unspecified	Unspecified	Unspecified	0.01; 0.1
8	Benzalkonium Chloride	Neurotoxicity	Rat	Juvenile	2-3;	Months	F	30
92	Benzalkonium Chloride	Immunotoxicity	Rat	Juvenile	2-3;	Months	F	52.84 ;37.64; 30

7.8 Show/Hide Columns

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

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Invitro Columns (+)							
Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of T
<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>	<div><div></div><div></div></div>
11	Benzalkonium Chloride	Cytotoxicity	Human	0.00005; 0.0001; 0.0005; 0.00 (...More)	%	Incubation	30
24	Benzalkonium Chloride	Corneal Toxicity	Human	0.02;0.01	%	Incubation	2
24	Benzalkonium Chloride	Corneal Toxicity	Human	0.02;0.01	%	Incubation	2

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.

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Invitro Columns							
Ref ID	Excipient	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of T
11	Benzalkonium Chloride			0.00005; 0.0001; 0.0005; 0.00 (...More)	%	Incubation	30
24	Benzalkonium Chloride	Corneal Toxicity	Human	0.02;0.01	%	Incubation	2
24	Benzalkonium Chloride	Corneal Toxicity	Human	0.02;0.01	%	Incubation	2
46	Benzalkonium Chloride	Cytotoxicity	Rabbit	0.02; 0.01; 0.005	%	Topical	45

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

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews			
Show/Hide Invitro Columns							
Ref ID	Study Type	Excipient Name	Route of Treatment	Duration Units	System/Organ	Safety / Tolerability / Adverse Effects	Result/Findings
<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>	<div></div>
11	Cytotoxicity			Min	Human Corneal Epithelial Cells ...More	Cytotoxic Effects-DNA Damage	Even At Low Concentration ...More
24	Corneal Toxicity	0.02;0.01	2	Days	Cornea Endothelium	Slight Clarification Of The Endothelium ...More	Caused On Slight Clarification ...More
24	Corneal Toxicity	0.02;0.01	2	Days	Cornea Endothelium	Slight Clarification Of The Endothelium ...More	Caused On Slight Clarification ...More
46	Cytotoxicity	0.02; 0.01; 0.005	45	Minutes	Cornea	Significant Corneal Superficial Inflammation ...More	LOEL - 0.01% Benzalkonium Chloride

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

Clinical Data	Non Clinical Data	Invitro Data	Regulatory Reference	Reviews
Show/Hide Invitro Columns				
Ref ID	Excipient Name	Study Type	Reference	Reference Type
11	Benzalkonium Chloride	Cytotoxicity		
24	Benzalkonium Chloride	Corneal Toxicity		
24	Benzalkonium Chloride	Corneal Toxicity		
46	Benzalkonium Chloride	Cytotoxicity		
46	Benzalkonium Chloride	Cytotoxicity		
93	Benzalkonium Chloride	Genotoxicity		
93	Benzalkonium Chloride	Genotoxicity		
103	Benzalkonium Chloride	Immunotoxicity		
103	Benzalkonium Chloride	Immunotoxicity		

7.9 Navigations in Search Results page

Whenever user selects more than one excipient as shown below

Excipient(s) Intermediate Page

Number of Excipient found: 2

- ☒ All
- ☒ Benzalkonium chloride
- ☒ Benzyl alcohol

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

Search Results Total References: 34 Record 1 of 2

General Information Excipient Chem ID

Excipient Chemical Name: Benzalkonium chloride
CAS Registry Number: 8001-54-5

Excipient Navigation: 1 [First](#) [Previous](#) [Next](#) [Last](#)

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Show/Hide Invitro Columns ☐

Ref ID	Excipient Name	Study Type	Species	Dose	Dose Units	Route Of Exposure Or Administration	Duration Of T
11	Benzalkonium Chloride	Cytotoxicity	Human	0.00005; 0.0001; 0.0005; 0.00 (...More)	%	Incubation	30
11	Benzalkonium Chloride	Cytotoxicity	Human	0.00005; 0.0001; 0.0005; 0.00 (...More)	%	Incubation	30

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.

And on clicking the “Next” navigation link other excipient “Benzoic acid” information appears as shown below

Search Results Total References: 34 Record 2 of 2

Excipient Navigation

General Information Excipient Chem ID

Excipient Chemical Name: Benzoic acid 2 Go First Previous Next Last

CAS Registry Number: 65-85-0

☐ Excipient Category/Function :
☐ Pharmacopoeial Status:
☐ Regulatory Status:
☐ Synonyms:
☐ Acceptable Daily Intake:
☐ Revision Date:

Clinical Data
Non Clinical Data
Invitro Data
Regulatory Reference
Reviews

Show/Hide Clinical Columns

Ref ID	Excipient Name	Study Type	Age Category	Age	Age Units	Gender	Route Of Exposure Or Administration	Dose
3	Benzoic Acid	Chronic Toxicity	Adults	64-98	Years	F,M	Intraocular	0.1
4	Benzoic Acid	Long Term	Adults	Unspecified	Unspecified	F,M	Intranasal	0.1

7.10 No records found

If there is no data available then the below message appears

Clinical Data
Non Clinical Data
Regulatory Reference
Safety Or Toxicological Reviews

No Records Found

8 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

The screenshot shows the 'Search Results' page for 'Benzyl alcohol'. The top navigation bar includes 'Basic Search', 'Advanced Search', 'Export', and 'Logout'. The 'Export' link is highlighted. Below the search results, there are tabs for 'General Information', 'Excipient Chem ID', 'Clinical Data', 'Non Clinical Data', 'Invitro Data', 'Regulatory Reference', and 'Reviews'. The 'Clinical Data' tab is selected, displaying a table with columns: Ref ID, Excipient Name, Study Type, Age Category, Age, Age Units, Gender, Route Of Exposure Or Administration, Dose, and Dose Units. The table is currently empty.

When user clicks “Export” link from the main menu bar then the below page appears

The screenshot shows the 'Select to Export' page. It has a header with 'Basic Search', 'Advanced Search', and 'Logout'. Below the header, there are checkboxes for selecting the information to export. The 'General Information' section includes checkboxes for 'All', 'Excipient ID', 'CAS Registry Number', 'Excipient Name', 'Excipient Category/Function', 'Pharmacopoeial Status', 'Regulatory Status', 'Synonyms', 'General Acceptable Daily Intake', 'Acceptable Daily Intake for Pediatrics', and 'Revision Date'. The 'Clinical Data' section includes checkboxes for 'All', 'Excipient ID', 'CAS Registry Number', 'Excipient Name', 'Excipient Category/Function', 'Pharmacopoeial Status', 'Regulatory Status', 'Synonyms', 'General Acceptable Daily Intake', 'Acceptable Daily Intake for Pediatrics', and 'Revision Date'. At the bottom, there are buttons for 'Export to Excel', 'Export to PDF', and 'Cancel Export'.

In this page all the information can be selected based on user requirements using the check boxes and the data in the corresponding categories is provided in collapsed mode and user can click “[+]” symbol besides the name of the category to view the expanded mode as shown below

Select to Export			
General Information			
<input type="checkbox"/> All	<input type="checkbox"/> Excipient ID	<input type="checkbox"/> CAS Registry Number	<input checked="" type="checkbox"/> Excipient Name
<input type="checkbox"/> Excipient Category/Function	<input type="checkbox"/> Pharmacopoeial Status	<input type="checkbox"/> Regulatory Status	<input type="checkbox"/> Synonyms
<input type="checkbox"/> General Acceptable Daily Intake	<input type="checkbox"/> Acceptable Daily Intake for Pediatrics	<input type="checkbox"/> Revision Date	
Clinical Data			
<input type="checkbox"/> All	<input type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Age Category	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units	<input type="checkbox"/> Gender
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input type="checkbox"/> Duration Of Treatment
<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type
Non Clinical Data			
<input type="checkbox"/> All	<input type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Exposure Period	<input type="checkbox"/> Species	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units
<input type="checkbox"/> Age Category	<input type="checkbox"/> Gender	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration
<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects	<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments
<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type		
In vitro Data			
<input type="checkbox"/> All	<input type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Species	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input type="checkbox"/> Route Of Exposure Or Administration
<input type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	
<input type="checkbox"/> Reference Type			
Reference			
<input type="checkbox"/> Reference			
<div> Export to Excel Export to PDF Cancel Export </div>			

Then select the required fields using the check boxes then after selecting the required fields using the check boxes clicks “Export to Excel” to export the data in excel format or “Export to PDF” to export the data in PDF format

Select to Export

General Information

<input type="checkbox"/> All	<input type="checkbox"/> Excipient ID	<input type="checkbox"/> CAS Registry Number	<input checked="" type="checkbox"/> Excipient Name
<input checked="" type="checkbox"/> Excipient Category/Function	<input checked="" type="checkbox"/> Pharmacopoeial Status	<input checked="" type="checkbox"/> Regulatory Status	<input checked="" type="checkbox"/> Synonyms
<input checked="" type="checkbox"/> General Acceptable Daily Intake	<input type="checkbox"/> Acceptable Daily Intake for Pediatrics	<input type="checkbox"/> Revision Date	

Clinical Data

<input type="checkbox"/> All	<input type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Age Category	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units	<input type="checkbox"/> Gender
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input type="checkbox"/> Duration Of Treatment
<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability / Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	<input checked="" type="checkbox"/> Reference Type

Non Clinical Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Exposure Period	<input type="checkbox"/> Species	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units
<input type="checkbox"/> Age Category	<input type="checkbox"/> Gender	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration
<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability / Adverse Effects	<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments
<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type		

Invitro Data

<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Route Of Exposure Or Administration
<input checked="" type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability / Adverse Effects
<input checked="" type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	
<input type="checkbox"/> Reference Type			

Reference

☒ Reference

Export to Excel Export to PDF [Cancel Export](#)

8.1 Export to Excel

When user selects “Export to Excel” button from the “Select to Export” page as shown below

Select to Export

General Information

All

Excipient ID

CAS Registry Number

Excipient Name

Excipient Category/Function

Pharmacopoeial Status

Regulatory Status

Synonyms

General Acceptable Daily Intake

Acceptable Daily Intake for Pediatrics

Revision Date

Clinical Data

All

Ref ID

Excipient Name

Study Type

Age Category

Age

Age Units

Gender

Route Of Exposure Or Administration

Dose

Dose Units

Duration Of Treatment

Duration Unit

Frequency Of Administration

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Non Clinical Data

All

Ref ID

Excipient Name

Study Type

Exposure Period

Species

Age

Age Units

Age Category

Gender

Dose

Dose Units

Route Of Exposure Or Administration

Duration Of Treatment

Duration Unit

Frequency Of Administration

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Invitro Data

All

Ref ID

Excipient Name

Study Type

Species

Dose

Dose Units

Route Of Exposure Or Administration

Duration Of Treatment

Duration Unit

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Reference

Reference

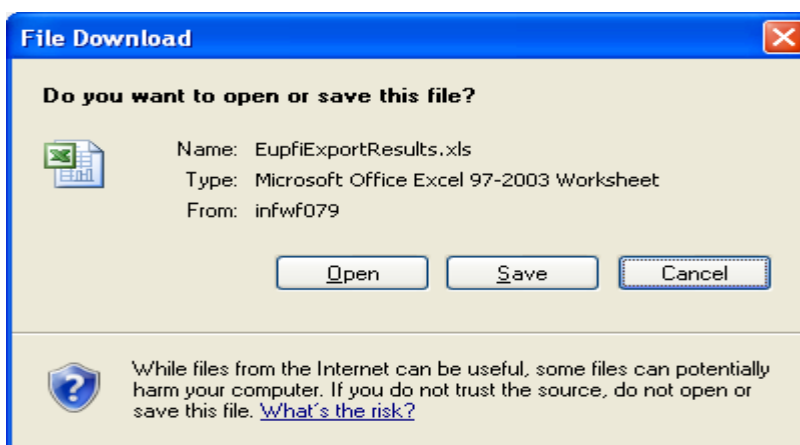
Export to Excel

Export to PDF

Cancel Export

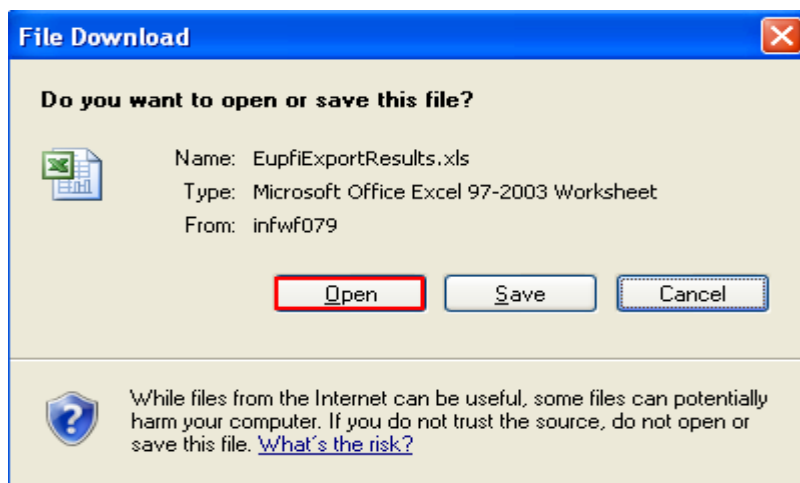
Select to Export			
General Information			
<input type="checkbox"/> All	<input type="checkbox"/> Excipient ID	<input type="checkbox"/> CAS Registry Number	<input checked="" type="checkbox"/> Excipient Name
<input checked="" type="checkbox"/> Excipient Category/Function	<input checked="" type="checkbox"/> Pharmacopoeial Status	<input checked="" type="checkbox"/> Regulatory Status	<input checked="" type="checkbox"/> Synonyms
<input checked="" type="checkbox"/> General Acceptable Daily Intake	<input type="checkbox"/> Acceptable Daily Intake for Pediatrics	<input type="checkbox"/> Revision Date	
Clinical Data			
<input type="checkbox"/> All	<input type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Age Category	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units	<input type="checkbox"/> Gender
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input type="checkbox"/> Duration Of Treatment
<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects
<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	<input checked="" type="checkbox"/> Reference Type
Non Clinical Data			
<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input type="checkbox"/> Study Type
<input type="checkbox"/> Exposure Period	<input type="checkbox"/> Species	<input type="checkbox"/> Age	<input type="checkbox"/> Age Units
<input type="checkbox"/> Age Category	<input type="checkbox"/> Gender	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units
<input type="checkbox"/> Route Of Exposure Or Administration	<input type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> Frequency Of Administration
<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects	<input type="checkbox"/> Dosage Form	<input type="checkbox"/> Conclusion / Comments
<input type="checkbox"/> Reference	<input type="checkbox"/> Reference Type		
Invitro Data			
<input type="checkbox"/> All	<input checked="" type="checkbox"/> Ref ID	<input checked="" type="checkbox"/> Excipient Name	<input checked="" type="checkbox"/> Study Type
<input checked="" type="checkbox"/> Species	<input type="checkbox"/> Dose	<input type="checkbox"/> Dose Units	<input checked="" type="checkbox"/> Route Of Exposure Or Administration
<input checked="" type="checkbox"/> Duration Of Treatment	<input type="checkbox"/> Duration Unit	<input type="checkbox"/> System/Organ	<input type="checkbox"/> Safety / Tolerability /Adverse Effects
<input checked="" type="checkbox"/> Dosage Form	<input checked="" type="checkbox"/> Conclusion / Comments	<input type="checkbox"/> Reference	
<input type="checkbox"/> Reference Type			
Reference			
<input checked="" type="checkbox"/> Reference			
<div> <div>Export to Excel</div> <div>Export to PDF</div> <div>Cancel Export</div> </div>			

Then the “File Download” window appears as shown below

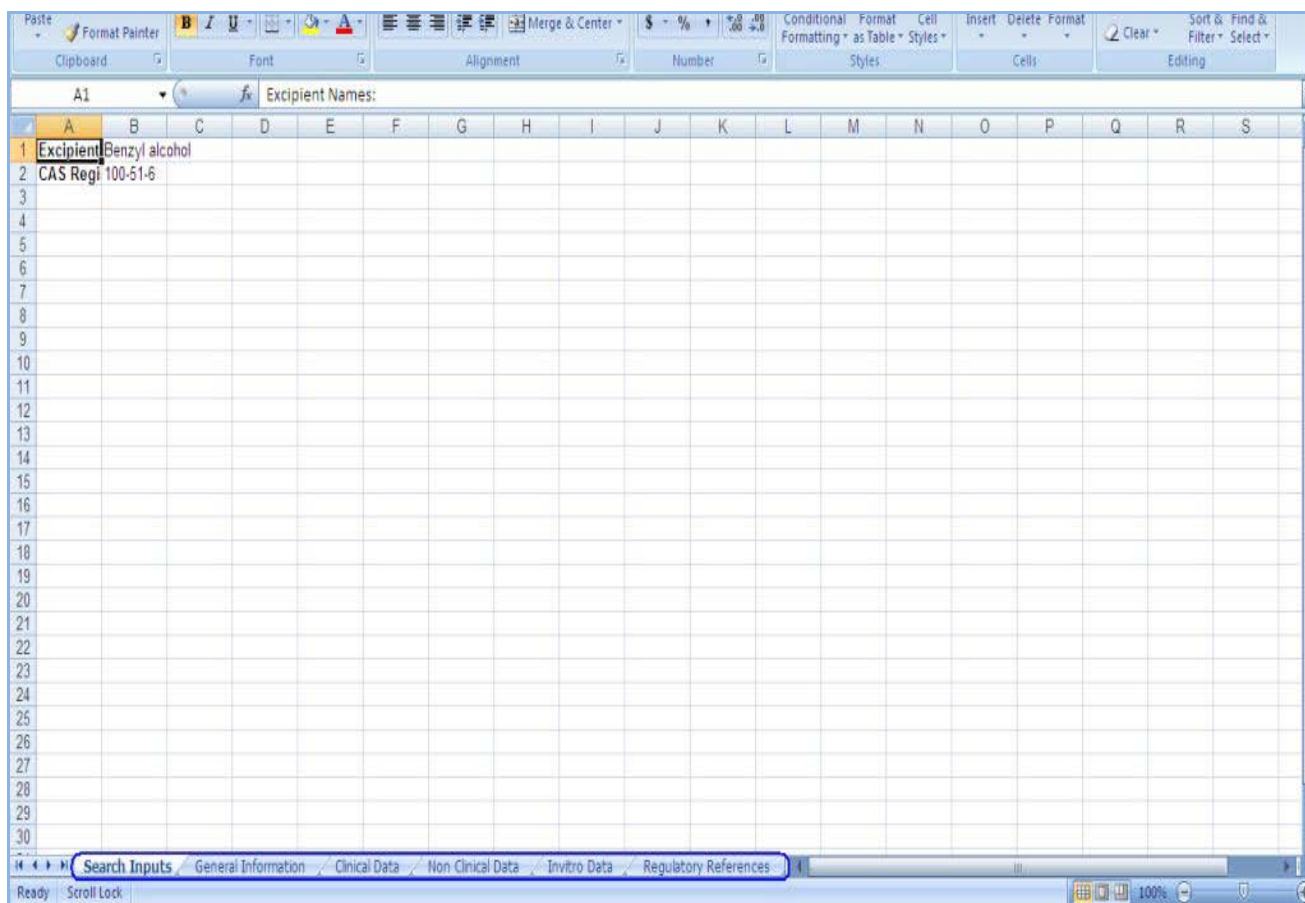


User can open or save or cancel the file download using “Open, Save, Cancel” button

When user clicks “Open” button as shown below



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



First page “Search Inputs” provides the information about the search criteria given by the user

8.2 Export to PDF

When user clicks “Export to PDF” button as shown below

Select to Export

General Information

All

Excipient ID

CAS Registry Number

Excipient Name

Excipient Category/Function

Pharmacoposial Status

Regulatory Status

Synonyms

General Acceptable Daily Intake

Acceptable Daily Intake for Pediatrics

Revision Date

Clinical Data

All

Ref ID

Excipient Name

Study Type

Age Category

Age

Age Units

Gender

Route Of Exposure Or Administration

Dose

Dose Units

Duration Of Treatment

Duration Unit

Frequency Of Administration

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Non Clinical Data

All

Ref ID

Excipient Name

Study Type

Exposure Period

Species

Age

Age Units

Age Category

Gender

Dose

Dose Units

Route Of Exposure Or Administration

Duration Of Treatment

Duration Unit

Frequency Of Administration

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Invitro Data

All

Ref ID

Excipient Name

Study Type

Species

Dose

Dose Units

Route Of Exposure Or Administration

Duration Of Treatment

Duration Unit

System/Organ

Safety / Tolerability /Adverse Effects

Dosage Form

Conclusion / Comments

Reference

Reference Type

Reference

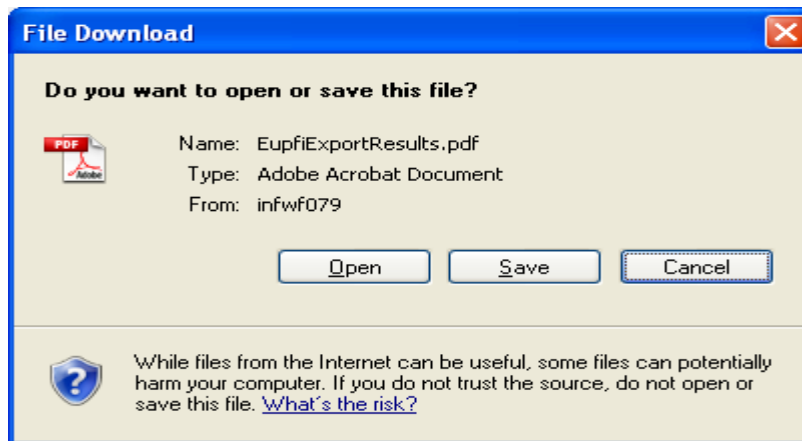
Reference

Export to Excel

Export to PDF

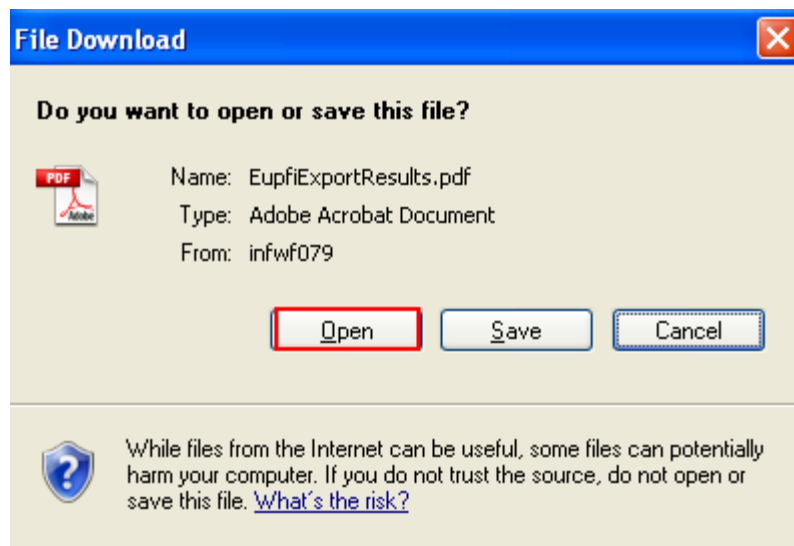
Cancel Export

Then the “File download” window appears as shown below



User can open or save or cancel the file download using “Open, Save, Cancel” button

When user clicks “Open” button as shown below



Then the PDF appears with the selected data as shown below

Eu – US PFI User Guide

Edit View Document Tools Window Help	
2 / 12 133% Find	
General Information :	
Record No : 1	
Excipient Name	Benzyl alcohol
Excipient Category/Function	Antimicrobial preservative`disinfectant`solvent.
Pharmacopoeial Status	JP XV; USP32–NF27 PhEur 6.5;
Regulatory Status	Included in the FDA Inactive Ingredients Database (dental injections, oral capsules, solutions and tablets, topical, and vaginal preparations). Included in parenteral and nonparenteral medicines licensed in the UK. Included in the Canadian List of Acceptable Non-medicinal Ingredients.
Synonyms	alpha hydroxytoluene,benzyllic alcohol,hydroxymethylbenzene,phenmethylo,phenylcarbinol,phenylmethanol
General Acceptable Daily Intake	0-5 mg/kg bw (1996)

First page “Search Inputs” provides the information about the search criteria given by the user and based on the categorization data in the PDF appears in separate pages

8.3 Cancel Export

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

Select to Export

General Information

☐ All
☒ Excipient Category/Function
☒ General Acceptable Daily Intake

☐ Excipient ID
☒ Pharmacopoeial Status
☐ Acceptable Daily Intake for Pediatrics

☐ CAS Registry Number
☒ Regulatory Status
☐ Revision Date

☒ Excipient Name
☒ Synonyms

Clinical Data

☐ All
☐ Age Category
☐ Route Of Exposure Or Administration
☐ Duration Unit
☐ Dosage Form

☐ Ref ID
☐ Age
☐ Dose
☐ Frequency Of Administration
☐ Conclusion / Comments

☒ Excipient Name
☐ Age Units
☐ Dose Units
☐ System/Organ
☐ Reference

☐ Study Type
☐ Gender
☐ Duration Of Treatment
☐ Safety / Tolerability /Adverse Effects
☒ Reference Type

Non Clinical Data

☐ All
☐ Exposure Period
☐ Age Category
☐ Route Of Exposure Or Administration
☐ System/Organ
☐ Reference

☒ Ref ID
☐ Species
☐ Gender
☐ Duration Of Treatment
☐ Safety / Tolerability /Adverse Effects
☐ Reference Type

☒ Excipient Name
☐ Age
☐ Dose
☐ Duration Unit
☐ Dosage Form

☐ Study Type
☐ Age Units
☐ Dose Units
☐ Frequency Of Administration
☐ Conclusion / Comments

Invitro Data

☐ All
☒ Species
☒ Duration Of Treatment
☒ Dosage Form
☐ Reference Type

☒ Ref ID
☐ Dose
☐ Duration Unit
☐ Conclusion / Comments

☒ Excipient Name
☐ Dose Units
☐ System/Organ
☐ Reference

☒ Study Type
☒ Route Of Exposure Or Administration
☐ Safety / Tolerability /Adverse Effects

Reference

☒ Reference

Export to Excel

Export to PDF

Cancel Export

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

9 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 consist 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.