

Pharmadex: User Guide for DGDA

April 2017



USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services





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About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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Key Words

Pharmadex, online medicine registration, CTD, ICH, quality, safety

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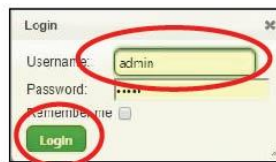
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1. ACCESSING PHARMADEX

- To log in, go to the homepage and click on the door in the upper right corner.



- Enter your username and the temporary password that was emailed to you, and then click “Login”.



- Once you login, you will see your username on the upper right corner.



1.1. Changing User Settings

- Once logged in, you can change your password and language settings by clicking on the “Settings” on the upper right corner.



- Enter in your current password (the one that was emailed to you) and a new password. Hit “Submit” once finished.

- You will receive a notification that your password has been successfully changed.

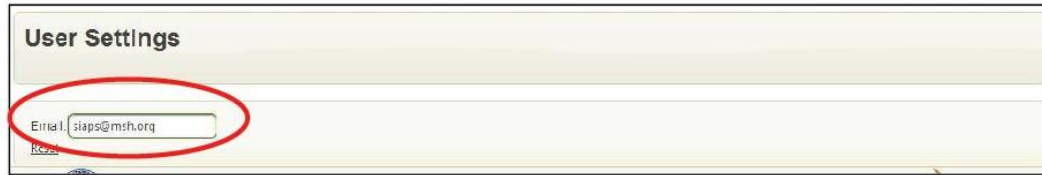
1.2. Resetting Password

- If you have forgotten your password, you can reset it. To do so, go to the homepage and click on the door icon in the upper right corner.



- Click on “Reset Password”.

- Enter the email address you used when you registered for Pharmadex and hit “Reset”. A new password will be emailed to you. To change your password, follow the instructions in the above section for changing passwords.



The screenshot shows a web form titled "User Settings". Below the title, there is a text input field labeled "Email:" containing the text "slaps@msh.org". This field is circled in red. Below the email field, there is a "Reset" button.

2. REGISTERING APPLICANT COMPANY AND COMPANY USERS

- To register an applicant company and their users, you have to click on **Registration > Registration Forms > Applicant Registration Form**.
- Currently Applicants cannot create their own Company Account or Associated Users. This task is handled by Pharmadex Admin User only. When a new application with CTD dossier will come, the Receiver at the DGDA receiving desk (assigned person) will fill-in up a form for the applicant company and authorized representative information.
- After creation of the Applicant Company User, an email will go to the authorized representative of that company informing them their User ID and initial Password. After that the Applicant Company’s user can log in the Pharmadex system and able to change their initial password themselves.
- The following section describe how can you create an Applicant Company and their User.

2.1. Create a Company Applicant

- To create a new Company Applicant you need to go to **Registration > Registration Forms > Application Registration Form**



- After clicking on the “Application Registration Form” menu the following screen will appear:



Applicant Registration

Applicant Detail

Applicant Name *

Address *

Country *

Applicant Type *

Manufacturing License #

Tax Number:

Email

Postal Code

Phone Number: *

Website

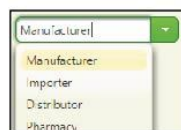
Person Responsible/Authorized to communicate with DGDA.

Registered Users Lookup

Add User

Responsible	Enabled	Name	Login Name	Email
No records found.				

- There are four types of Applicants. Admin user need to select one of the types:



Manufacturer

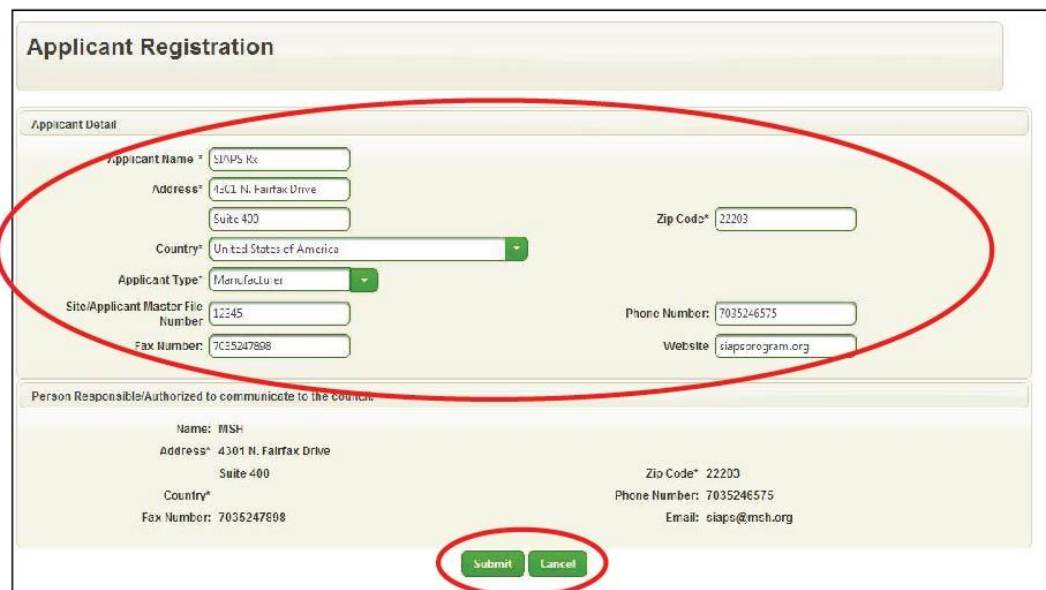
Manufacturer

Importer

Distributor

Pharmacy

- Fill in the required information and click on "Submit" button.



Applicant Registration

Applicant Detail

Applicant Name *

Address *

Suite 400

Country *

Applicant Type *

Site/Applicant Master File Number:

Fax Number:

Zip Code *

Phone Number:

Website:

Person Responsible/Authorized to communicate to the Council

Name:

Address *

Suite 400

Country *

Fax Number:

Zip Code *

Phone Number:

Email:

2.2. Add User or Registered Users with Company

- Without linking with existing registered users or adding a new user, you cannot create the Company Applicant.

- If you click on the “Submit” button without adding a new User or linking the Company Applicant with an existing user, the following error message will be displayed:

Applicant Registration

Applicant Detail

Applicant Name *
 Address *

 Country *
 Applicant Type *
 Manufacturing License #
 Fax Number:
 Email:
 Postal Code:
 Phone Number: *
 Website:
 Person Responsible: Authorized to communicate with DGDA.

☒ Please specify the details of person's responsible to contact on behalf of the applicant. Please specify the details of person's responsible to contact on behalf of the applicant.

Registered Users Lookup

Add User:

Responsible	Enabled	Name	Login Name	Email
No records found				

- Click on “New User” link
- Fill up the fields of the following popup –

Add User

Name: *
 Address: *

 Country: *
 Fax Number:
 Postal Code:
 Phone Number: *
 Email: *

- You cannot use one email address for creating more than one user and if the system finds such duplicate email address, the following error will be displayed:

Add User

☒ is already in use.

Name: *
 Address: *

 Country: *
 Fax Number:
 Postal Code:
 Phone Number: *
 Email: *

- After pressing the “Add” button, the user will receive an e-mail containing **User ID** and **Password** as shown in the following screen:



- The Company Applicant is now ready to submit application.

3. SCREENER VERIFY THE NEW APPLICATION

Once an application has been submitted, it goes to the DGDA for review. In Pharmadex, the first person who starts screening the application and ensures its completeness is known as the “**Screeener**”. To log in as the Screener, go to the homepage and click on the door on the upper right corner.

3.1. Log on as a Screener

- Log in as Screener



- Write your user id and password like (User: mahhub, PW: *****)
- Once you login, you will see your username on the upper right corner.
- After logging in, go to **Registration > Submitted Application** menu
- The Received Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”



Product Name	Generic Name	Application Number	Application Type	Registration Status	Submitted Date	Applicant Name	Manufacturer Name
ACE PLUS	ACE	0115/NM/2016	Generic	Screening Completed	Dec 8, 2016	TEST APPLI CANT	ADD TEST Pharma
NALARINETS	ATONAGUONE	0115/NM/2016	Generic	Verified	Dec 18, 2016	TEST APPLI CANT	Test Pharma
COOSPRINE	ASPIRIN	0123/NM/2017	Generic	Verified	Jan 2, 2017	SOFTWORKS	ACE Pharmaceuticals Limited
ALBEN 05	ALBENJAZOL	0138/NM/2017	New Chemical Drug	New Application	Mar 26, 2017	EDKAYOT RANIS ATFSH ILM/TFD	Esavief Bangladesh Limited

3.2. Application Information

- After clicking on the hyperlink the following screen will arrive:

ALBEN DS

Application Type:

NEW_CHEMICAL_ENTITY

Application Number:

0138/NMR/2017

Applicant Name:

ESKAYEF BANGLADESH LIMITED

Manufacturer Name:

Eskayef Bangladesh Limited

Registration Status:

New Application

Submitted By:

Mahmudul Islam Sohel

Applications Responsible:

Mahmudul Islam Sohel

Submitted Date:

Mar 29, 2017

Application

March 2017

Thu 30

Fri 31

Sat 1

Sun 2

Mon 3

Tue 4

Wed 5

April 2017

Application Information

Verification

Comments

Timeline

Attachments

Letters

Additional Information

Proprietary Name (Brand Name):

ALBEN DS

Generic Name:

ALBENDAZOLE

Dosage Form:

TABLET

Dosage Unit:

mg

Age Group:

Adult

Product Category:

Human

Application Type:

New Chemical Entity

Dosage Strength:

400

Route of administration:

ORAL

Pharmacological Classification:

Product Description and Physical Appearance:

Alben-Ds Tablet is a medicine that is used for the treatment of infections Caused By Pinworm, Infections Caused By Roundworm, Infections Caused By Tapeworm and other conditions. The complete list of uses and indications for Alben-Ds Tablet is as follows: Infections Caused By Pinworm Infections Caused By Roundworm Infections Caused By Tapeworm

Medicine Detail

Click here

- The newly received **Application Information** can be viewed from here. No need to do anything in this tab.
- To view the Applicant's submitted application you need to click on "Click Here" button and the following screen will arrive:

3.3. Verification

- After logging in, you need to fill up the following fields from the **Verification** tab:



The screenshot shows the 'Verification' tab selected in a navigation bar. Below the navigation bar, there are four questions, each with a 'No' button:

- Fee Received:
- Ensure that the applicant details are complete:
- Check that medicine inputs are correct:
- Dossier received and complete?:

- After filled in up the above mentioned fields the **Verification** tab screen will look like this:



The screenshot shows the 'Verification' tab selected in a navigation bar. Below the navigation bar, there are four questions, each with a 'Yes' button:

- Fee Received:
- Ensure that the applicant details are complete:
- Check that medicine inputs are correct:
- Dossier received and complete?:

- The **Verification** tab will automatically be replaced by **Screening** tab

3.4. Screening

- The screener now can check each and every received documents with the following checklist and mark as one of the followings :
 - Yes
 - No
 - N/A
- Also may put his remarks. The Dossier Deficiency Letter will be automatically generated with the list if he clicks on the **No** button.

Application Information Screening Sample Request Comments Timeline Attachments Letters Additional Information

Save Complete Send to Applicant Print

Moderator Name:

		Applicant	Staff			Remarks	
1	Letter of application	Yes	Yes	No	N/A		
1.1	Comprehensive table of content (module 1)	Yes	Yes	No	N/A		
1.2	Application - Hasan	Yes	Yes	No	N/A		
1.3	Bangladesh labelling and packaging	Yes	Yes	No	N/A		
1.4	Information about the experts	Yes	Yes	No	N/A		
1.5	Specific requirements for different types of application	Yes	Yes	No	N/A		
1.6	Environmental risk assessment	Yes	Yes	No	N/A		
1.7	Good manufacturing practice	Yes	Yes	No	N/A		
1.8	Foreign regulatory status	Yes	Yes	No	N/A		
1.9	Pharmacovigilance plan	Yes	Yes	No	N/A		
1.1	Details of compliance with screening outcomes	N/A	Yes	No	N/A		
1.11	Bioequivalence trial information	Yes	Yes	No	N/A		
1.12	Information on price	Yes	Yes	No	N/A		
1.13	Paediatric development	Yes	Yes	No	N/A		
1.14	Risk management plan	Yes	Yes	No	N/A		
2.1	CTD Table of contents (Modules 2 to 5)	Yes	Yes	No	N/A		
2.2	CTD introduction	Yes	Yes	No	N/A		
2.3	Quality overall summary	Yes	Yes	No	N/A		
2.4	Nonclinical overview	Yes	Yes	No	N/A		
2.5	Clinical overview	N/A	Yes	No	N/A		
2.6	Nonclinical written and tabulated summaries	Yes	Yes	No	N/A		
2.7	Clinical summary	Yes	Yes	No	N/A		
3.1	Table of contents of Module 3	Yes	Yes	No	N/A		
3.2	Body of Data	No	Yes	No	N/A		
3.3	Literature references	No	Yes	No	N/A		
4.1	Table of contents of Module 4	No	Yes	No	N/A		
4.2	Study reports	N/A	Yes	No	N/A		
4.3	Literature references	N/A	Yes	No	N/A		
5.1	Table of contents of Module 5	N/A	Yes	No	N/A		
5.2	Tabular listings of all clinical studies	N/A	Yes	No	N/A		
5.3	Clinical study reports	No	Yes	No	N/A		
5.4	Literature references	No	Yes	No	N/A		

Complete Send to Applicant Print

3.4.1. Save

- To keep your screened answer you have to click on “Save” button. Without clicking on the save button if you exit, your answers will not be saved.

Application Information		Screening	Sample Request	Comments	Timeline	Attachments	Letters	Additional Information
<div> Save Complete Send to Applicant Print </div>								
Moderator Name:								
		Applicant	Staff			Remarks		
1	Letter of application	Yes	Yes	No	N/A			
1.1	Comprehensive table of content (module 1)	Yes	Yes	No	N/A			
1.2	Application - Hasan	Yes	Yes	No	N/A			
1.3	Bangladesh labelling and packaging	Yes	Yes	No	N/A			

3.4.2. Complete

- After completion of screening, the screener needs to press on the **“Complete”** button to send the document to a Moderator to be assigned under a Reviewer.

Complete Pre-screening

Moderator Name

Dossier Location

Submit

- Select a Moderator from the **“Moderator Name”** combo and write the Dossier location as shown below:

Complete Pre-screening

Moderator Name:

Moderator One

Dossier Location

Room-2

Submit

3.4.3. Send to Applicant

- The following screen is showing the list which was given **No** by the screener while checking the documents with the checklist and by clicking **“Generate Letter”** the **Dossier Deficiency Letter** will be automatically generated in the system.

Generate Letter
Back

Deficiency Report

		Remarks
3.2	Body of Data	Required this document
3.3	Literature references	Required this document
4.1	Table of contents of Module 4	Required this document
5.3	Clinical study reports	Required this document
5.4	Literature references	Required this document

- A pop-up message will appear.

Deficiency Report
✕

Congratulations!
 You can download new letter from the Letters tab

Back

3.4.5. Print

- After completing screening Screener can print the checklist as shown below:

		Applicant	Staff	Remarks	
1	Letter of application	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.1	Comprehensive table of content (module 1)	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.2	Application - Hasan	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.2.1	Application - Hasan Addition	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.3	Bangladesh labelling and packaging	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.4	Information about the experts	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.5	Specific requirements for different types of application	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.6	Environmental risk assessment	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.7	Good manufacturing practice	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.8	Foreign regulatory status	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.9	Pharmacovigilance plan	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.1	Details of compliance with screening outcomes	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.11	Bioequivalence trial information	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.12	Information on price	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.13	Paediatric development program	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
1.14	Risk management plan	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.1	CTD Table of contents (Modules 2 to 5)	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.2	CTD introduction	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.3	Quality overall summary	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.4	Nonclinical overview	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.5	Clinical overview	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.6	Nonclinical written and tabulated summaries	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
2.7	Clinical summary	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
3.1	Table of contents of Module 3	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
3.2	Body of Data	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>
3.3	Literature references	Yes	<input type="button" value="Yes"/> <input type="button" value="No"/> <input type="button" value="N/A"/>	<input type="text"/>	<input type="checkbox"/>

3.5. Sample Request

- Screener can ask Applicant for testing of items on submitted sample. There are six types of tests for which applicant may be asked for.

Application Information	Screening	Sample Request	Comments	Timeline	Attachments	Letters	Additional Information								
<div>Request to Applicant</div> <div>Sample request to Applicant</div> <table border="1"> <thead> <tr> <th>Requested Date</th> <th>Current Status</th> <th>Created By</th> <th>Sample Recieved</th> </tr> </thead> <tbody> <tr> <td colspan="4">No records found.</td> </tr> </tbody> </table>								Requested Date	Current Status	Created By	Sample Recieved	No records found.			
Requested Date	Current Status	Created By	Sample Recieved												
No records found.															

- To do this Screener need to click on “Request to Applicant” button and the following screen will arrive.

Items Requested	<input checked="" type="checkbox"/> Medicine Sample <input type="checkbox"/> Internal Standard <input type="checkbox"/> HPLC Column <input checked="" type="checkbox"/> Specific Chemicals <input type="checkbox"/> Reference Standard <input checked="" type="checkbox"/> Test Method
Request details *	<div> <div> </div> <div>Need to test above mentioned items</div> </div> <div>body p</div>

Application Information	Screening	Sample Request	Comments	Timeline	Attachments	Letters	Additional Information								
<div>Request to Applicant</div> <div>Sample request to Applicant</div> <table border="1"> <thead> <tr> <th>Requested Date</th> <th>Current Status</th> <th>Created By</th> <th>Sample Recieved</th> </tr> </thead> <tbody> <tr> <td>Apr 20, 2017</td> <td>Requested</td> <td>A.T.M. Golam Kibria</td> <td></td> </tr> </tbody> </table>								Requested Date	Current Status	Created By	Sample Recieved	Apr 20, 2017	Requested	A.T.M. Golam Kibria	
Requested Date	Current Status	Created By	Sample Recieved												
Apr 20, 2017	Requested	A.T.M. Golam Kibria													

- If you have any comments, attachments, or additional information you would like to provide, select the appropriate tab(s) and add them as shown below.

3.6 Comments

- On the “Comments” tab, you can view comments from others or add your own comment by clicking on “Add Comment”.

Application Information	Verification	Screening	Comments	Timeline	Attachments	Letters	Additional Information		
<div>Add Comment</div> <table border="1"> <tbody> <tr> <td> Screener One Nov 12, 2016 </td> <td>Screening completed</td> </tr> </tbody> </table>								Screener One Nov 12, 2016	Screening completed
Screener One Nov 12, 2016	Screening completed								

3.7 Timeline

- The “Timeline” tab shows the status of the application during the different processing stages. The status of all processes after submission of application you can see at a glance here.

Application Information	Verification	Screening	Comments	Timeline	Attachments	Letters	Additional Information
Shows the evolution of the Product Registration.							
Application Status	Status Change Date	Updated By	Comment				
Fee Received	Nov 12, 2016	Screener One					
New Application	Nov 12, 2016	Hasan Mahmud	New Product registration application submitted.				

3.8 Attachment

- If you would like, you can add additional attachments or additional information by clicking on the appropriate tab(s) and following the screenshots below. If you need to add any document you need to click on “Add Documents” and the pop-up window will arrive to add documents which will be attached by applicant.

Application Information	Verification	Screening	Comments	Timeline	Attachments	Letters	Additional Information
Attachments have a 4mb size limit.							
Add Document							
Title	File Name	Upload Date	Uploaded By	Registration Status			
Label	Montair 10mg.jpg	Nov 12, 2016	Hasan Mahmud	Saved	Download	Delete	

3.9. Letter

- All system generated letters will be listed under this “Letter” tab one after another.

Application Information	Screening	Sample Request	Comments	Timeline	Attachments	Letters	Additional Information
Create Acceptance Letter							
Title	File Name	Upload Date	Uploaded By	Registration Status			
Acknowledgment letter	LOSECTIL_ack5098223794808116149.pdf	Apr 20, 2017	SoftWorks	New Application	Download	Delete	
Sample Request Letter	LOSECTIL_samplerequest3896637787508551957.pdf	Apr 20, 2017	A.T.M. Golam Kibria	Verified	Download	Delete	
Acceptance letter	LOSECTIL_accept8843283758261255495.pdf	Apr 20, 2017	SoftWorks	Verified	Download	Delete	
Deficiency Letter	LOSECTIL_defScr6102295687262224815.pdf	Apr 20, 2017	SoftWorks	Verified	Download	Delete	

3.9.1. Acknowledgement Letter

- The “Acknowledgement Letter” generated by the applicant can also be printed by anyone from DGDA –



Government of the Peoples Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212

Dossier Acknowledgement Letter

Memo No: _____ Date: _____

Hasan Pharma
21/15 Babor Road, Mohammadpur
Attention: Hasan Mahmud

Subject: Acceptance Letter

Application Reference Number: 0102/NMR/2016

Trade name: MONTAIR
Generic name(s): SINGULAIR
Strength(s) per dosage unit: 10 mg
Dosage form: TABLET

Your application has been accepted for evaluation. It is anticipated that the evaluation will be completed by approximately 1 year from the date of submission. The anticipated date of completion of the evaluation has been provided for your convenience and it is an estimate only.

If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.

Yours faithfully

Director General,
Directorate General of Drug Administration
&
Licencing Authority (Drugs)
Government of the People's Republic of Bangladesh

3.9.2. Sample Request Letter

- When Screener sends “Request for Sending Sample” letter to Applicant for Sample Testing and the following printable view will be generated as PDF format –



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



Memo No: _____

Date: _____

To,
SOFTWARES
21/15 Babar Road, Block-B
Mohammadpur, Dhaka
1207
Bangladesh
Attention: Mahmud Pharma

Subject: Request for sending samples for testing

Application Reference Number: 0127/NMB/2017

Dear Sir,

You are requested to send samples of your product for testing and analysis to the Drug Testing Laboratory (DTL) or Chittagong Drug Testing Laboratory (CDTL). In your submission, make sure to include:



- Medicine Sample, Internal Standard, HPLC Column, Specific Chemicals, Reference Standard, Test Method
- Would you requested to test the above ticked items.
- Relevant analytical documentation for better understanding
- Copy of The Bank Treasury Chalan receipt

Yours faithfully

Director General,
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh



3.9.3. Dossier Acceptance Letter

- After completion of screening the “Acceptance Letter” will be generated and the following printable view will be generated as PDF format –

	Government of the People's Republic of Bangladesh Directorate General of Drug Administration (DGDA) Aushad Bhavan, Mohakhali, Dhaka-1212	
Memo No: _____		Date: _____
ESKAYEF BANGLADESH LIMITED Tongi, Gazipur Bangladesh Attention: Mahmudul Islam Sohel		
Subject: Acceptance Letter		
Application Number:	<u>0138/NMR/2017</u>	
Trade name:	<u>ALBEN DS</u>	
Generic name:	<u>ALBENDAZOLE</u>	
Strength:	<u>400 mg</u>	
Dosage form:	<u>TABLET</u>	
Manufacturer:	<u>Eskayef Bangladesh Limited</u>	
Type of Application:	<u>New Chemical Entity</u>	
<p>Your application has been accepted for evaluation. It is anticipated that the evaluation will be completed by approximately 1 year from the date of submission. The anticipated date of completion of the evaluation has been provided for your convenience and it is an estimate only.</p> <p>If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.</p> <p>Yours faithfully</p> <p style="text-align: right;">Director General, Directorate General of Drug Administration & Licensing Authority (Drugs) Government of the People's Republic of Bangladesh</p>		

3.9.4. Dossier Deficiency Letter

- If Screener could not find documents while checking the Dossier checklist, s/he can click on **Send Letter to Applicant** which will generate a letter with required list of documents. A sample **Dossier Deficiency Letter** shown in the following screen:

	<p>Government of the People's Republic of Bangladesh Directorate General of Drug Administration (DGDA) Aushad Bhaban, Mohakhali, Dhaka-1212</p>	
Memo No: _____		Date: _____
To: ESKAYEF BANGLADESH LIMITED Tongi, Gazipur Bangladesh Attention: Mahmudul Islam Sohel		
Subject: DOSSIER DEFICIENCY LETTER		
Application Reference Number:		<u>0138/NMR/2017</u>
In response to your application number mentioned above related to the Marketing Authorization of the following product, you are requested to provide the following information(s) as early as possible.		
Trade name	<u>ALBEN DS</u>	
Generic name(s)	<u>ALBENDAZOLE</u>	
Strength(s) per dosage unit	<u>400 mg</u>	
Dosage form	<u>TABLET</u>	
The application has not been accepted for evaluation because the following documents are not complete or missing.		
Module 3: Body of Data Required this document		
Module 3: Literature references Required this document		
Module 4: Table of contents of Module 4 Required this document		
Module 5: Clinical study reports Required this document		
Module 5: Literature references Required this document		
The review of the application will commence once you submit the above missing documents.		
Yours faithfully		
Director General, Directorate General of Drug Administration & Licensing Authority (Drugs)		

3.10. Additional Information

- Here in the Additional Information tab, Screener will write the Dossier location:

Application Information	Screening	Sample Request	Comments	Timeline	Attachments	Letters	Additional Information
Dossier Location <input type="text" value="Shelf 1-1"/>							

- After Screener completes the screening, the Registration Status of the Application will be changed from New Application Received to Screening Completed as shown in the following screen:



Directorate General of Drug Administration

Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

[Logout](#) | [My Profile](#) | [Settings](#) | [Logout](#)

[Home](#) | [Registration](#)

[Registration](#)
[Registered Products](#)
[Registered Products](#)
[Registered Products](#)
[Registered Products](#)
[Application Processing](#)
[Post Registration Processing](#)
[Funding Registration](#)
[Payment Details](#)

Success Success

Received Applications

Product Name	Generic Name	Application Number	Application Type	Registration Status	Submitted Date	Applicant Name	Manufacturer Name
TEST	TEST	0115NM/R/2016	Generic	Screening Completed	Dec 5, 2016	TEST APPLICANT	TEST Pharma
TEST	TEST	0115NM/R/2016	Generic	Validated	Dec 10, 2016	TEST APPLICANT	TEST Pharma
TEST	TEST	0123NM/R/2017	Generic	Validated	Jun 2, 2017	TEST APPLICANT	TEST Pharma
TEST	TEST	0130NM/R/2017	New Chemical Entity	Screening Completed	Mar 29, 2017	TEST APPLICANT	TEST Pharma

4. REVIEWERS' ASSIGNMENT BY MODERATOR

- Once the Screener ensures that the application is complete and forwards it to a Moderator, it will appear in the Moderator's queue. To log in as a Moderator, go to the homepage, and click on the door on the upper right corner.

4.1. Log on as a Moderator

- Log on as Moderator

Login

Username: Mahmud

Password: *****

Remember me ☐

Login

- Write your user id and password like (User: mahmud, PW: *****)

Directorate General of Drug Administration

Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Mahmud | Settings | Logout

Home Registration

Welcome to Directorate General of Drug Administration

Quick Links

- Registered Products
- Registered Applicants
- Logged In Users
- User Setting

- After logging in, go to **Registration > Process Product Application** menu
- The Received Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is "ACE PLUS"

Directorate General of Drug Administration

Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Mahmud | Settings | Logout

Home Registration

Received Applications

Product Name	Generic Name	Application Number	Application Type	Registration Status	Submitted Date	Applicant Name	Manufacturer Name
ACE PLUS	ABACAVIR	0136/N/MD/2017	New Chemical Fully	Review Board	Mar 26, 2017	ESKAYFF BANGLADESH LIMITED	Dio-Drugs Pharma
ALDONDOL	ALDONDOL	0136/N/MD/2017	New Chemical Fully	Creating Complaint	Mar 26, 2017	ESKAYFF BANGLADESH LIMITED	Fabany Bangladesh Limited

(1 of 1)

4.2. Assign Reviewers by Moderator

- After logging in the system, go to **Assignment** tab and click on “**Assign Reviewer**” button.

Reviewer	Secondary Reviewer	Assign Date	Due Date	Completed Date	Review Status	Module
Reviewer Two		Nov 12, 2016	Nov 15, 2016		Assigned	MODULE_1

- After clicking on the “**Assign Reviewer**” button under Assessment tab the following screen will arrive to assign Reviewers.
- If Moderator decides to assign two reviewers – Primary and Secondary reviewer, then he needs to click on “Will there be a secondary reviewer?”
- Click on “**No**” button, if there will be only one reviewer.

- If you click “**Yes**”, then two Reviewer combo will be visible for selection.
- Reviewer:** First select a reviewer from the Reviewer list as the **Primary** Reviewer.
- Secondary Reviewer:** Select a secondary reviewer from the Reviewers list.
- Module:** Then you need to select module from Module combo, it’s also mandatory field.
- Due Date:** Need to mention a date by which the Reviewers need to submit their reviews and the date will always be future date.



Assign Reviewer

Will there be a secondary reviewer? ☒ Yes

You will not be able to change the selection of using or not using a secondary user after the assignment is done.

Reviewer *

Secondary Reviewer *

Module *

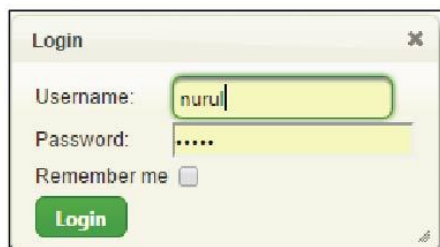
Due Date *

5. PRIMARY REVIEW: MODULE 1 REVIEW BY REVIEWER

- Once the Moderator assigns the Reviewer(s), it will appear in their list of pending applications. To login as a Reviewer, go to the homepage, click the door on the upper right corner and use the username and password for the primary reviewer.

5.1. Log on as a Reviewer

- Log on as Reviewer



Login

Username:

Password:

Remember me ☐

- Write your user id and password like (User: nurul, PW: *****)



Directorate General of Drug Administration
Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Md. Nurul Islam | Settings | Logout

Home Registration

Welcome to Directorate General of Drug Administration

Quick Links
Registered Products
Registered Applicants
Logged In Users
User Setting

- After logging in, go to **Registration > Submitted Application** menu
- The Received Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is "ACE PLUS"

Product Name	Review Type	Review Status	Reference to Dossier (module/section)	Assign Date	Due Date	Submitted Date	Decision
ROCTHIN	PRIMARY	Accepted	MODULE_1	Jan 24, 2017	Jan 31, 2017	Jan 29, 2017	Recommendation
AUDIN-DS	PRIMARY	RR Received	MODULE_1	Feb 1, 2017	Feb 3, 2017	Feb 11, 2017	
ADON-2017	PRIMARY	Assigned	MODULE_1	Mar 19, 2017	Mar 23, 2017		
ZIADON	PRIMARY	Accepted	MODULE_1	Mar 20, 2017	Mar 22, 2017	Mar 20, 2017	Recommendation
ADON	PRIMARY	Assigned	MODULE_2	Mar 20, 2017	Mar 23, 2017		
ADON-15	PRIMARY	Assigned	MODULE_1	Mar 29, 2017	Mar 31, 2017		

- The above screen shows the Reviewer's Review Applications list status. The RED color marked review application means the deadline of review application has lapsed.

5.2. Review of Module 1

- If you are assigned for Module 1 the following screen will be visible:

Application Details:

- Application Type: GENERIC
- Application Number: 0133/NMR/2017
- Applicant Name: INCEPTA PHARMACEUTICALS LIMITED
- Manufacturer Name: Eskayef Bangladesh Limited

Registration Status: Submitted By: Applications Responsible: Submitted Date:

Review Board: SoftWorks SoftWorks Apr 20, 2017

Primary Reviewer: [Name]

Review Evaluation Units:

ADMINISTRATIVE INFORMATION

A. GMP Certification

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturers, packers and FPRCs or a copy of appropriate license? **Yes No N/A**

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site? **Yes No N/A**

Has the applicant provided the GMP documents required by the inspectorate/ Including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contract
- 1.7.6 Certificate of Pharmaceutical Product (CPP): WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (COA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent Authority in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy? **Yes No N/A**

- Module 1 would have Administrative Information and the review questions are divided into 4 (four) sections.
A) GMP Certification

- B) Foreign Regulatory Status
- C) Pharmacovigilance Plan
- D) Interchangability

- The reviewer reviews all these questionnaires one by one as described in the following section:

ADMINISTRATIVE INFORMATION

A. GMP Certification

B. Foreign Regulatory Status

C. Pharmacovigilance Plan

D. Interchangability

Review Evaluation Units

Is the information in this section of the application satisfactory?

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturers, packers and FPRCs or a copy of appropriate license?

Yes No N/A

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?

Yes No N/A

Has the applicant provided the GMP documents required by the Inspectorate including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contract
- 1.7.6 Certificate of a Pharmaceutical Product (CPP); WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (CoA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent Authorities in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy?

- Under each section there are 3 (three) types of answers, one of which the Reviewers can select – Yes/No/NA.
- If the reviewer clicks on “Yes”, then the following screen will arrive.

Reviewer's Response - YES

Submit Cancel

Reference to Dossier (module/volume/pages): Rack-9

Answer Applicant's response (picture)

Please do not insert tables. You can upload applicant's response as a picture

Primary Reviewer Secondary Reviewer

ADMINISTRATIVE INFORMATION

A. GMP Certification

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturer/s, packer/s and FPRCs or a copy of appropriate license?

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?

YES the applicant has provided the copy of latest 3 years GMP Certificates

AND

Also the applicant provided inspection reports not older than 3 years

body p

- After clicking on “Yes” the above screen will be visible and the following fields will need to be filled up:

1) **Reference to Dossier (module/volume/pages):** It's a mandatory field and the reviewer has to write here the location of the document where the CTD Dossier located.

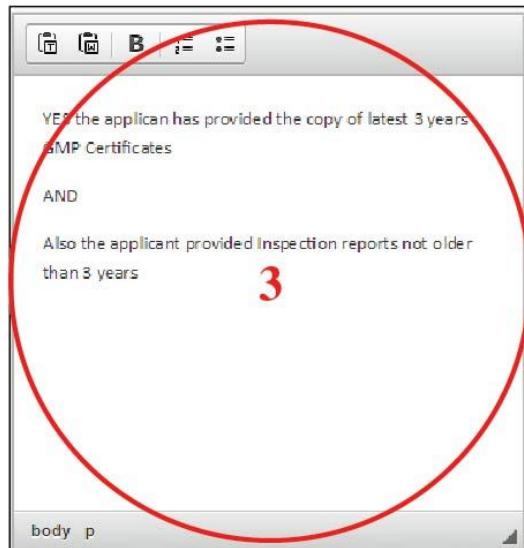
Reference to Dossier (module/volume/pages): Rack-8

2) **Reviewers Tab:** If there is one reviewer to review the module, you will find one reviewer's tab i.e. Primary Reviewer. On the other hand, if there are two reviewers you will see two reviewers' tab – Primary Reviewer and Secondary Reviewer.

Primary Reviewer Secondary Reviewer

body p

- 3) **Reviewer's body p:** In this notepad like template, reviewers(s) can write response to the question. Reviewer(s) can only write plain text here with basic formatting, table cannot be inserted.



- 4) **Applicant's response (picture):** Here you only attach Applicant's response as image by uploading from the computer drive.



- After filling up all required fields the reviewer needs to press “Submit” button to close the question answer tab and the following screen will view.

ADMINISTRATIVE INFORMATION

A. GMP Certification

Review Evaluation Units

Is the information in this section of the application satisfactory?

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturers, packers and FPRCs or a copy of appropriate license? Yes No N/A

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?

Has the applicant provided the GMP documents required by the inspectors? Including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contract
- 1.7.6 Certificate of a Pharmaceutical Product (CPP); WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (CoA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Yes No N/A

- If the reviewer clicks on “No” button, then the following screen will arrive.

Reviewer's Response - NO Submit Cancel

Reference to Dossier (module/volume/pages):

Answer **Applicant's response (picture)**

Please do not insert tables. You can upload applicant's response as a picture

ADMINISTRATIVE INFORMATION


A. GMP Certification

Has the applicant provided the GMP documents required by the inspectorate? Including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contract
- 1.7.6 Certificate of a Pharmaceutical Product (CPP); WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (CoA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent Authorities in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy?

Primary Reviewer **Secondary Reviewer** **Reasons**



Reviewer given review response as NO

body p

ADMINISTRATIVE INFORMATION

A. GMP Certification

Has the applicant provided the GMP documents required by the Inspectorate? Including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contract
- 1.7.6 Certificate of a Pharmaceutical Product (CPP); WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (CoA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent Authorities in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy

Primary Reviewer **Secondary Reviewer** **Reasons**

The Reviewer has given review result NO that is why need to put Reason

body p

- If clicked NO, the reviewer will find an extra tab i.e. “Reasons” tab to clarify why the reviewer has selected “No”. All other fields are same as described in the above “Yes” answer section.
- Without writing reason the reviewer cannot close the form. If no reason is given, the following pop-up message “Reasons is mandatory” will appear.

Reviewer's Response - NO

Reasons is mandatory

Reference to Dossier (module/volume/pages): Risk

Answer

Applicant's response (picture)

Please do not insert tables. You can upload applicant's response as a picture

Primary Reviewer **Secondary Reviewer** **Reasons**

body p

- If the reviewer given “No” answer and click on “Submit” button then the following screen will arrive.

ADMINISTRATIVE INFORMATION

A. GMP Certification

B. Foreign Regulatory Status

C. Pharmacovigilance Plan

D. Interchangeability

Review Evaluation Units

Is the information in this section of the application satisfactory?

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturers, packers and PFRs or a copy of appropriate license?

Yes No N/A

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MIRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?

Yes No N/A

Has the applicant provided the GVP documents required by the inspectorate? Including:

- 1.7.1 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FPRR) criteria
- 1.7.5 Confirmation of contact
- 1.7.6 Certificate of Pharmaceutical Product (CPP); WHO certification scheme applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample
- 1.7.8.3 Certificate of Analysis (CoA) of the sample
- 1.7.9 Certified copy of permit to manufacture
- 1.7.10 Inspection flow diagram (self-inspection)
- 1.7.11 Organogram

Has the applicant provided Certificate of Pharmaceutical Product (CPP) issued by competent authorities in the exporting country? Is the CPP valid and authenticated by the Bangladesh Embassy?

Yes No N/A

- If you click on the “NA” then same as above mentioned procedure needs to be followed and after that the following screen will arrive.

Reviewer's Response - NA

Submit Cancel

Reference to Dossier (module/volume/pages): Rack-8

Answer **Applicant's response (picture)**

Please do not insert tables. You can upload applicant's response as a picture

Primary Reviewer **Secondary Reviewer**

ADMINISTRATIVE INFORMATION

B. Foreign Regulatory Status

List the countries in which this product has been granted a marketing authorization, together with any restrictions on sales or distribution.

Reviewer review as NA

ADMINISTRATIVE INFORMATION

A. GMP Certification
B. Foreign Regulatory Status
C. Pharmacovigilance Plan
D. Interchangeability

Review Evaluation Units

Is the information in this section of the application satisfactory?

List the countries in which this product has been granted a marketing authorization, together with any restrictions on sales or distribution.

Has the applicant provided copies of the product marketing authorization certificates (Free Sales Certificate, Sales Certificates from at least 2 other developing countries) in other countries where the product is available?

List any countries in which the product has been withdrawn from the market, or where an application for marketing has been rejected, deferred or withdrawn, and the reason:

Has the applicant provided the proof of information of agency agreement including name, address, and signature of manufacturer's authorized agent in Bangladesh?

Has the applicant provided the estimated market of the product/product group in Bangladesh including proposed prices for the product in Bangladesh?

Has the applicant provided the foreign prescribing and patient information if the marketing authorization has been granted by other Health Authorities?

Has the applicant provided explanation on the similarities/differences in the data packages submitted in other countries?

5.3. Dossier Review Deficiency

- If the reviewer finds any deficiency and needs to send to the applicant, s/he needs to go to “Deficiency Report” tab to generate Letter –

LOSECTIL

Application Type: GENERIC
 Application Number: 0132/NMR/2017
 Applicant Name: INCEPIA PHARMACEUTICALS LIMITED
 Manufacturer Name: Eskayef Bangladesh Limited

Registration Status:
 Submitted By: SoftWorks
 Applications Responsible: SoftWorks
 Submitted Date: Apr 20, 2017

Primary Reviewer

No records found.

- The Reviewer needs to click on “Generate Letter” to generate deficiency letter and the following pop-up screen will arrive:

Generate Letter

Due Date: 24/04/2017

Summary

Need to submit the following documents:

- 1) GMP Certificate
- 2) Manufacturing License

body p

- After the Reviewer receives requested document from the Applicant, Reviewer needs to click on “Received” button.

Primary Reviews

Review Detail Comment Deficiency Report Letters Sample Request

Medicine Detail Print Save Back

Title	File Name	Upload Date	Uploaded By	
Further Information Request	LOSECTL_revde(Su1754 517311/90522713.pdf	Apr 22, 2017	MD Nurul Islam	Download Received

- The reviewer needs to select “Submitted Date” of received deficiency documents and write comments and press “Submit” button.

Acknowledge Deficiency Received

Sent Date: Apr 22, 2017

Due Date: Apr 24, 2017

Submitted Date: 22/04/2017

Evaluator Summary *

The pending deficiency two reports submitted.

body p g

Submit


- After clicking on the “Received” button, the following screen will appear.

Review Detail Comment Deficiency Report Letters Sample Request

Generate Letter

Title	File Name	Upload Date	Uploaded By	
Further Information Request	LOSECTIL_revde(Su1754 517311/90522713.pdf	Apr 22, 2017	MD Nurul Islam	Download

- The generated Deficiency Letter will look like as follows:



Government of the Peoples Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212

Memo No: _____ Date: _____

INCEPTA PHARMACEUTICALS LIMITED
 40 Shahid Tajuddin Ahmed Sarani Tejgaon I/A
 Dhaka
 1208
 Bangladesh
 Attention: SoftWorks

Subject: REVIEW DEFICIENCY LETTER

Application Reference Number: 0133/NMR/2017

In response to your application number mentioned above related to the Registration/Marketing Authorization of the following product, you are requested to provide response or submit the necessary document(s) to the following deficiency(ies) in order to complete the dossier evaluation process.

Trade name	LOSECTIL
Generic name(s)	OMEPRazole
Strength(s) per dosage unit	20 mg
Dosage form	TABLET

See below on the attached file(s) for the list of deficiency(ies) to be addressed.

Need to submit the following documents:
 1) GMP Certificate
 2) Manufacturing License

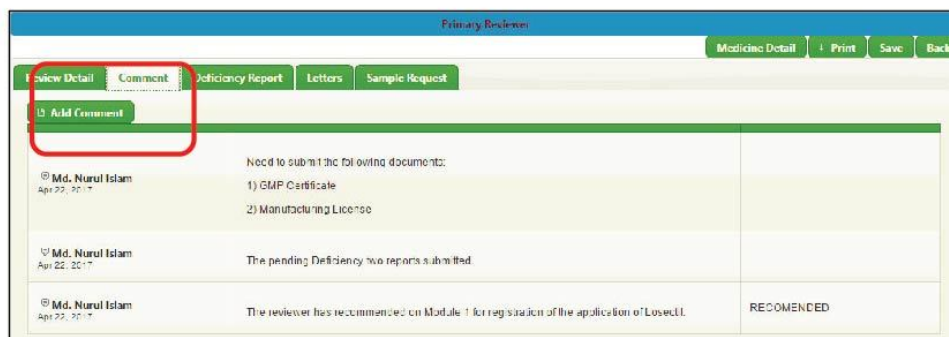
The review of the application will commence again once you submit your responses. If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.

Yours faithfully

Director General,
 Directorate General of Drug Administration &

5.4. Comments by Primary Reviewer

- The primary reviewer can put comments as shown in the following screen.



Primary Reviewer		
		Medicine Detail Print Save Back
Review Detail	Comment	Deficiency Report Letters Sample Request
Add Comment		
@ Md. Nurul Islam Apr 22, 2017	Need to submit the following documents: 1) GMP Certificate 2) Manufacturing License	
@ Md. Nurul Islam Apr 22, 2017	The pending Deficiency two reports submitted	
@ Md. Nurul Islam Apr 22, 2017	The reviewer has recommended on Module 1 for registration of the application of Losectil.	RECOMMENDED

5.5. Submit Recommendation by Primary Reviewer

- After completed review of all questionnaires, the primary reviewer needs to recommend by clicking “Submit” button.

LOSECTIL

Application Type:	GENERIC	Registration Status:	Review Board
Application Number:	013/NNH/2017	Submitted By:	SoftWorks
Applicant Name:	INCEPTA PHARMACEUTICALS LIMITED	Applications Responsible:	SoftWorks
Manufacturer Name:	Lskayer Ungladesch Limited	Submitted Date:	Apr 20, 2017

Primary Reviewer

Medicine Detail + Print Save Submit Back

Review Detail Comment Deficiency Report Letters Sample Request

ADMINISTRATIVE INFORMATION

A. GMP Certification

B. Foreign Regulatory Status

C. Pharmacovigilance Plan

D. Interchangeability

Review Evaluation Unit

Is the information in this section of the application satisfactory?

List the countries in which this product has been granted a marketing authorization, together with any restrictions on use or distribution.

Has the applicant provided copies of the product marketing authorization certificates (Free Sales Certificate, Sales Certificates from at least 2 other developing countries) in other countries where the product is available?

List any countries in which the product has been withdrawn from the market, or where an application for marketing has been rejected, deferred or withdrawn, and the reason.

Yes No N/A

- After clicking on “Submit” button the following screen will appear.

Complete Review

Recommendation *

Evaluator Summary *

Submit

- From the “Recommendation” combo there are three options from which the reviewer can select one based on their assessment 1) --, 2) Satisfactory, 3) Unsatisfactory.

Complete Review

Recommendation *

Satisfactory

Unsatisfactory

- Also the reviewer needs to write his comments in the “Executive Summary” section as shown below:

Complete Review

Recommendation * Satisfactory

The reviewer has recommended on Module 1 for registration of the application of Losectil.

Evaluator Summary *

body p

Submit

- After filling in up all fields the reviewer need to press “Submit” button –

Directorate General of Drug Administration
Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Md. Nurul Islam | Settings | Logout

Home Registration

Registration

- Registered Applicants
- Registered Products
- Suspended Products
- Canceled Products
- Application Processing
- Review Applications

Medicine Registration

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare (MOHFW) of Bangladesh is changing and improving its medicine registration system to ensure the safety and efficacy of medicines as well as to strengthen the potential for the registration of medicines. The DGDA is therefore adopting the International Standard Common Technical Document (CTD) format and guidelines for the preparation of registration dossiers for pharmaceuticals that are submitted to the application for registration. The DGDA is also planning to implement Pharmadex, a web-based information system to keep registration applications and to enhance its capacity to successfully manage the registration process in a timely manner.

The registration activities are summarized below:

- Medicine application dossiers from Applicants are received and screened for completeness and that application fees have been included.
- Data on the dossier is entered into the registration database, an application number is allocated and information communicated to the applicant.
- Dossiers are scheduled for evaluation by DGDA officials who are nominated as reviewer, reviewer and moderator. A detailed evaluation report is also generated.
- Advice, advice and/or other information, etc. is communicated to the applicants to the dossier to respond to the queries.
- Marketing authorization letter will be provided by DGDA after complete evaluation and approval of the dossier.

In order to register a new product, you must first register as a user of the Pharmadex website and login if required please contact your administrator for help.

- After the review is completed the Application marked as “Satisfactory” will be shown in the screen as below-

Directorate General of Drug Administration
Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Md. Nurul Islam | Settings | Logout

Home Registration

Registration

- Registered Applicants
- Registered Products
- Suspended Products
- Canceled Products
- Application Processing
- Review Applications

Review Applications

Product Name	Review Type	Review Status	Reference to Dossier (module/section)	Assign Date	Due Date	Submitted Date	Discussion
BETESOL	PRIMARY	Accepted	MODULE 1	Jan 24, 2017	Jan 31, 2017	Jan 25, 2017	Satisfactory
ALBIDOL	PRIMARY	PR Review	MODULE 1	Feb 1, 2017	Feb 8, 2017	Feb 13, 2017	
CLONIDINE	PRIMARY	Assigned	MODULE 1	Mar 10, 2017	Mar 22, 2017		
ZINBEX	PRIMARY	Accepted	MODULE 1	Mar 20, 2017	Mar 23, 2017	Mar 20, 2017	Satisfactory
ZINBEX	PRIMARY	Assigned	MODULE 2	Mar 20, 2017	Mar 23, 2017		
LOSSECTIL	PRIMARY	PR Submitted	MODULE 1	Mar 29, 2017	Apr 4, 2017	Apr 4, 2017	Satisfactory
ACETAS	PRIMARY	Accepted	ALL	Apr 5, 2017	Apr 6, 2017	Apr 6, 2017	Satisfactory
NARAFIL	PRIMARY	Accepted	MODULE 1	Apr 13, 2017	Apr 16, 2017	Apr 13, 2017	Satisfactory
LOSSECTIL	PRIMARY	Secondary Review	MODULE 1	Apr 20, 2017	Apr 26, 2017	Apr 22, 2017	Satisfactory

6. SECONDARY REVIEW: MODULE-1 REVIEW BY REVIEWER

- To login as a Reviewer, go to the homepage, click the door in the upper right corner and use the username and password for the Secondary reviewer.

6.1. Log on as Secondary Review

- Log on as Reviewer

- Write your user id and password like (User: ayub, PW: *****)

- After logging in, go to **Registration > Review Application** menu
- The Review Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”

Product Name	Review Type	Review Status	Reference to Decision (products/visa/impapers)	Assign Date	Due Date	Submitted Date	Decision
REFRESH LABS	PRIMARY	Accepted	MODULE_2	Jan 24, 2017	Jan 31, 2017	Jan 25, 2017	Satisfactory
ACE PLUS	PRIMARY	Assigned	MODULE_3	Mar 15, 2017	Mar 23, 2017		
ACE PLUS	PRIMARY	Assigned	MODULE_3	Mar 20, 2017	Mar 22, 2017		
ENTACID PLUS	PRIMARY	Accepted	MODULE_2	Mar 28, 2017	Apr 4, 2017	Apr 9, 2017	Satisfactory
NADA PLUS	PRIMARY	Accepted	MODULE_3	Apr 13, 2017	Apr 13, 2017	Apr 13, 2017	Satisfactory
MODULIS	SECONDARY	Secondary Review	MODULE_1	Apr 20, 2017	Apr 25, 2017	Apr 22, 2017	Satisfactory

6.2. Secondary Review of Module-1

- After signing in by Secondary Reviewer, the following screen will be visible:

The screenshot shows the 'Secondary Reviewer' role selected. The interface includes tabs for 'Review Detail', 'Comment', 'Deficiency Report', 'Letters', and 'Sample Request'. Under the 'ADMINISTRATIVE INFORMATION' section, there are four sub-sections: A. GMP Certification, B. Foreign Regulatory Status, C. Pharmacovigilance Plan, and D. Interchangeability. A 'Review Evaluation Units' section asks 'Is the information in this section of the application satisfactory?' with 'Yes', 'No', and 'N/A' options.

- In the same way as the Primary Reviewer has completed review, the Secondary Reviewer also need to follow all the steps to review Module 1 and same question set under Administrative Information will appear before the reviewer for review and the secondary reviewer will have to complete review accordingly.
- The Secondary Reviewer needs to complete all these questionnaires one by one as described in the earlier section.

The screenshot shows the 'Reviewer's Response - YES' screen. It includes a 'Reference to Dossier (module/volume/pages):' field with 'Mod-9' entered. Below this is a 'Primary Reviewer' section with a 'Comment' tab. The comment text reads: 'YES the Primary Reviewer Md Nurul Islam reviewed the GMP certification documents and also find all document relating to GMP.'

6.3. Comments by Secondary Reviewer

- The Secondary Reviewer can also write comment by click on "Comment" tab as shown below:

Secondary Reviews

Medicine Detail + Print Save Submit Back

Review Detail **Comment** Deficiency Report Letters Sample Request

Add Comment

Md. Nurul Islam Apr 22, 2017	Need to submit the following documents: 1) GMP Certificate 2) Manufacturing License	
Md. Nurul Islam Apr 22, 2017	The pending Deficiency two reports submitted	
Md. Nurul Islam Apr 22, 2017	The reviewer has recommended on Module 1 for registration of the application of 1 used	RECOMMENDED

Add Comment

Evaluator Summary

I have completed the review of Module 1 and only one point I disagree with Md. Nurul Islam

Submit

Review Detail **Comment** Deficiency Report Letters Sample Request

Add Comment

Md. Nurul Islam Mar 20, 2017	The Primary Reviewer Mr Md. Nurul Islam has completed his Quality Review and find following findings: 1) All required documents has been submitted by the applicant 2) Submit all documents in the copy as well as in CTD format	
Md. Nurul Islam Mar 26, 2017	Mr. Nurul Islam, as a Primary Reviewer has been recommended for the applicant for product registration name Alben DS 400mg	RECOMMENDED
Md. Ayub Hussain Mar 20, 2017	I have completed the review of Module 1 and only one point I disagree with Md. Nurul Islam	

6.4. Submit Recommendation by Secondary Reviewer on Module-1

- After completing review (answering all the questions), the secondary reviewer also needs to click on the “Submit” button.

Secondary Reviewer

Medicine Detail + Print Save **Submit** Back

Review Detail **Comment** Deficiency Report Letters Sample Request

ADMINISTRATIVE INFORMATION

A. GMP Certification
B. Foreign Regulatory Status
C. Pharmacovigilance Plan
D. Interchangeability

Review Evaluation Units

Is the information in this section of the application satisfactory?

Has the applicant provided the copy of latest (not older than three years) GMP certificate for manufacturers, products and ITT/CTA or a copy of appropriate license?

Yes No N/A

Has the applicant provided inspection reports or equivalent document (not older than three years) from the Health Authorities of either DGDA, USFDA, MHRA, TGA, EU, Canada, PIC/S country, at each site as well as the date of last inspection of each site?

Yes No N/A

Has the applicant provided the UMI documents required by the inspectorate? Including:

- 1.7.4 Batch release procedures
- 1.7.4.1 Active pharmaceutical ingredients
- 1.7.4.2 Inactive pharmaceutical ingredients
- 1.7.4.3 Finished Product Release Control (FPRC) tests
- 1.7.4.4 Finished Product Release Responsibility (FRR) criteria
- 1.7.5 Confirmation of control
- 1.7.5 Certificate of a Pharmaceutical Product (CTP): WHO certification scheme if applicable
- 1.7.7 Proof of current registration of the Responsible Pharmacist
- 1.7.8 Sample and Documents
- 1.7.8.1 Confirmation of submission of the sample
- 1.7.8.2 Batch manufacturing record of the sample

Yes No N/A

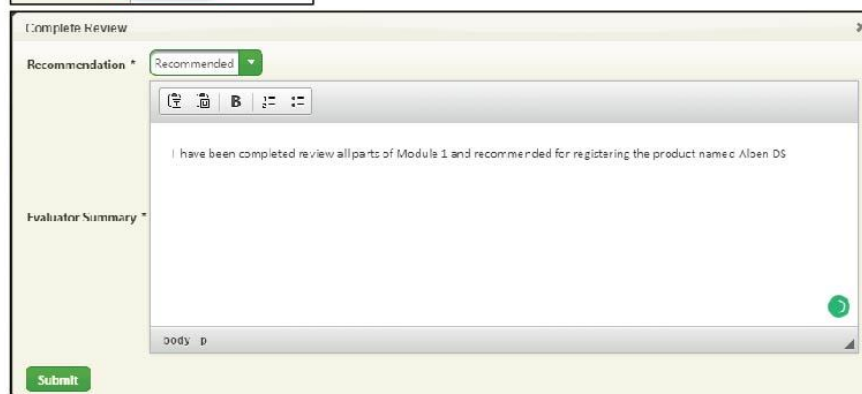
- Same as the Primary Reviewer, the Secondary Reviewer also needs to follow the same procedure to recommend for product registration as shown in the following section:



The screenshot shows a web form titled 'Complete Review'. The 'Recommendation' dropdown menu is highlighted with a red box. Below it, there is a text area for 'Evaluator Summary' and a 'Submit' button at the bottom left.



This screenshot shows the 'Recommendation' dropdown menu expanded, with 'Satisfactory' and 'Unsatisfactory' options visible. A red box highlights the dropdown menu.



The screenshot shows the 'Recommendation' dropdown menu set to 'Recommended'. The 'Evaluator Summary' text area contains the text: 'I have been completed review all parts of Module 1 and recommended for registering the product named Alogen DS'. A 'Submit' button is at the bottom left.



The screenshot shows the Pharmadex web application interface. The header includes the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh. The left sidebar contains navigation links: Home, Registration, Registered Applicants, Registered Products, Suspended Products, Canceled Products, Application Processing, and Review Applications. The main content area displays a 'Success' message: 'Medicine Registration'. Below the message, there is a detailed description of the DGDA's mission and a list of registration activities.

Success

Medicine Registration

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare (MOHFW) of Bangladesh is changing and improving its medicines registration system to ensure the safety and efficacy of medicines as well as to strengthen the potential for the exportation of medicines. The DGDA is therefore adopting the International Standard Common Technical Document (CTD) format and guidelines for the preparation of registration dossiers for pharmaceuticals that are submitted with the application for registration. The DGDA is also planning to implement Pharmadex, a web-based information system to track registration applications and to enhance its capacity to successfully manage the registration process in a timely manner.

The registration activities are summarized below:

- Medicine application dossiers from Applicants are received and screened for completeness and that application fees have been included.
- Data on the dossiers is entered into the registration data base; an application number is allocated and information communicated to the applicant.

7. PRIMARY REVIEW: MODULE-3 REVIEW BY REVIEWER

- To login as a Reviewer, go to the homepage, click the door on the upper right corner and use the username and password for the primary reviewer.

7.1. Log on as Assigned Primary Review

- Log on as Reviewer

- Write your user id and password like (User: Reviewer2, PW: *****)

- After logging in, go to **Registration > Review Applications** menu
- The Review Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”

Product Name	Review Type	Review Status	Reference to Dossier (Module/Module response)	Assign Date	Due Date	Submitted Date	Decision
ACE PLUS	PRIMARY	Assigned	01	Mar 8 2017	Mar 23 2017		
ACE PLUS	PRIMARY	Assigned	MODULE 2	Mar 25 2017	Apr 5 2017		

- Similar ways as defined in the Primary Review on Module 1 section, the Primary Reviewer has to complete his/her review on Module 3 of **Quality Overall Summary (QoS)** questionnaires. The QoS questionnaires are divided into two sections -

1) Active Pharmaceutical Ingredients (API) - A to G question set

2) Pharmaceutical Products (Finished Pharmaceutical Products) - H to N question set

- The Primary Reviewer needs to complete all these questionnaires one by one as described in the earlier section.

The screenshot displays the 'Primary Reviewer' interface. At the top, there are tabs for 'Review Detail', 'Comment', 'Deficiency Report', 'Letters', and 'Sample Request'. To the right are buttons for 'Medicine Detail', 'Print', 'Save', 'Submit', and 'Back'. The interface is divided into two main sections:

ACTIVE PHARMACEUTICAL INGREDIENT (API)

On the left, a list of questions is shown: A. General Information, B. Manufacture of API, C. Control of API, D. Characterization of API, E. Reference Standard, F. Container Closure System, and G. Stability. The right side contains a 'Review Evaluation Units' table with two rows of questions and their corresponding 'Yes', 'No', and 'N/A' options.

PHARMACEUTICAL PRODUCT (FINISHED PHARMACEUTICAL PRODUCT)

On the left, a list of questions is shown: I. Component of the pharmaceutical product, J. Container Closure System & other packaging, K. Manufacture/Control of Drug Product, L. Characterization of Impurities, M. Stability Testing of Finished Product, and N. Appendices. The right side contains a 'Review Evaluation Units' table with four rows of questions and their corresponding 'Yes', 'No', and 'N/A' options.

7.2. Submit Recommendation by Primary Reviewer on Module 3

- Same as Primary Review of Module 1, the Primary Reviewer of Module 3 also needs to follow the same procedure to recommend for product registration as shown in the following section:

The image shows two screenshots from the Pharmadex system. The top screenshot is a 'Complete Review' window with a 'Recommendation' dropdown set to 'Satisfactory'. The text area contains 'Completed reviewed and recommended by Reviewer 2'. Below this is an 'Evaluator Summary' section and a 'Submit' button. The bottom screenshot is the DGDA homepage, featuring the Directorate General of Drug Administration logo and a 'Review Applications' table.

Product Name	Review Type	Review Status	Reference to Document (module/role/rolepage)	Assign Date	Due Date	Submitted Date	Decision
ALLEN DS	PRIMARY	Assigned	MODUL F_2	Mar 23, 2017	Apr 5, 2017	Mar 29, 2017	Recommended

8. SECONDARY REVIEW: MODULE-3 REVIEW BY SECONDARY REVIEWER

- To login as a Reviewer, go to the homepage, click the door on the upper right corner and use the username and password for the secondary reviewer.

8.1. Log on as Assigned Secondary Review

- Log on as Reviewer

The image shows a 'Login' window with fields for 'Username' (containing 'Reviewer1') and 'Password' (containing '*****'). There is a 'Remember me' checkbox and a 'Login' button.

- Write your user id and password like (User: Reviewer1, PW: *****)



- After logging in, go to **Registration > Review Applications** menu
- The Review Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”



- In the same way, the Secondary Reviewer have to complete the review of Module-3 of QoS questionnaires.

Review Evaluation Units	Yes	No	N/A
What are the nomenclature, molecular structure, molecular formula, and molecular weight? Are isomers of this product possible? If yes, indicate which isomer or combination of isomers comprises the medicine?			
What are the physicochemical properties including physical description, pKa, polymorphism, aqueous solubility (as function of pH), hygroscopicity, melting points, and partition coefficient?			

- The Secondary Reviewer of Module-3 will be reviewed all these questionnaires one by one same as described in the earlier section.

Reviewer's Response YES

Reference to Dossier (module/volume/pages): Rack-3

Answer Applicant's response (picture)

Please do not insert tables. You can upload applicant's response as a picture

Primary Reviewer Secondary Reviewer

Reviewed by Secondary Reviewer on Module 3

ACTIVE PHARMACEUTICAL INGREDIENT (API)

A. General Information

What are the physicochemical properties including physical description, pKa, polymorphism, aqueous solubility (as function of pH), hygroscopicity, melting points, and partition coefficient?

8.2. Submit Recommendation by Secondary Reviewer on Module-3

- Same as Primary Review, the Secondary Reviewer of Module-3 also need to follow the same procedure to recommend for product registration as shown in the following section:

Complete (review)

Recommendation *

Satisfactory
Unsatisfactory

Complete Review

Recommendation Satisfactory

Review completed by Reviewer 1 on Module 3 and recommended

Evaluator Summary *

body p

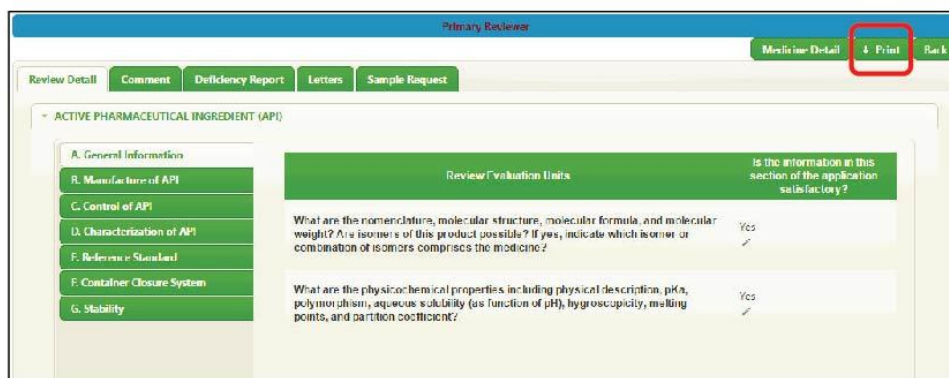
Submit



8.3. QoS Report



- To generate QoS report you need to click on **“Print”** button.



- After clicking on **“Print”** button the following pop-up window will arrive -

Print

PAPER SUBMISSION * 22/04/2017

TYPE II DMF # (if any)

For domestic site, has the applicant provided a copy of a current and satisfactory site licence issued by DGDA? Or from WHO, USFDA, MHRA, TGA, EU, Canada, PIC/s country

Print

- You need to fill up the following fields –
 - Paper Submission:** Pick the date of Paper submission.
 - Type II DMF # (If Any):** Write Type II DMF if any
 - “For domestic site...” (Checkbox):** Click on the checkbox if require.

QoS report

Congratulations!
You can download new QoS from the Letters tab

Back

- A message box will arrive showing the successful generation of QoS report.
- After generation of QoS report, you will find the report divided into two parts in “Letter” tab as shown below:

Primary Reviewer					
Medicine Detail + Print Back					
Review Detail	Comment	Deficiency Report	Letters	Sample Request	
Title	File Name	Upload Date	Uploaded By	Registration Status	
Acknowledgment letter	LOSECTIL_201509223794808116149.pdf	Apr-20, 2017	SoftWorks	New Application	Download
Sample Request Letter	LOSECTIL_sample request c3806637787508561957.pdf	Apr-22, 2017	A.T.M. Goldm Kibito	Verified	Download
Acceptance letter	LOSECTIL_020018843283758261255495.pdf	Apr-20, 2017	SoftWorks	Verified	Download
Deficiency Letter	LOSECTIL_dofscs10220568/262024813.pdf	Apr-20, 2017	SoftWorks	Verified	Download
Further Information Request	LOSECTIL_revscs1754b17311460522113.pdf	Apr-22, 2017	SoftWorks	Review Board	Download
QoS report, part1	LOSECTIL_Howto18601128/023030849518.pdf	Apr-22, 2017	Nayem Golcer	Review Board	Download
QoS report, part2	LOSECTIL_Howto2517208116/06333/23.pdf	Apr-22, 2017	Nayem Golcer	Review Board	Download

- There are two parts of QoS report. Now you need to click on **Download** button to view/download the QoS report. A QoS report is shown in the following section:



Directorate General of Drug Administration

QUALITY OVERALL SUMMARY (QOS) AND QUALITY REVIEW TEMPLATE
(Question-based Review format)

APPLICATION NUMBER: 0133/NMR/2017

APPLICATION DATE: 20/04/2017

APPROVED TRADE NAME: LOSFECTIL

GENERIC NAME(S) (INN if any): OMEPRAZOLE

STRENGTH(S) PER DOSAGE UNIT: 20 mg

DOSAGE FORM: TABLET

RECEIVED DATE: 11/04/2017

☐ FIRST GENERIC (New Product in Bangladesh)

☒ GENERIC (Existing Product in Bangladesh)

☒ LOCAL MANUFACTURER

☐ IMPORTER

PAPER SUBMISSION: 22/04/2017

TYPE II DMF # (if any):

APPLICANT NAME: INCEPTA PHARMACEUTICALS LIMITED

APPLICANT ADDRESS: 40 Shahid Tajuddin Ahmed Sarani Tejgaon LA

Dhaka

1208

Bangladesh

APPLICANT POINT OF CONTACT/POSITION: SoftWorks

APPLICANT TELEPHONE/FAX NUMBER: 88020891688 - 793 / 88020891190

APPLICANT EMAIL ADDRESS: dhaka@inceptapharma.com

QUALITY REVIEWER:	Mr. Nurul Islam	OVERALL QUALITY REVIEW RESULT:
DATE:	22/04/2017	SATISFACTORY
QUALITY REVIEWER:	Mr. Ayub Hossain	OVERALL QUALITY REVIEW RESULT:
DATE:	22/04/2017	SATISFACTORY
QUALITY REVIEWER:	Nayson Golder	OVERALL QUALITY REVIEW RESULT:
DATE:	22/04/2017	SATISFACTORY
QUALITY REVIEWER:	Dr. Manishin	OVERALL QUALITY REVIEW RESULT:
DATE:	22/04/2017	SATISFACTORY

QUALITY EXECUTIVE SUMMARY

SUMMARY OF PRODUCT INFORMATION

Generic name of the pharmaceutical product	OMEPRAZOLE
Trade name of the pharmaceutical product	LOSECTIL
International non-proprietary name(s) of the active pharmaceutical ingredient(s) (API(s)), including form (salt, hydrate, polymorph), if available	Antacid
For domestic site, has the applicant provided a copy of a current and satisfactory site license issued by DGDA? Or from WHO, USFDA, MHRA, TGA, EU, Canada, PIC/s country	No
Applicant name and address	INCEPTA PHARMACEUTICALS LIMITED,
Dosage form	TABLET
Reference Number(s)	
Strength(s)	20 mg
Route of administration	ORAL
Proposed indication(s)	
Contact information	Name: INCEPTA PHARMACEUTICALS LIMITED Phone: 88026861688 - 703 Fax: 86026991190 Email: dhaka@inceptapharma.com

Reviewer's Comments:

Primary Reviewer:

Completed reviewed and recommended by Reviewer 2

Secondary Reviewer:

Review completed by Reviewer 1 on Module 3 and recommended

References to Refer to During Dossier Review:

- Quality Overall Summary (QOS)
- Bangladesh CTD Module 2 (QOS) and 3 – Quality
- International Conference on Harmonization (ICH) documents
- WHO Guidelines for Pharmaceuticals

Pharmadex User Guide for DGDA

ACTIVE PHARMACEUTICAL INGREDIENT (API)

Note: Copy and Paste the Relevant Tables from Applicant QOS for each Section

A. General Information

Volume & Page(s): Rack-8

What are the nomenclature, molecular structure, molecular formula, and molecular weight? Are isomers of this product possible? If yes, indicate which isomer or combination of isomers comprises the medicine?

Detailed Applicant Response:

Reviewer's Response:

Primary Reviewer:

Reviewed by Reviewer

Is the information in this section of the application satisfactory?

☒ Yes

☐ No

Other Comments:

Volume & Page(s): Rack-8

What are the physicochemical properties including physical description, pKa, polymorphism, aqueous solubility (as function of pH), hygroscopicity, melting points, and partition coefficient?

Detailed Applicant Response:

Reviewer's Response:

Secondary Reviewer:

Reviewed by Secondary Reviewer on Module 3

Is the information in this section of the application satisfactory?

☒ Yes

☐ No

Other Comments:

B. Manufacture of API

Has the applicant provided the names and street addresses for each facility where manufacture occurs (including synthesis and production), including for any alternative manufacturers?

If it is a domestic site, did the applicant provide a copy of a current and satisfactory site licence issued by DGDA?

For a foreign site, has the applicant provided a current and satisfactory certificate issued by the relevant authority?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes

☐ No

Other Comments:

Has the applicant provided a description of the manufacturing processes and process controls? Including:

- Flow diagram of synthesis process (es), alternate processes, and reprocessing steps and justification?
- Details of the route of synthesis for each API in sufficient detail, including reagents and reaction conditions, together with specifications for starting materials, reagents and intermediates in the synthesis?
- Identified likely synthetic by-products and degradation products, and provided sample certificates of analysis for each site and method of manufacture?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

C. Control of API

Has the applicant provided full details of the controls performed at critical steps of the manufacturing process and intermediates? Including:

- Set of specifications for each API? Does it include all the critical API attributes that affect the manufacturing and quality of the drug product? Do the specifications ensure compliance with DGDA standards?
- For each specification is the analytical method suitable for its intended use, and, if necessary, validated? What is the justification for the acceptance criterion?
- Results of validation methods for assay of API and of impurities, and are they satisfactory?
- Is particle size determination necessary for this API, if yes, are the test method and limits satisfactory?
- Have Certificate of Analysis (CoA) been provided for at least two batches produced at each site of manufacture?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

D. Characterization of API

Has the applicant provided full details of the characterization of the API?

- How was the API structure elucidated and characterized?
- How were potential impurities identified and characterized? Basis for setting the acceptance criteria for impurities?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other Comments:	
E. Reference Standard	
Has the applicant provided full details of the reference standards or materials of the API? Source?	
<ul style="list-style-type: none">• How were the primary reference standards certified? (If pharmacopoeia monograph is claimed, the pharmacopoeia standard should be used)• Purification method if applicable?	
Detailed Applicant Response:	
Reviewer's Response:	
Is the information in this section of the application satisfactory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other Comments:	
F. Container Closure System	
Has the applicant provided full details of the container closure system?	
<ul style="list-style-type: none">• What container closure system is used for packaging and storage of the API?• What is the suitability of the materials used with respect to e.g. protect the product from moisture and light?	
Detailed Applicant Response:	
Reviewer's Response:	
Is the information in this section of the application satisfactory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Other Comments:	
G. Stability	
Has the applicant provided full details of the stability data of the API? Including:	
<ul style="list-style-type: none">• What API stability studies support the retest or expiration date and storage conditions?• Were results provided? Were the entire necessary test performed?• Is the assay procedure sufficiently specific for the purpose (i.e. is it 'stability-indicating')?• Are the proposed shelf-life and storage conditions for the API in the proposed container stated, and whether they are justified by the results of stability test?• Is post-approval stability protocol for batches provided?	
Detailed Applicant Response:	
Reviewer's Response:	
Is the information in this section of the application satisfactory?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Quality Review-Module 3, Version 1	
Page 6	

Other Comments:

PHARMACEUTICAL PRODUCT (FINISHED PHARMACEUTICAL PRODUCT)
Note: Copy and Paste the Relevant Tables from Applicant QOS for each Section

H. Description and Composition of the pharmaceutical product

Volume & Page(s): Rack-8

What are the components and composition of the final product?

Differences between this formulation and the reference product present potential concerns with respect to therapeutic equivalence?

For fixed-dosed combinations, what is the compatibility of APIs with each other?

Detailed Applicant Response:

Reviewer's Response:

Primary Reviewer:

Reviewed

Is the information in this section of the application satisfactory?

☒ Yes ☐ No

Other Comments:

Has the applicant provided a detailed description of the manufacturing procedure for each strength, formulation, and packaging?

A copy of the master formula; and a copy of a manufacturing record for a real batch should be provided.

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

I. Component of the pharmaceutical product

Has the applicant provided the names and street addresses for each facility where manufacture occurs (including synthesis and production), including for any alternative manufacturers?

If it is a domestic site, did the applicant provide a copy of a current and satisfactory site license issued by DGDA?

For a foreign site, has the applicant provided a current and satisfactory certificate issued by the relevant authority?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Quality Review-Module 3, Version 1

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Other Comments:

Has the applicant provided a detailed description and validation of the manufacturing procedure for the finished products? Including:

- Which properties or physico-chemical characteristics of the API affect the drug product development, manufacture, or performance?
- How are the manufacturing steps (unit operations) related to the drug product quality?
- How was the critical process parameters identified, monitored, validated, and /or controlled?
- What is the scale-up experience with the unit operations in this process?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

Are there any Overages? If yes, what are the justifications in the formulation?

Are there discussions of the parameters relevant to the performance of the Finished Pharmaceutical Product (FPP) (e.g. pH, ionic strength, dissolution, particle size distribution, polymorphism, rheological properties?)

Are there discussions of the development of the manufacturing process of the FPP? (e.g. optimization of the process, selection of the method of sterilization)

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

J. Container Closure System & other packaging

Has the applicant provided:

- A detailed description of the container/closure system(s), including any liner?
- Details of the composition of each component?
- A description of any other (e.g. outer) packaging and the materials from which they are made? Is it safe for use with this dosage form?
- Specifications for any part of the container/closure system which comes into contact with the product or is protective?
- Description of pack sizes? Child protective measures?

Is there discussion of the suitability of the container closure system used for the storage, transportation (shipping) and use for the FPP (e.g. choice of materials, protection from moisture and light, compatibility of the materials with the FPP)?

In the case of liquid dosage forms, have suitable studies been performed to investigate potential extractables?

Detailed Applicant Response:

Reviewer's Response:

Quality Review-Module 3, Version 1

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Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

K. Manufacture/Control of Drug Product

Is the list of all components of the FPP to be used for the manufacturing process and their amounts on a per batch basis included? (e.g. coatings)

Did the applicant describe the controls of critical steps and intermediates of FPP?

What are the specifications for the FPP?

Are there any data submitted for analytical procedure and process validation of FPP?

Is the complete batch analysis data for at least two batches of the FPP submitted? If imported products at least the identification and assay of the API should be submitted?

Is the limit of acceptance of Assay Content for the API and Uniformity of dosage unit submitted?

Did the applicant submit the dissolution and disintegration data?

Are there any data submitted for the control of excipients, including specifications (compendial or noncompendial)? Justification if noncompendial?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

L. Characterization of Impurities

Has the applicant provide information on the characterization of impurities? (Identification of potential and actual impurities)

What is the basis for setting the acceptance criteria and justification for impurities? Maximum daily dose (i.e. the amount of API administered per day)

Has there any data on observed impurities for relevant batches?

Did the applicant submit information on purification method, establishment of purity, and CoA if noncompendial API? If pharmacopoeia monograph is claimed, is the standard used

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

M. Stability Testing of Finished Product

Has the applicant provided full stability data and results?

- Stress testing and results? (e.g. photostability studies, cyclic studies, freeze-thaw studies)
- Was accelerated and long-term testing parameters done?
- What are the stability protocol for Primary stability and Ongoing batches (e.g. storage conditions, including tolerances), batch numbers and batch size, tests and acceptance criteria, testing frequency, container closure?

What information has been provided concerning the chemical and physicochemical stability of the finished product, including:

- Number of batches tested and whether the batches were tested on the formulation and the packaging that has been registered?
- Conditions under which it was tested? And duration of testing?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

Was the design of the stability study satisfactory?

Do the results of the study show any trend towards instability? If YES, give details of the conditions under which this trend was observed, and the nature of the changes?

State the shelf life and storage conditions proposed by the applicant.

Are the proposed shelf life and storage conditions acceptable given the analysis/assessment of the results of the stability study, and the difference between release and expiry specifications? If NO, recommend an alternative shelf life and conditions and/or any additional testing that should be conducted.

Did the applicant submit post-approval stability data and commitment?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

N. Appendices

For Biotech: Did the applicant provide the diagram of the manufacturing facilities (manufacturing flow diagram)?

Information provided on assessing the risk of potential contamination with adventitious agents? (both viral and nonviral agents?)

Has the applicant submitted any additional information on the API/drug product in the region?

Detailed Applicant Response:

Reviewer's Response:

Is the information in this section of the application satisfactory?

☐ Yes ☐ No

Other Comments:

9. RECOMMENDATION BY MODERATOR

- Once the Reviewers complete their review, the Moderator will need to log back in to advance the application further.

9.1. Log on as Moderator

- Log on as Moderator

- Write your user id and password like (User: mahmud, PW: *****)

- After logging in, go to **Registration > Process Product Application** menu
- The Received Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”

Product Name	Generic Name	Application Number	Application Type	Registration Status	Submitted Date	Applicant Name	Manufacturer Name
ACE PLUS	ADACAPUR	0133NM/R/D01	New Chemical Entity	Review Done	Mar 23, 2017	ESKAYET DANGLADESH LIMITED	Bio Swiss Pharma
ACE PLUS	ADACAPUR	0133NM/R/D01	New Chemical Entity	Review Done	Mar 23, 2017	ESKAYET DANGLADESH LIMITED	Bio Swiss Pharma

9.2. Recommendation of Moderator

- Based on the Reviewers' recommendations and his/her own observations, the Moderator can now either recommend or not recommend the product.

- Here you need to go to the “Assessment” tab as shown in the below screen:

Application Information	Verification	Screening	Sample Request	Comments	Timeline	Attachments	Letters
Additional Information	Assessment						
<div> <div>Executive Summary</div> </div>							
Reviewer	Secondary Reviewer	Assign Date	Due Date	Completed Date	Review Status	Module	
Md. Nurul Islam	Md. Ayub Hossain	Apr 20, 2017	Apr 26, 2017	Apr 22, 2017	Accepted	MODULE_1	
Naveem Golder	Dr. Mahshin	Apr 22, 2017	Apr 27, 2017	Apr 22, 2017	Accepted	MODULE_3	

- Click on “Executive Summary” from the Assessment tab. After clicking on Executive Summary button the following screen will arrive:

IOSFCTB Application Type: GENERIC Application Number: 0133/NMR/2017 Applicant Name: INCLIPIA PHARMACEUTICALS LIMITED Manufacturer Name: Eskayel Bangladesh Limited		Registration Status: Submitted By: SOFTWARES Applications Responsible: SOFTWARES Submitted Date: Apr 20, 2017	Review Status: Submitted By: SOFTWARES Applications Responsible: SOFTWARES Submitted Date: Apr 20, 2017
---	--	--	--

Back Submit

Md. Nurul Islam, Md. Ayub Hossain
 Module: **MODULE_1** Review Status: **ACCEPTED**
 Assign Date: **Apr 20, 2017** Due Date: **Apr 26, 2017**
 Submitted Date: **Apr 22, 2017**
 Evaluator Summary: The reviewer has recommended on Module 1 for registration of the application of Iosecill.
 Recommended on Module 3: Quality Overall Reviews (QOS) by Primary Reviewer

Muayenn Gulder, Dr. Mainulain
 Module: **MODULE_3** Review Status: **ACCEPTED**
 Assign Date: **Apr 22, 2017** Due Date: **Apr 27, 2017**
 Submitted Date: **Apr 22, 2017**
 Evaluator Summary: Completed reviews and recommended by Reviewer 2.
 Reviewer completed by Reviewer 1 on Module 3 and recommended

Executive Summary
 Recommendation * ▼
 Add Evaluator's Summary

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Summary *

- Here Moderator needs to select Satisfactory/Unsatisfactory/Follow-up from the **Recommendation** combo and write his/her comments under **Summary** section as shown in the following screen:

Executive Summary

Recommendation: Satisfactory

[Add Evaluator's Summary](#)

Executive Summary by Reviewer on Module 1:

The reviewer has recommended on Module 1 for registration of the application of Losectil.

Recommended on Module 3: Quality Overall Summary (QOS) by Primary Reviewer:

Executive Summary by Reviewer on Module 3:

Completed reviewed and recommended by Reviewer 2.

Review completed by Reviewer 1 on Module 3 and recommended.

Summary +

- Make the appropriate selection from the dropdown menu and click on “Submit” button.

LOSECTIL

<p>Application Type: GENERIC</p> <p>Application Number: 0133/NMR/2017</p> <p>Applicant Name: INCEPTA PHARMACEUTICALS LIMITED</p> <p>Manufacturer Name: Eskayef Bangladesh Limited</p>	<p>Registration Status: Satisfactory</p> <p>Submitted By: SoftWorks</p> <p>Applications Responsible: SoftWorks</p> <p>Submitted Date: Apr 20, 2017</p>
---	---

Timeline:

08:00 12:00 16:00 20:00 00:00 04:00 08:00 12:00 16:00 20:00 00:00 04:00 08:00 12:00 16:00

Thursday 20 April 2017 Friday 21 April 2017 Saturday 22 April 2017

Success

[Application Information](#)

[Verification](#)

[Screening](#)

[Sample Request](#)

[Comments](#)

[Timeline](#)

[Attachments](#)

[Letters](#)

[Additional Information](#)

[Assessment](#)

<p>Proprietary Name (Brand Name): LOSECTIL</p> <p>Generic Name: OMEPRAZOLE</p> <p>Dosage Form: TABLET</p> <p>Dosage Unit: mg</p> <p>Age Group: Adult</p>	<p>Product Category: Human</p> <p>Application Type: Generic</p> <p>Dosage Strength: 20</p> <p>Route of administration: ORAL</p> <p>Pharmacological Classification:</p>
--	--

Directorate General of Drug Administration
Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh

Logged in as Mahmud | Settings | Logout

Home Registration

- Registration
 - Registered Applications
 - Registered Products
 - Suspended Products
 - Canceled Products
- Application Processing
 - Process Product Application

Received Applications

Product Name	Generic Name	Application Number	Application Type	Registration Status	Submitted Date	Applicant Name	Manufacturer Name
ZIAGEN	ABACAVIR	0133/NMR/2017	New Chemical Entity	Review Board	Mar 20, 2017	ESKAYEF BANGLADESH LIMITED	Eskayef Pharma

(1 of 1) 1 20

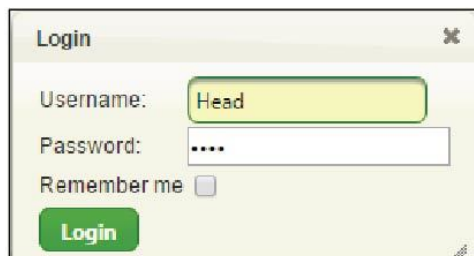
- The registration status will change accordingly.

10. REGISTER PRODUCT BY HEAD

- Once the **Moderator** makes his/her last recommendation, the **Head** is the one who can finally register or reject the product. To login as Head, go to the homepage and click on the door on the upper right corner.

10.1. Log on as Head

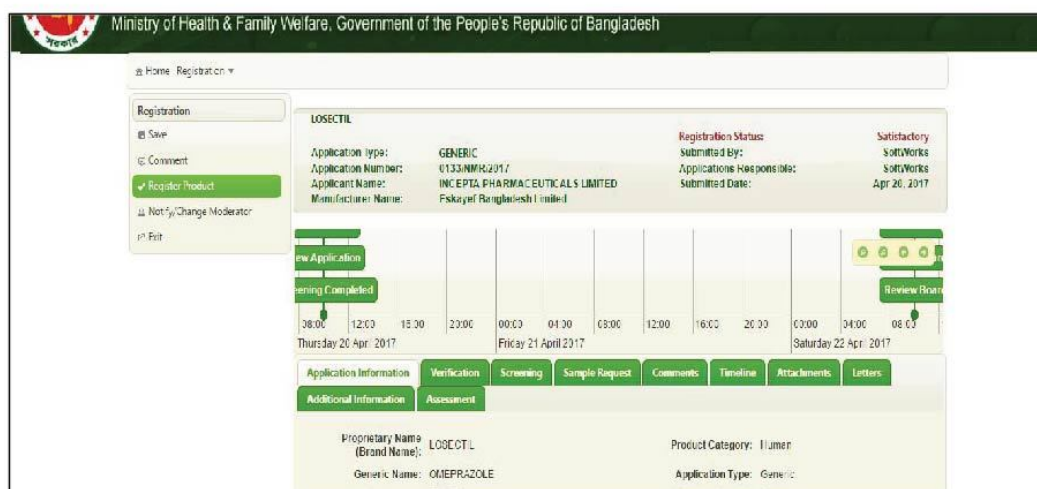
- Log in as “**Head**” user to register a product.



The screenshot shows a 'Login' dialog box with the following fields and controls:

- Username:** A text input field containing the text 'Head'.
- Password:** A password input field with four dots (****).
- Remember me:** A checkbox that is currently unchecked.
- Login:** A green button to submit the login information.

- The **Head** has access to all the same tabs of the Screener, Reviewer and Moderator.
- Click on the “**Product Name**” hyperlink which product you want to give registration to and after clicking the following screen will arrive –



The screenshot displays the 'Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh' portal. The main content area shows details for a product named 'LOSECTIL'.

Registration Details:

- Application type:** GENERIC
- Application Number:** 0133/NMH/2017
- Applicant Name:** INC EPTA PHARMACEUTICALS LIMITED
- Manufacturer Name:** Fskayel Bangladesh Limited
- Registration Status:** Satisfactory
- Submitted by:** sotyWorks
- Applications Responsible:** sotyWorks
- Submitted Date:** Apr 20, 2017

Timeline:

- New Application:** Thursday 20 Apr 2017, 08:00
- Review Completed:** Friday 21 April 2017, 00:00
- Review Date:** Saturday 22 Apr 2017, 08:00

Navigation Tabs:

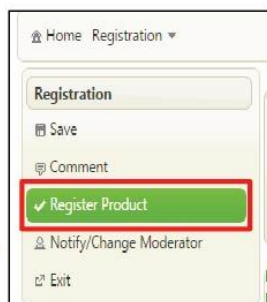
- Application Information
- Verification
- Screwing
- Sample Request
- Comments
- Timeline
- Attachments
- Letters

Product Information:

- Proprietary Name (Brand Name):** LOSECTIL
- Generic Name:** OMEPRAZOLE
- Product Category:** Tablet
- Application Type:** Generic

10.2. Product Registration

- Go to **Registration > Register Product** menu.



- After clicking on the “**Register Product**” from the left menu and the following pop-up entry screen will arrive:

- The following fields need to be filled-up:

1. **Registration Date:** Select the date from which the registration will be effective.
 2. **Expiry Date:** After putting the registration date, the date of expiry will be calculated automatically and displayed which may be edited if required.
 3. **Registration Number:** Also generated automatically.
- Then you need to press “**Register Product**” button and the following screen will arrive -

Registration

LOSECTIL

Application type: GENERIC
 Application Number: 0133/NMR/2017
 Applicant Name: INCEPTA PHARMACEUTICALS LIMITED
 Manufacturer Name: Eskay of Bangladesh Limited

Registration Status: Registered
 Submitted By: SoftWorks
 Applications Responsible: SoftWorks
 Submitted Date: Apr 20, 2017
 Expiry Date: Apr 21, 2022

Success

Application Information | Verification | Screening | Sample Request | Comments | Timeline | Attachments | Letters

Additional Information | **Marketing Authorization Letter** | Assessment

Proprietary Name (Brand Name): LOSECTIL
 Generic Name: OMEPRAZOLE
 Dosage Form: TABLET
 Dosage Unit: mg
 Age Group: Adult

Product Category: Human
 Application Type: Generic
 Dosage Strength: 20
 Route of administration: ORAL
 Pharmacological Classification:

Product Description and Physical: Treating heartburn or irritation of the esophagus caused by gastroesophageal reflux disease (GERD). It may also be used for short-term treatment of ulcers of the stomach or small intestine. It may also be used to decrease the

Medicine Detail: [Click here](#)

- After giving approval of registration of the product by Head you need to generate the Marketing Authorization Letter (Registration Certificate). To do this you need go to “Marketing Authorization Letter” tab to create click on the “Marketing Authorization Letter” button and the following PDF file will be generated.

Application Information | Verification | Screening | Sample Request | Comments | Timeline | Attachments | Letters

Additional Information | **Marketing Authorization Letter** | Assessment

[Marketing Authorization Letter](#)

Previous Applications

Application Number	Registration Number	Application Type	Registration Date	Expiry Date
No records found.				

10.3. Registration Certificate

- To print the certificate you need to click on “Registration Certificate” button and the following certificate will be viewed:



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



Memo No: _____

Date: _____

To
INCEPTA PHARMACEUTICALS LIMITED
40 Shahid Tajuddin Ahmed Sarani, Teggaon RA
Dhaka
1208
Bangladesh

Subject: Certificate for Marketing Authorization of Drug

In response to application, reference number 11/0133/NMR/2017 for marketing authorization of the following product, DGDA hereby inform you that the evaluation of the application has been completed.

Trade name	LOSECTIL
Generic name(s)	OMEPRazole
Strength(s) per dosage unit	20 mg
Dosage form	<u>TABLET</u>
Presentation	<u>10</u>

Approval under The Drug Control Ordinance-1982, section 5 is granted, subject to the conditions in this letter and it's attachments. This letter and its attachments constitute the Marketing Authorization. The details of this Authorization are as follows.

Marketing Authorization Number: _____
Date of Marketing Authorization: 22/04/2017
Expiry date of Marketing Authorization: 21/04/2022
(Before the expiry date you have to apply for renewal of the registration)

Conditions which apply to this approval are as follows:

- The product(s) must conform with all the details provided in your application and as modified in subsequent correspondence.
- No changes may be made to the product without prior approval of the Licensing Authority (Drugs)
- The approved sites of manufacturer stated in Attachment 1.
- The Approved shelf life is that in Attachment 2. The shelf life may be changed having the prior approval of Licensing Authority.
- The only Product Information (PI) that may be supplied with or for this product must be the PI that is approved. Attachment 3 is a copy of the approved PI.

Pharmadex User Guide for DGDA



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



- The Product Information (PI) may not be altered without prior approval of Licensing Authority, except for safety updates that further restrict use of the product. Any such safety-related changes must be notified to the Licensing Authority within five days of making the changes.

Director General,
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



Attachment 1

Product:

Trade name LOSECTIL
Generic name(s) OMEPRAZOLE
Strength(s) per dosage unit 20 mg
Dosage form TABLET
Name of Authorization holder INCEPTA PHARMACEUTICALS LIMITED
Marketing Authorization Number
Date of Marketing Authorization 22/04/2017
Expiry date of Marketing Authorization 21/04/2022

The approved manufacturers are as follows.

Product stage	Name of site	Address of site	Manufacturing step
Antacid	Square Pharmaceuticals Limited	SQUARE Centre 48, Mohakhali C/A, Dhaka 1212, 1212, Bangladesh	AP Manufacturer
OMEPRAZOLE	Eskayef Bangladesh Limited	400 Squibb Road, Tongi I/A, Tongi, Gazipur, Bangladesh, 1711, Bangladesh	Excipient manufacturer
LOSECTIL	Eskayef Bangladesh Limited	400 Squibb Road, Tongi I/A, Tongi, Gazipur, Bangladesh, 1711, Bangladesh	Fill/Contract Manufacturer



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



Attachment 2

Approved shelf-life:

The approved shelf life of this product when packaged and labeled on the basis of accelerated stability study as detailed in the application and modified in subsequent correspondence is as follows:

Product	Name of site	Address of site	Approved Shelf Life	Storage condition(PI)
LOSECTIL	Eskayef Bangladesh Limited	400 Squibb Road, Tongi IA, Tongi, Gazipur, Bangladesh, 1711, Bangladesh	24 months	Normal



Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212



Attachment 3

Copy of Approved Product Information (PI) this will be attached manually.

Indication, contraindication, side effect, pregnancy.

Pharmadex User Guide for DGDA

- The following screen show the Registered Product list –

Registered Products						
Product Name ⌵	Generic Name ⌵	Product Category ⌵	Registered Applicants ⌵	Registration Date ⌵	Expiry Date ⌵	Manufacturer Name ⌵
<input type="text"/>	<input type="text"/>	Select One	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
ALATROL	CETIRIZINE HYDROCHLORIDE	HUMAN	ESKAYEF BANGLADESH LIMITED	Jan 22, 2017	Jan 21, 2022	Eskayef Bangladesh Limited
ANTACID	ALUMINUM HYDROXIDE	HUMAN	ESKAYEF BANGLADESH LIMITED	Jan 25, 2017	Jan 24, 2022	Bio-Swiss Pharma
ALBEN_DS	ALBENDAZOLE	HUMAN	ESKAYEF BANGLADESH LIMITED	Mar 29, 2017	Mar 28, 2022	Eskayef Bangladesh Limited
ADORA	CEFADROXIL	HUMAN	INCEPTA PHARMACEUTICALS LIMITED	Dec 13, 2016	Dec 12, 2021	Rangs Pharma
PARACETAMOL	PARACETAMOL	HUMAN	INCEPTA PHARMACEUTICALS LIMITED	Jan 18, 2017	Jan 17, 2022	KIM Pharma
ZENIQUIN	MARBOFLOXACIN	VETERINARY	INCEPTA PHARMACEUTICALS LIMITED	Jan 25, 2017	Jan 24, 2022	Zoetis Inc
LOSECTIL	OMEPRAZOLE	HUMAN	INCEPTA PHARMACEUTICALS LIMITED	Apr 22, 2017	Apr 21, 2022	Eskayef Bangladesh Limited
FEXO	FEXOFENADINE HCL	HUMAN	INCEPTA PHARMACEUTICALS LIMITED	Mar 15, 2017	Mar 14, 2022	Square Pharmaceuticals Limited
MONTAIR	LEUKOTRIENE RECEPTOR ANTAGONIST	HUMAN	SOFTWORKS	Jan 18, 2017	Jan 17, 2022	Incepta
MONTAIR	LEUKOTRIENE RECEPTOR ANTAGONIST	HUMAN	SOFTWORKS	Dec 12, 2016	Dec 11, 2021	Incepta
NAPA	PARACETAMOL	HUMAN	SOFTWORKS	Dec 12, 2016	Dec 11, 2021	Beximco Pharma
NAPA EXTRA	PARACETAMOL	HUMAN	SOFTWORKS	Dec 13, 2016	Dec 12, 2021	Beximco Pharma
OLMEZEST	OLMESARTAN	HUMAN	SOFTWORKS	Jan 18, 2017	Jan 17, 2022	SOFTWORKS
RIMSTAR 4FDC	ISONIAZID	HUMAN	SOFTWORKS	Jan 22, 2017	Jan 21, 2022	Novartis India limited

- END -



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<http://www.dgda.gov.bd>

<https://pharmadexbd.org>