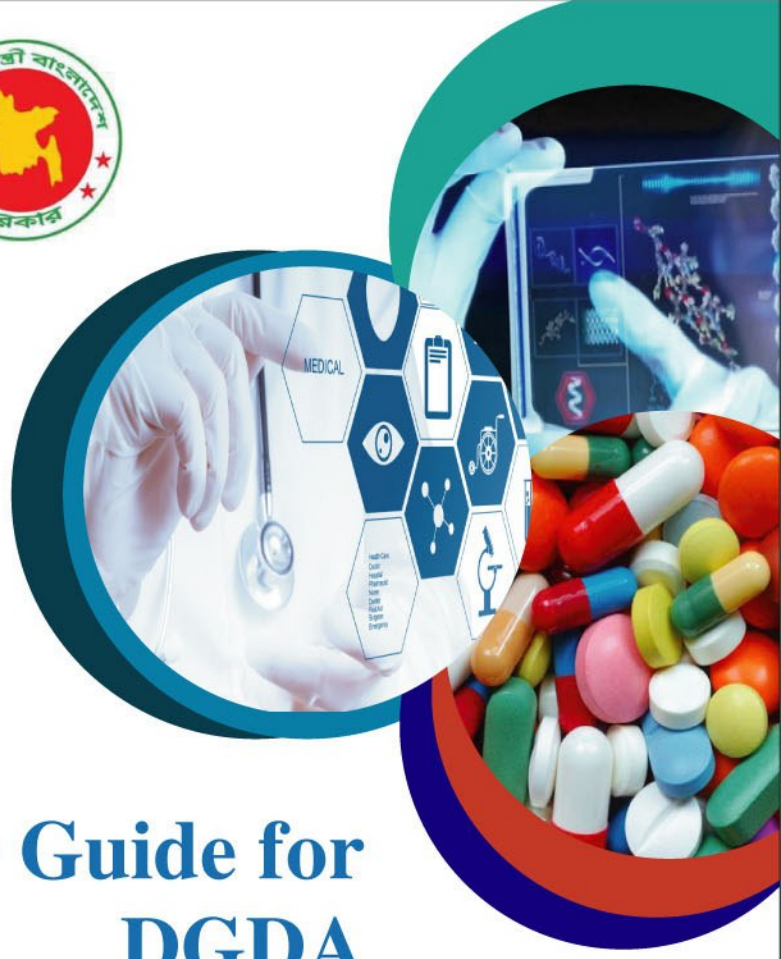

Pharmadex: User Guide for DGDA

April 2017

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

DGDA

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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.

Recommended Citation

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Key Words

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

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Contents

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.

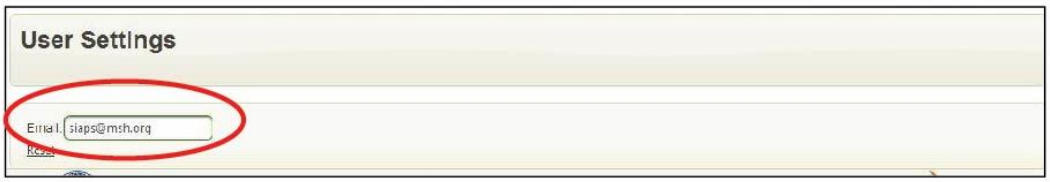
- You will receive a notification that your password has been successfully changed.

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 on 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.



2. REGISTERING APPLICANT COMPANY AND COMPANY USERS

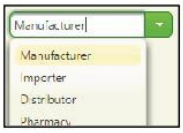
- To register an applicant company and their users, you have to click on **Registration > Registration Forms > Applicant Registration Form**.
- Currently Applicants cannot create their own Company Account or Associated Users. This task is handled by Pharmadex Admin User only. When a new application with 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

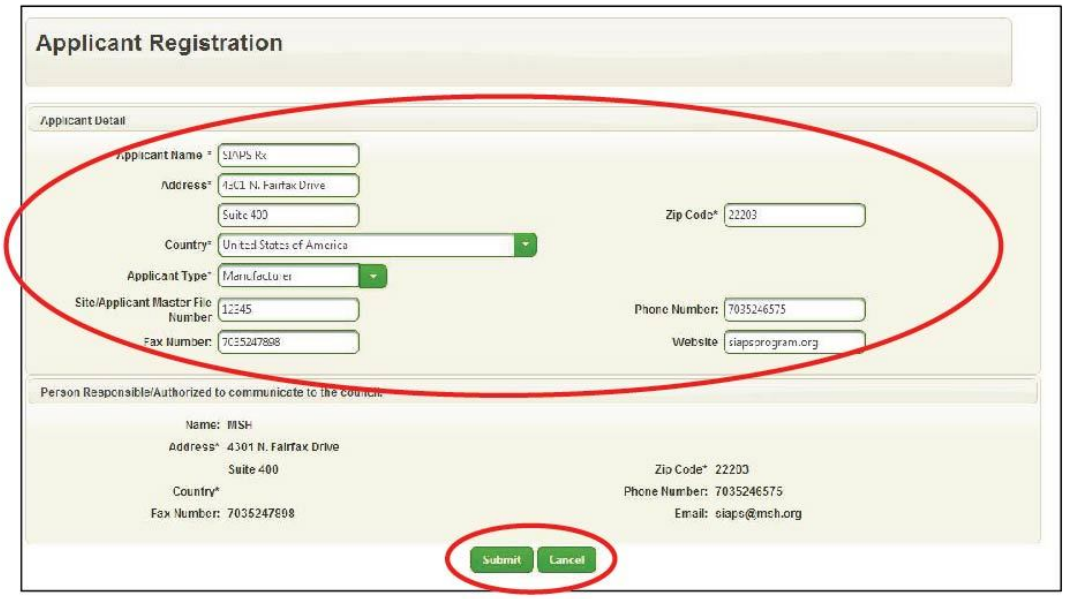
- To create a new Company Applicant you need to go to **Registration > Registration Forms > Application Registration Form**

- After clicking on the **"Application Registration Form"** menu the following screen will appear:

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



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



2.2. Add User or Registered Users with Company

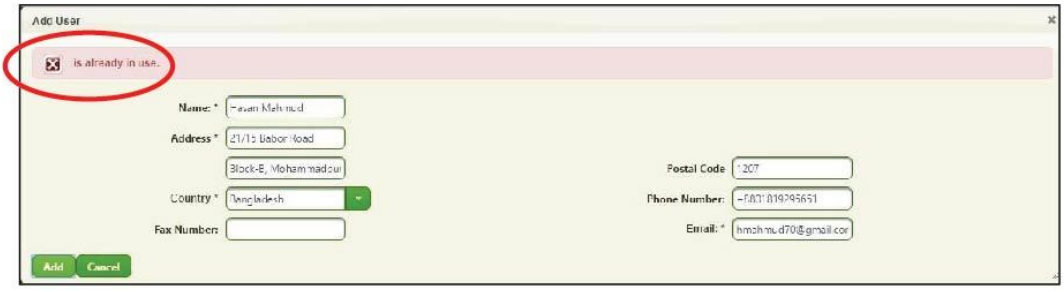
- Without linking with existing registered users or adding a new user, you cannot create the Company Applicant.

- 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:

- Click on "New User" link

- Fill up the fields of the following popup –

- 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:



- 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.

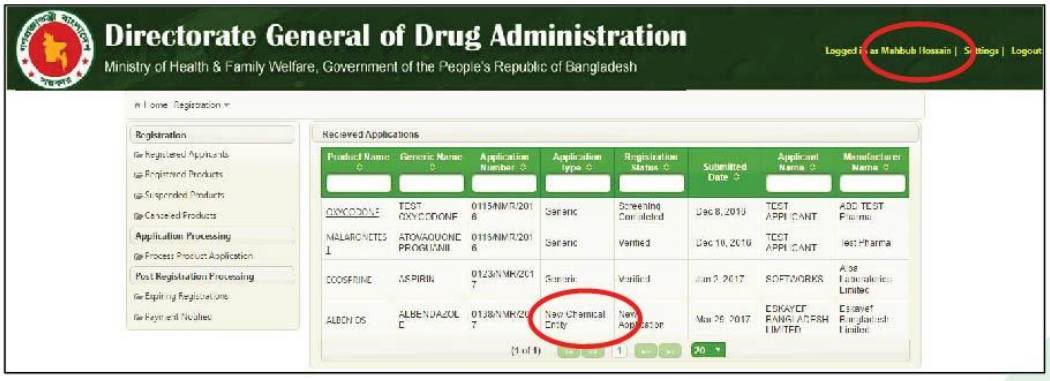
3. SCREENER VERIFY THE NEW APPLICATION

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 **"Screener"**. 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

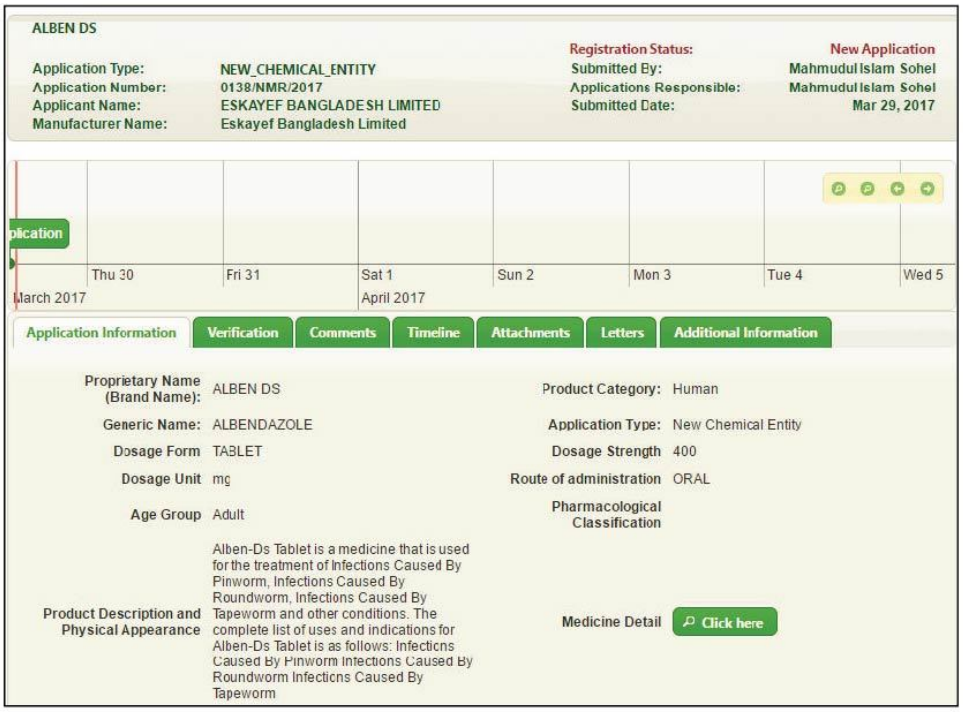
- Log in as Screener

- Write your user id and password like (User: mahbub, 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"



3.2. Application Information

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



- 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:

LOSECTIL

Application Type:	GENERIC	Registration Status:	New Application
Application Number:	[illegible]	Submitted By:	SoftWorks
Applicant Name:	INCEPTA PHARMACEUTICALS LIMITED	Applications Responsible:	Softworks
Manufacturer Name:	Eskayef Bangladesh Limited	Submitted Date:	Apr 20, 2017

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Print

Applicant Detail

Applicant Name * INCEPTA PHARMACEUTICALS LIMITED
Address * 40 Shahid Tajuddin Ahmed Sarani Tejgaon I/A
Dhaka — Postal Code 1208
Country * Bangladesh
Applicant Type * Manufacturer
Manufacturing License # — Phone Number: * 88028891088 - 703
Fax Number: 8802889119 — Website www.inceptapharma.com
Email dhaka@inceptapharma.com

Person Responsible/Authorized to communicate with DGDA

Name * Softworks
Address * 2/15 Babor Road, Block-B
Mohammadpur, Dhaka-1207 — Postal Code 1207
Country * Bangladesh — Phone Number:
Fax Number: — Email * [illegible]@gmail.com

Medicine Detail

Proprietary Name (Brand Name) LOSECTIL — Product Category Human
Generic Name OMEPRAZOLE — Application Type Generic
Dosage Form TABLET — Dosage Strength 20
Dosage Unit mg — Route of administration ORAL
Age Group Adult — Pharmacological Classification
Product Description and Physical Appearance: 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 risk of stomach bleeding in severely ill patients. It may also be used for other conditions as determined by your doctor. More: http://www.gmedication.com/?s=losectil More: http://www.gmedication.com/?s=losectil

Product Composition

Active Ingredients

INN Name	Dosage Strength	Dosage Unit	Pharmacopoeial Reference	Manufacturer Name
Antacid	500	mg		Square Pharmaceuticals Limited

Inactive Ingredients

Excipient Name	Dosage Strength	Dosage Unit	Function	Pharmacopoeial Reference	Manufacturer Name
OMEPRAZOLE	20	mg			Eskayef Bangladesh Limited

Pharmacotherapeutic group

Pharmacotherapeutic group	ATC Code	ATC Name
	A02BC01	omeprazole

Additional Info

Proposed Indication for Use: Losectil and Sodium Bicarbonate (omeprazole/sodium bicarbonate) is indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Proposed Posology and Method of Administration: Losectil is a proton pump inhibitor used in the treatment of dyspepsia, peptic ulcer disease (PUD), gastroesophageal reflux disease (GORD/GERD) and Zollinger-Ellison syndrome. It was first marketed in the US in 1989 by AstraZeneca under the brand names Losec and Prilosec, and is now also available from generic manufacturers under various brand names.

Product Type PHARMACEUTICAL — Formulary National Medicine (FNM)
Shelf Life (in Months) 24 — Pack Size 10
Container/Closure Type Parcel — Storage Conditions/Climate Zone Normal
Use Category Prescription only

Foreign Country Application Status

Country	Foreign Country Status Type	Product Name	Market Authorization Holder	Market Authorization Date
No records found.				

Manufacturing Activity

Applicant Name	Country	Applicant Type	Phone Number:
Eskayef Bangladesh Limited	Bangladesh	Toll/Contract Manufacturer	+88029812592
Square Pharmaceuticals Limited	Bangladesh	API Manufacturer	008018192959551
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592

Pricing Detail

Proposed Maximum Retail Price (MRP)/Indicative Price: 1 — Estimated Price per Dose: 10
Estimated Price per day of Treatment: 4 — Estimated Cost for recommended course of Treatment: 10

Name of marketed drugs which have the same indications	Approved Maximum Retail Price (MRP)/Indicative Price
No records found.	

Evidence of Payment

Name of the Bank Rupali Bank Limited
Receipt Number 432
Fee Submission Date Jan 20, 2017

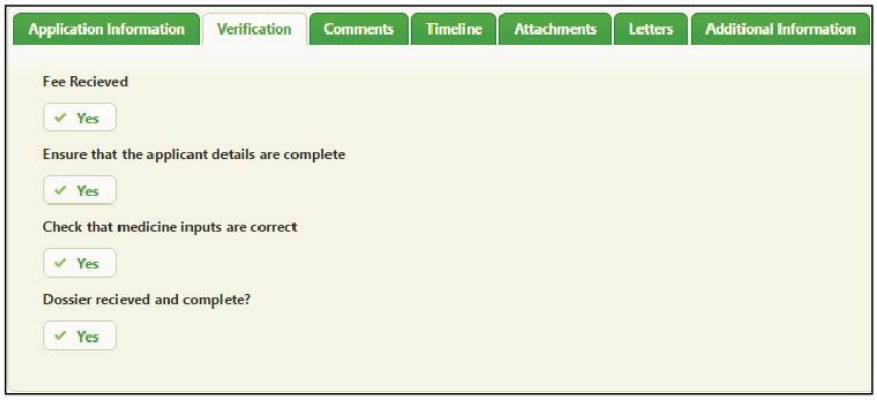
Checklist

Module 1	1	Letter of application	Yes
Module 1	1.1	Comprehensive table of content (module 1)	Yes
Module 1	1.2	Application - Hasar	Yes
Module 1	1.2.1	Application - Hasar Addition	Yes
Module 1	1.3	Bangladesh labelling and packaging	Yes
Module 1	1.4	Information about the experts	Yes

3.3. Verification

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

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



- 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 :
  1. Yes
  2. No
  3. 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.

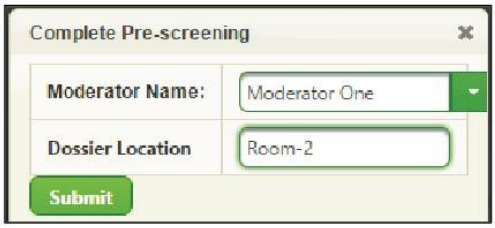
3.4.1. Save

- 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.

3.4.2. Complete

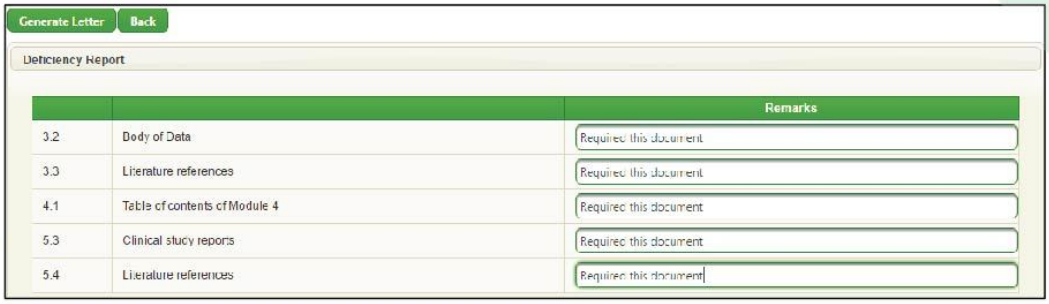
- After completion of screening, the screener needs to press on the **"Complete"** button to send the document to a Moderator to be assigned under a Reviewer.

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



3.4.3. Send to Applicant

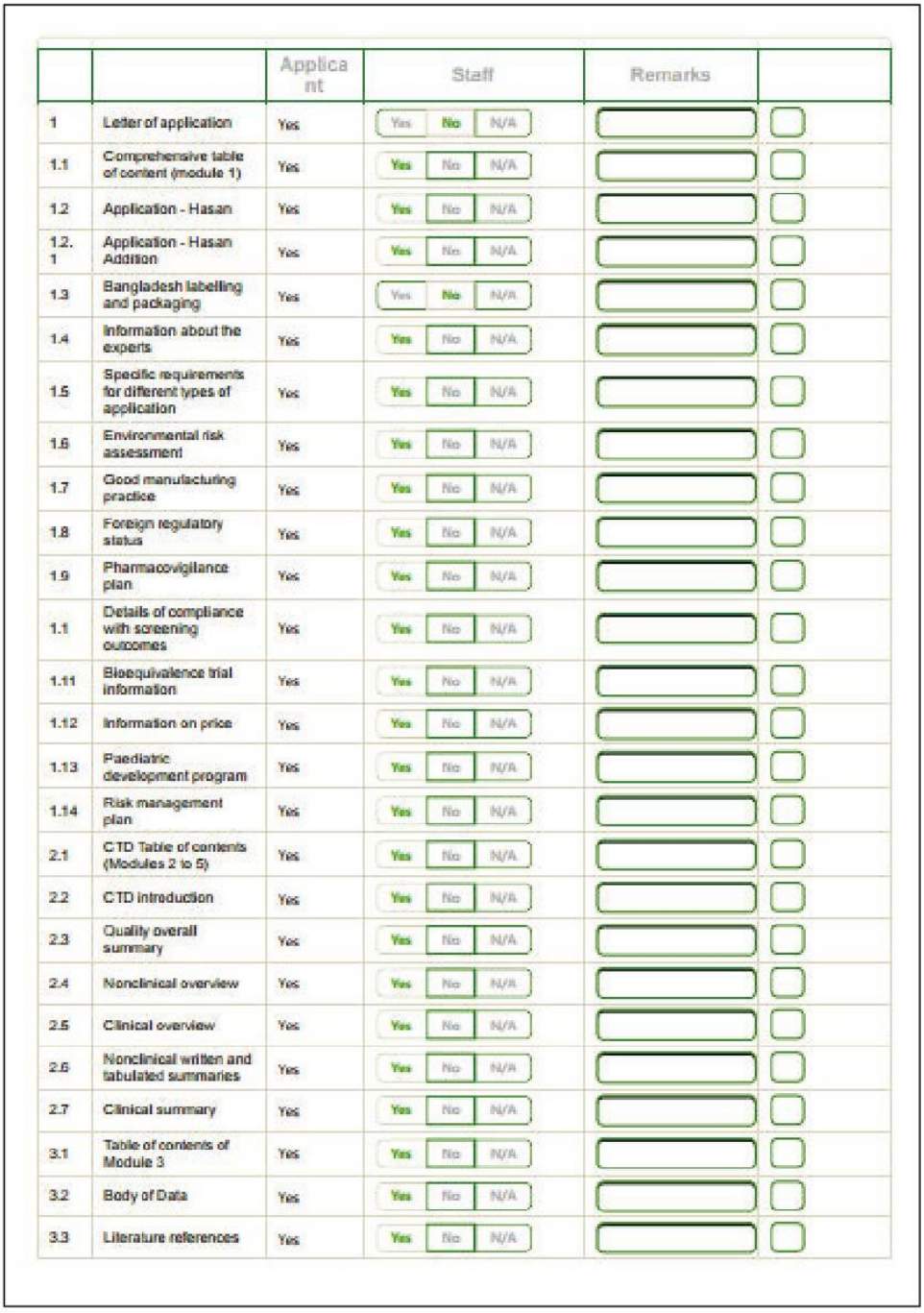
- The following screen is showing the list which was given **No** by the screener while checking the documents with the checklist and by clicking **"Generate Letter"** the **Dossier Deficiency Letter** will be automatically generated in the system.



- A pop-up message will appear.

3.4.5. Print

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

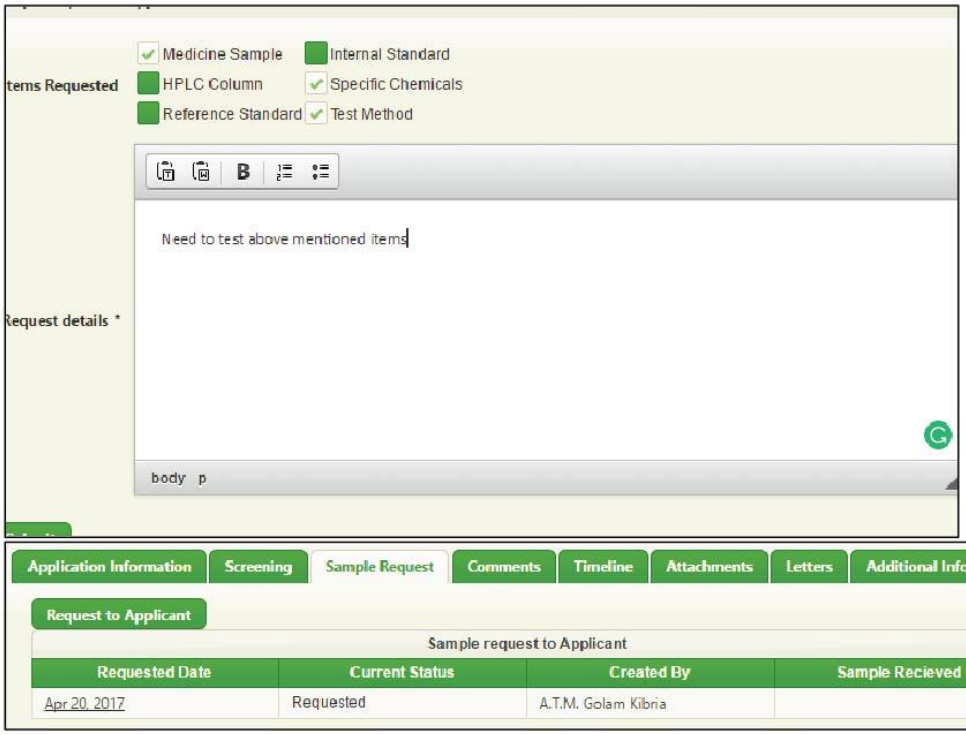


		Applicant	Staff	Remarks	
1	Leter of application	Yes	Yes No N/A		
1.1	Comprehensive table of content (module 1)	Yes	Yes No N/A		
1.2	Application - Hasan	Yes	Yes No N/A		
1.2.1	Application - Hasan Addition	Yes	Yes No N/A		
1.3	Bangladesh labelling and packaging	Yes	Yes No N/A		
1.4	Information about the 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	Yes	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 program	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	Yes	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	Yes	Yes No N/A		
3.3	Literature references	Yes	Yes No N/A		

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.

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



- 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"**.

3.7 Timeline

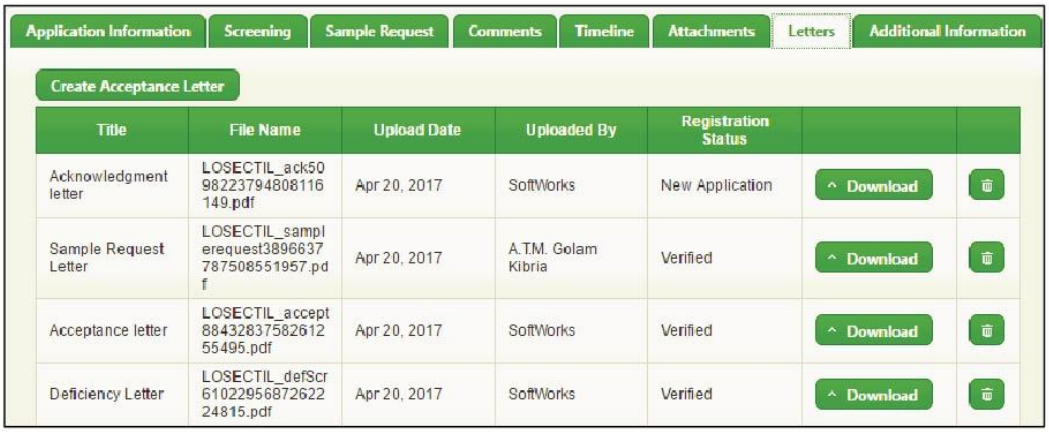
- The **"Timeline"** tab shows the status of the application during the different processing stages. The status of all processes after submission of application you can see at a glance here.

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.

3.9. Letter

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



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,
SOFTWORKS
21/15 Babor Road, Block-B
Mohammadpur, Dhaka
1207
Bangladesh
Attention: Mahmud Pharma

Subject: Request for sending samples for testing

Application Reference Number: 0127/NMR/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 licked 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 Bhaban, Mohakhali, Dhaka-1212

Memo No: _____ Date:

ESKAYEF BANGLADESH LIMITED
Tongi, Gazipur
Bangladesh
Attention: Mahmudul Islam Sohel

Subject: Acceptance Letter

Application Number:	0138/NMR/2017
Trade name:	ALBEN DS
Generic name:	ALBENDAZOLE
Strength:	400 mg
Dosage form:	TABLET
Manufacturer:	Eskayef Bangladesh Limited
Type of Application:	New Chemical Entity

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.

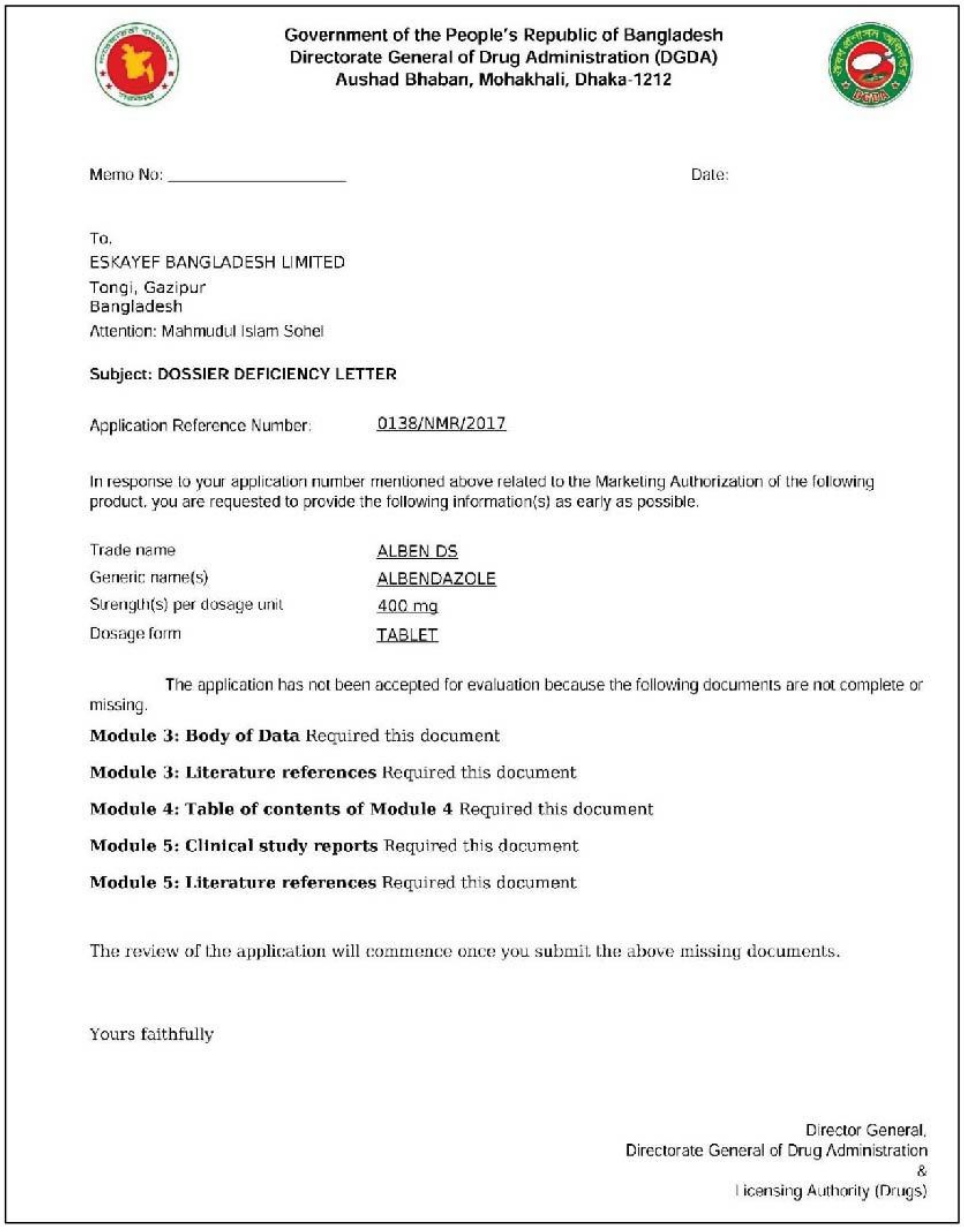
If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.

Yours faithfully

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

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:



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

Memo No: _____ Date:

To,
ESKAYEF BANGLADESH LIMITED
Tongi, Gazipur
Bangladesh
Attention: Mahmudul Islam Sohel

Subject: DOSSIER DEFICIENCY LETTER

Application Reference Number: 0138/NMR/2017

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	ALBEN DS
Generic name(s)	ALBENDAZOLE
Strength(s) per dosage unit	400 mg
Dosage form	TABLET

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:

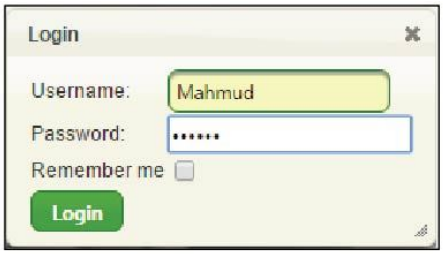
- After Screener completes the screening, the Registration Status of the Application will be changed from New Application Received to Screening Completed as shown in the following screen:

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

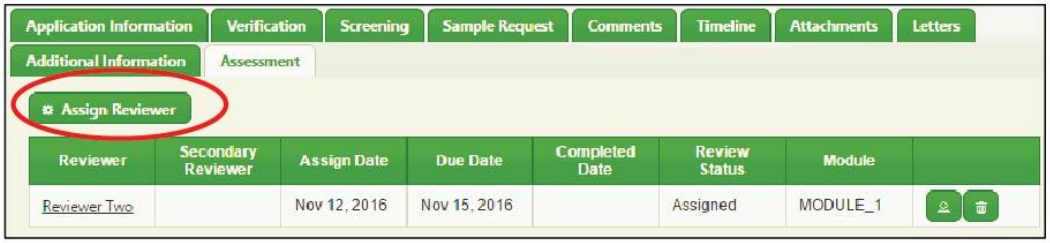


- Write your user id and password like (User: mahmud, PW: *******)

- 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"

4.2. Assign Reviewers by Moderator

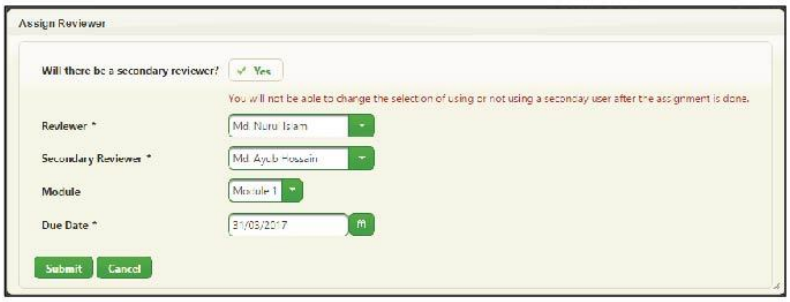
- After logging in the system, go to **Assignment** tab and click on "**Assign Reviewer"** button.



- 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.



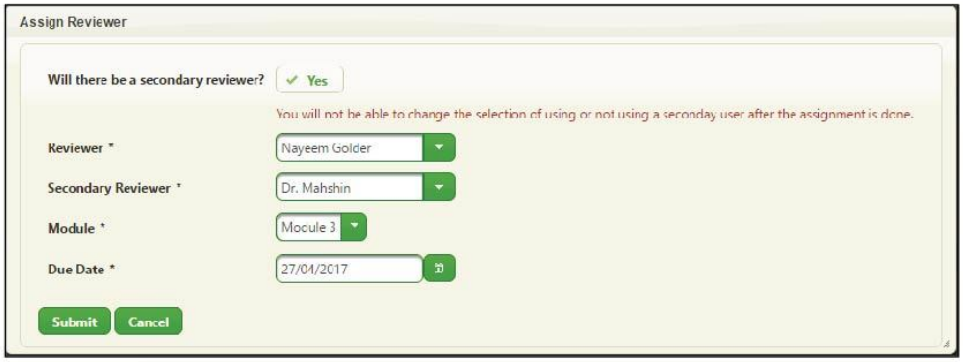
- If you click **"Yes",** then two Reviewer combo will be visible for selection.

- **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.

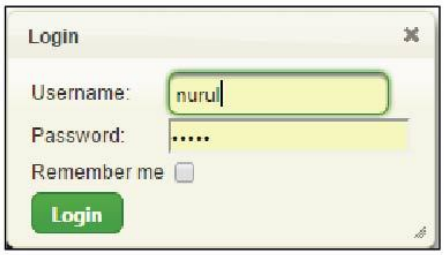


5. PRIMARY REVIEW: MODULE 1 REVIEW BY REVIEWER

- 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



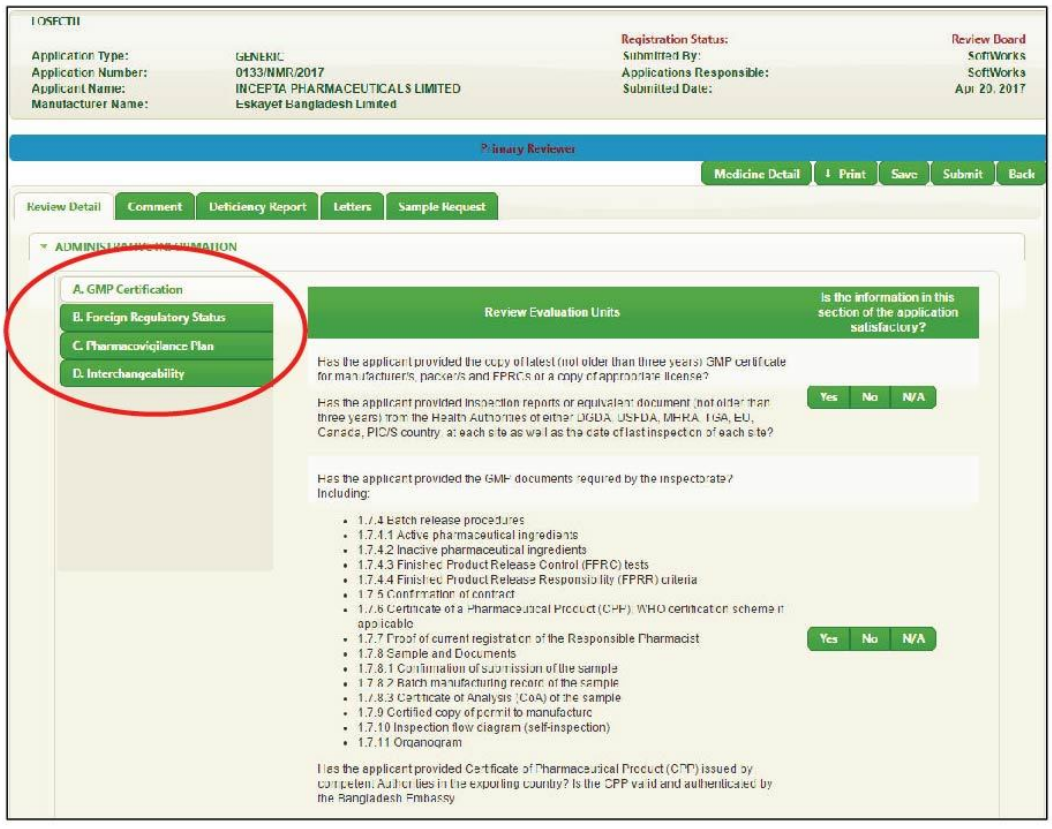
- Write your user id and password like (User: nurul, PW: *****)

- 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”

- 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

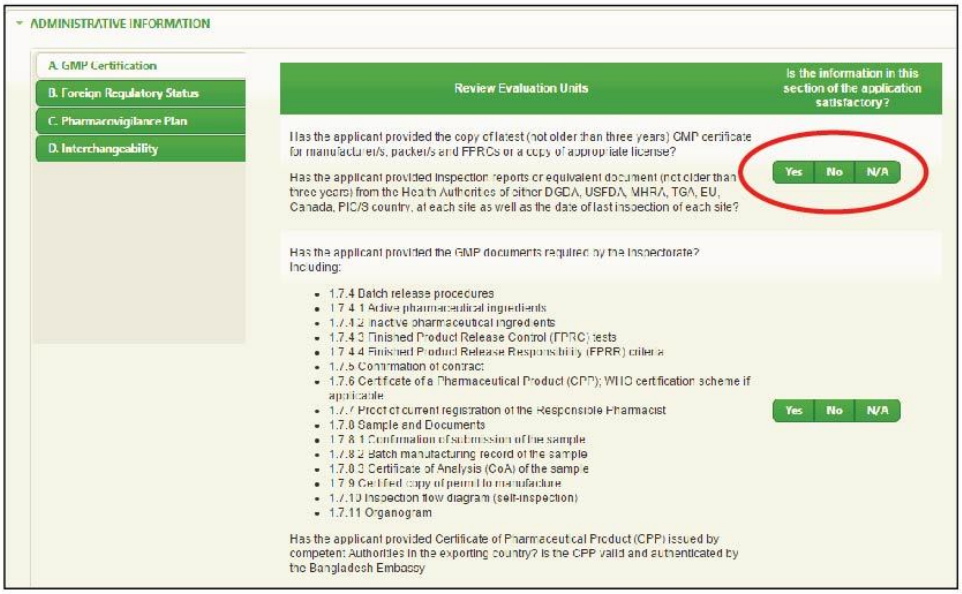
- If you are assigned for Module 1 the following screen will be visible:



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

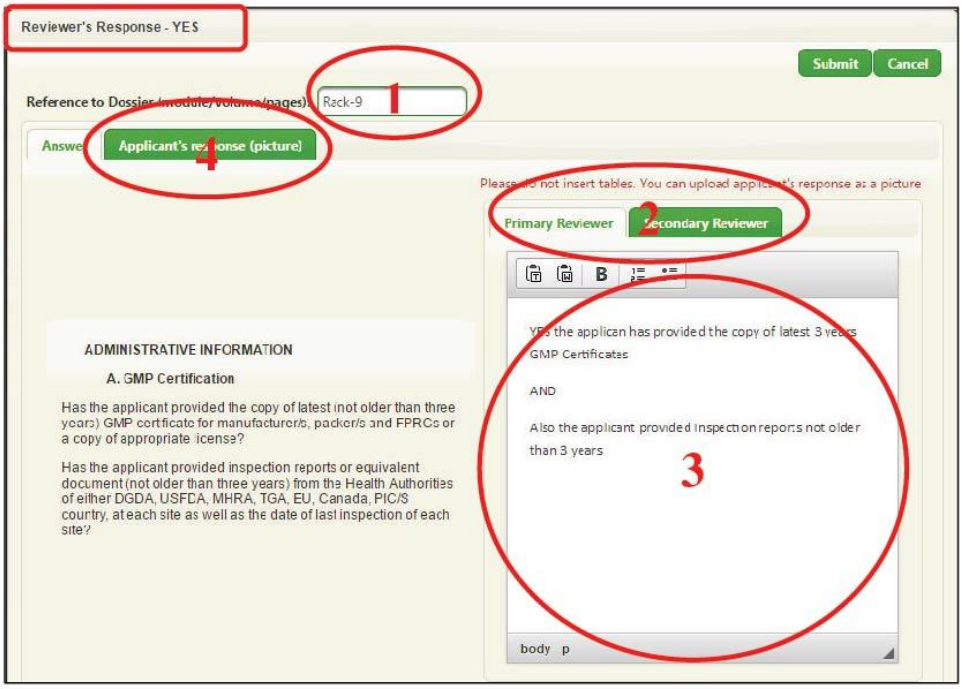
B) Foreign Regulatory Status
C) Pharmacovilgilance Plan
D) Interchangability

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



- Under each section there are 3 (three) types of answers, one of which the Reviewers can select – **Yes/No/NA**.

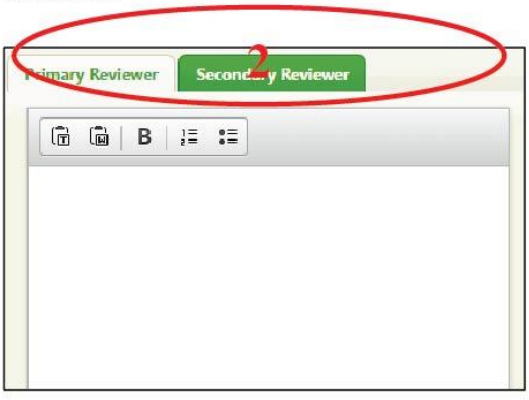
- If the reviewer clicks on **"Yes",** then the following screen will arrive.



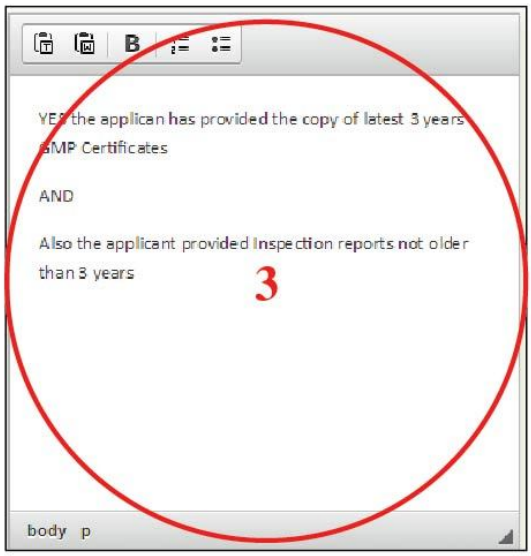
- After clicking on **"Yes"** the above screen will be visible and the following fields will need to be filled up:

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.

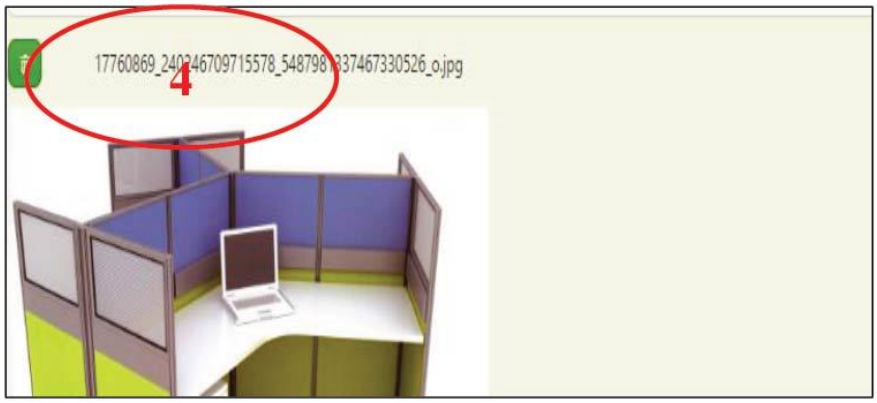
2) ***Reviewers Tab:*** If there is one reviewer to review the module, you will found one reviewer's tab i.e. Primary Reviewer. On the other hand, if there are two reviewers you will see two reviewers' tab – Primary Reviewer and Secondary Reviewer.



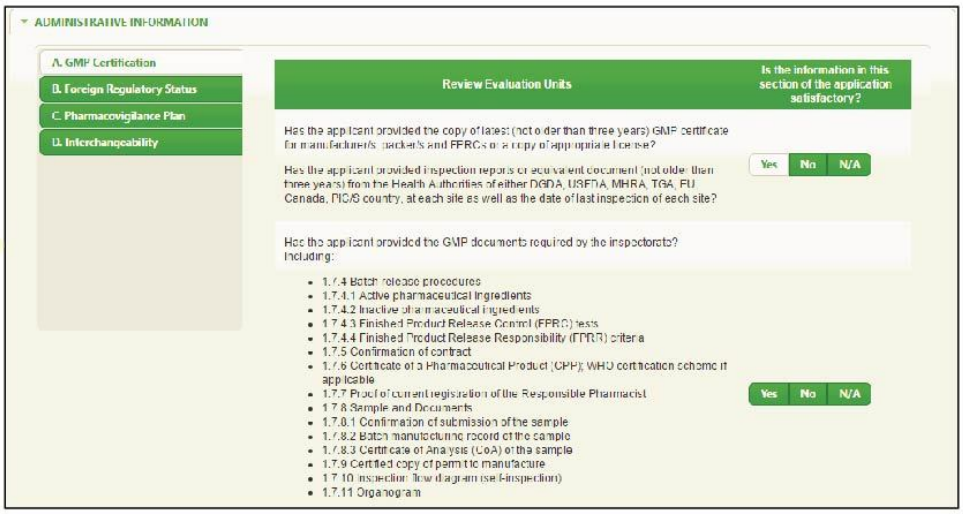
3) ***Reviewer's body p:*** In this notepad like template, reviewers(s) can write response to the question. Reviewer(s) can only write plain text here with basic formatting, table cannot be inserted.



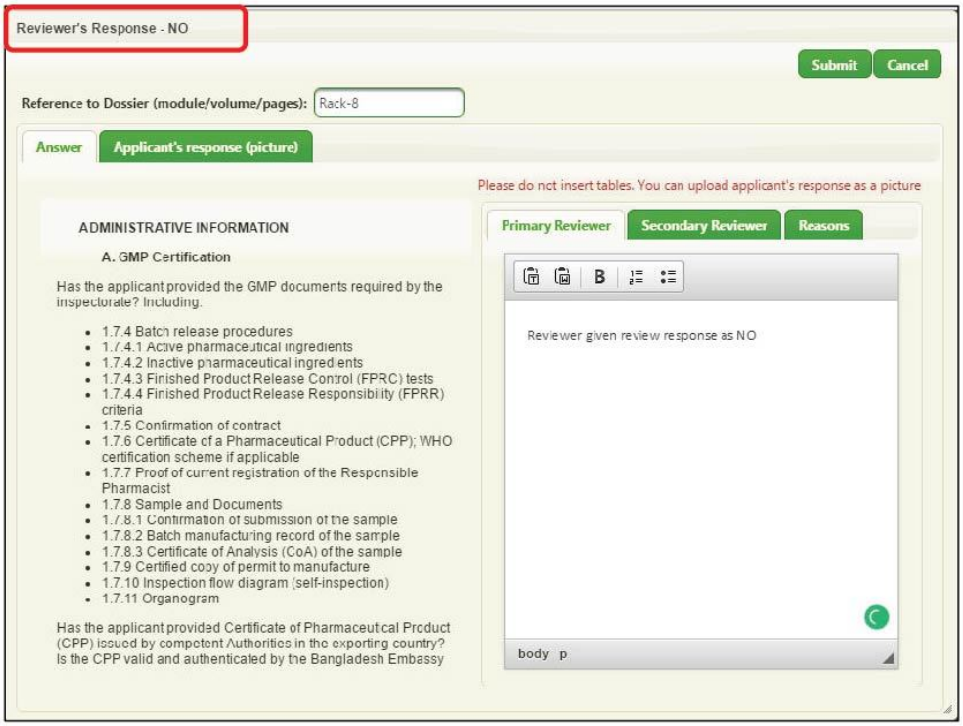
4) ***Applicant's response (picture):*** Here you only attach Applicant's response as image by uploading from the computer drive.

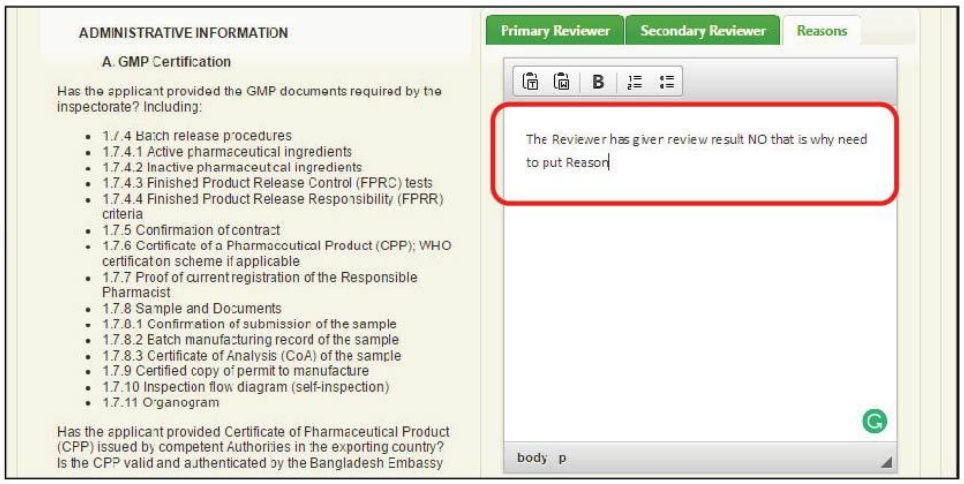


- After filling up all required fields the reviewer needs to press **"Submit"** button to close the question answer tab and the following screen will view.



- If the reviewer clicks on **"No"** button, then the following screen will arrive.

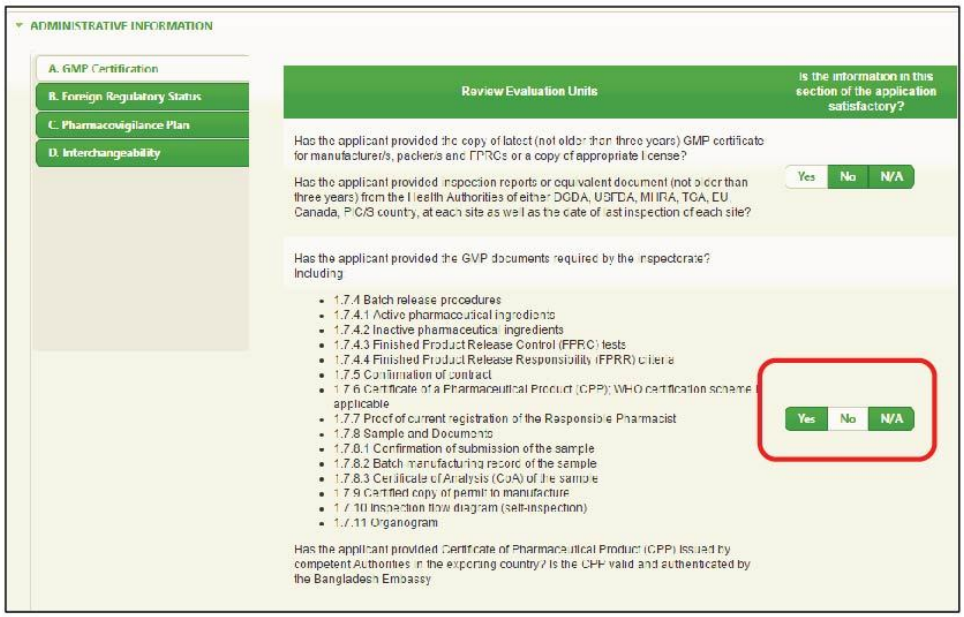




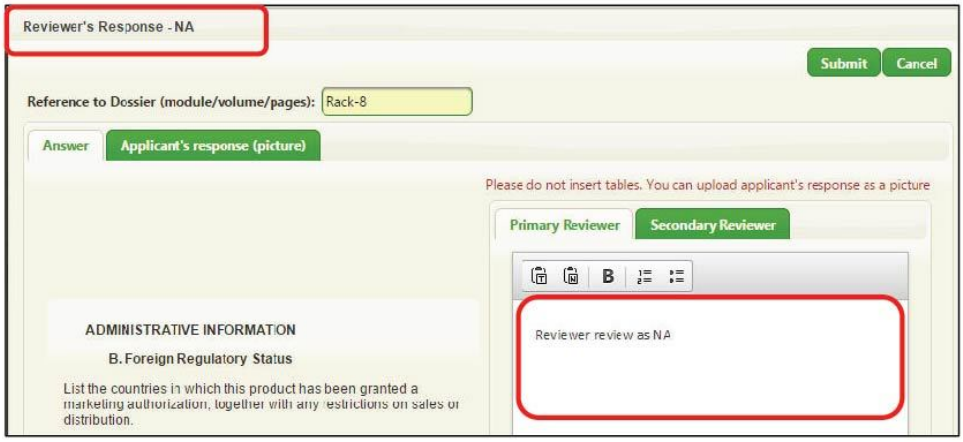
- If clicked NO, the reviewer will find an extra tab i.e. **"Reasons"** tab to clarify why the reviewer has selected **"No".** All other fields are same as described in the above "Yes" answer section.

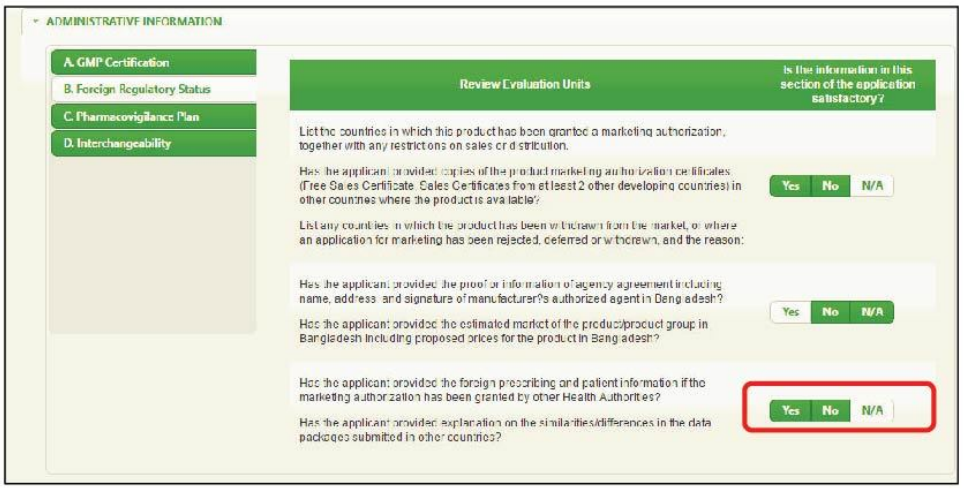
- Without writing reason the reviewer cannot close the form. If no reason is given, the following pop-up message **"Reasons is mandatory"** will appear.

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



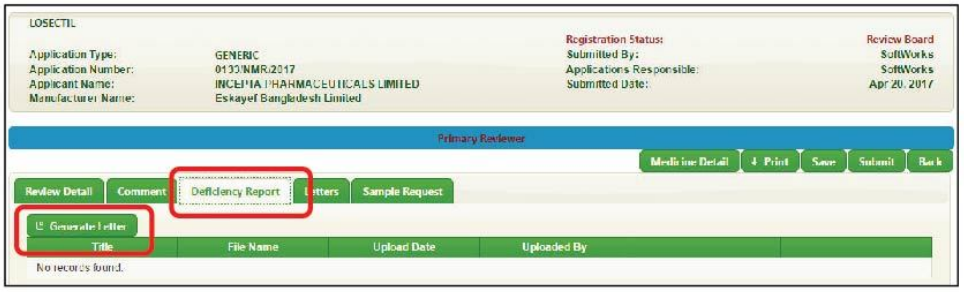
- If you click on the **"NA"** then same as above mentioned procedure needs to be followed and after that the following screen will arrive.



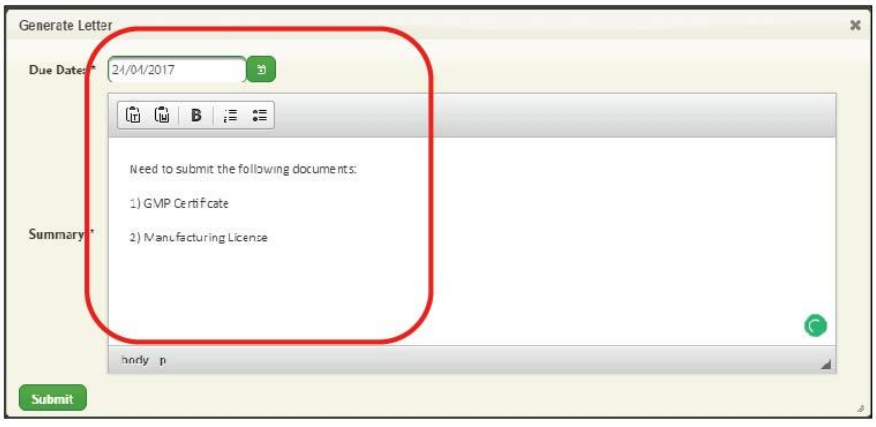


5.3. Dossier Review Deficiency

- 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 –

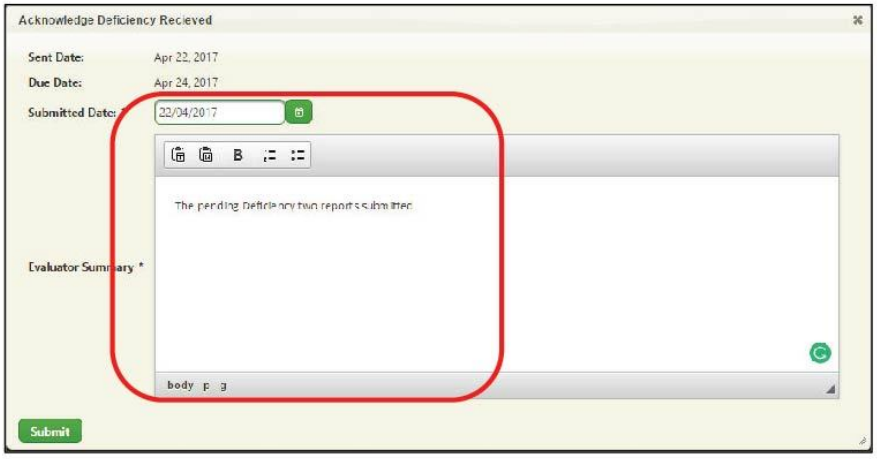


- The Reviewer needs to click on **"Generate Letter"** to generate deficiency letter and the following pop-up screen will arrive:



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

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



- After clicking on the **"Received"** button, the following screen will appear.

- 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 or 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

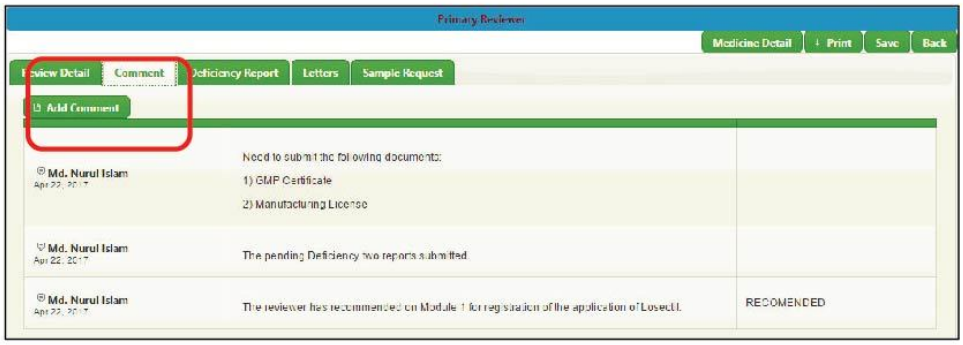
The review of the application will commence again once you submit your responses. If you have any queries as to the meaning of this letter, you should contact the undersigned immediately.

Yours faithfully

Director General,
Directorate General of Drug Administration
&

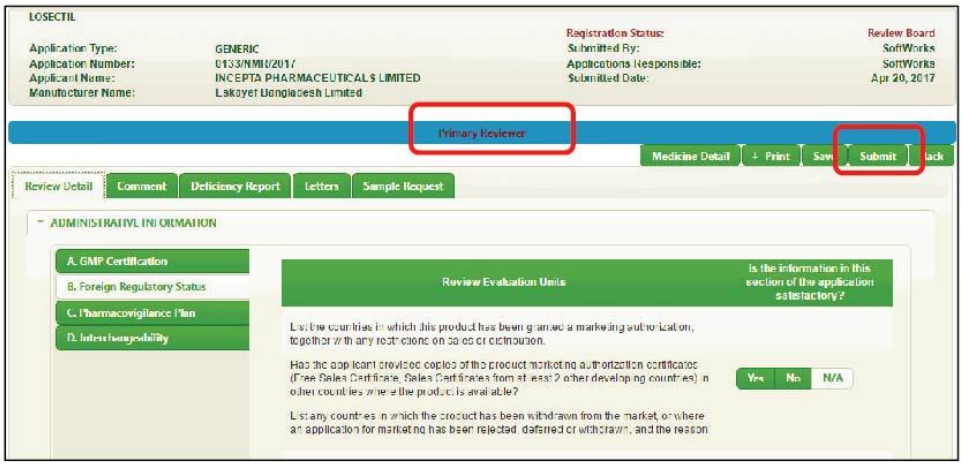
5.4. Comments by Primary Reviewer

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



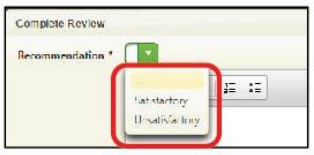
5.5. Submit Recommendation by Primary Reviewer

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

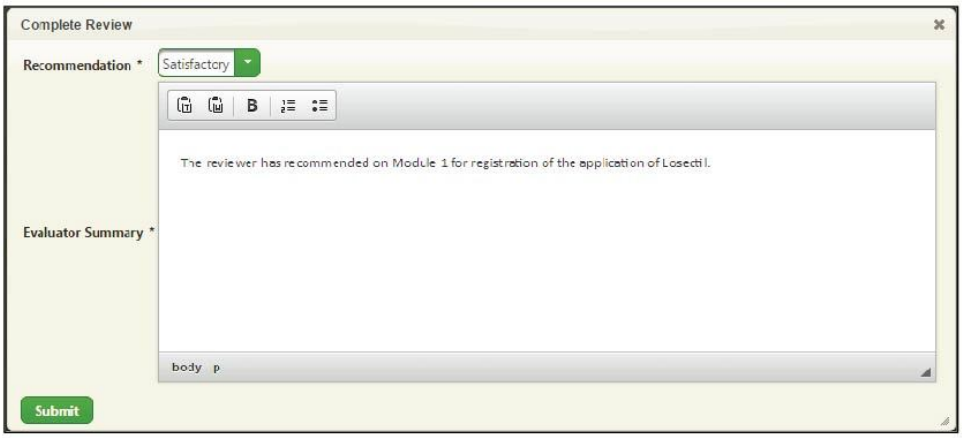


- After clicking on **"Submit"** button the following screen will appear.

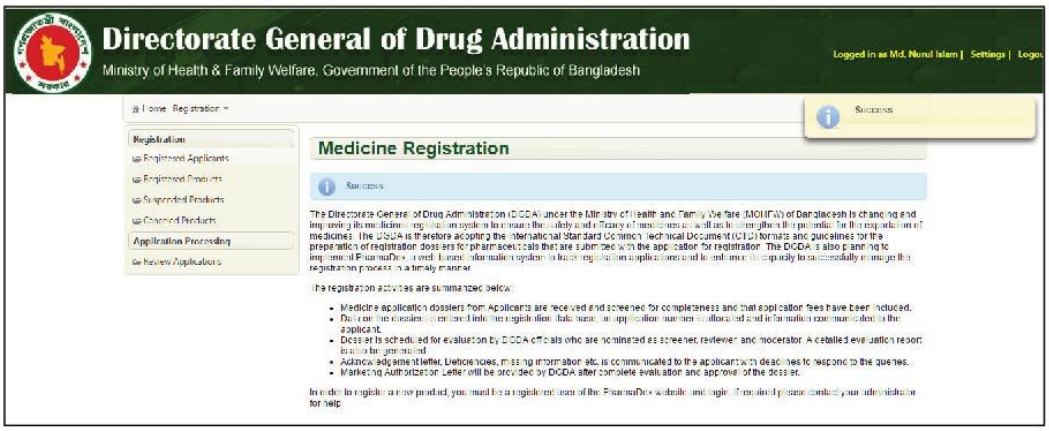
- From the **"Recommendation"** combo there are three options from which the reviewer can select one based on their assessment 1)--, 2) Satisfactory, 3) Unsatisfactory.



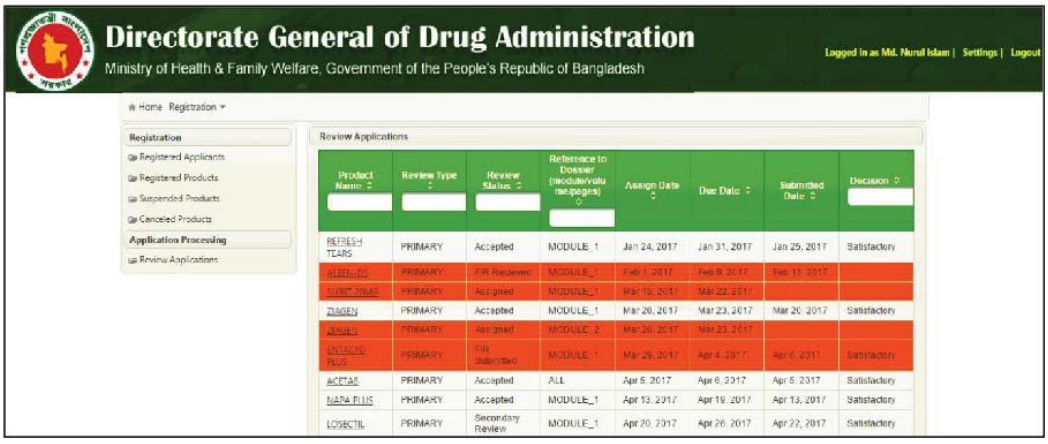
- Also the reviewer needs to write his comments in the **"Executive Summary"** section as shown below:



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



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



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

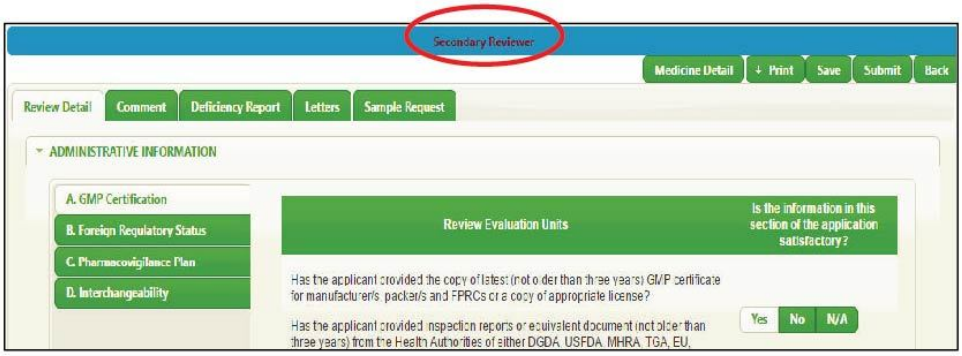
- Log on as Reviewer

- 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"

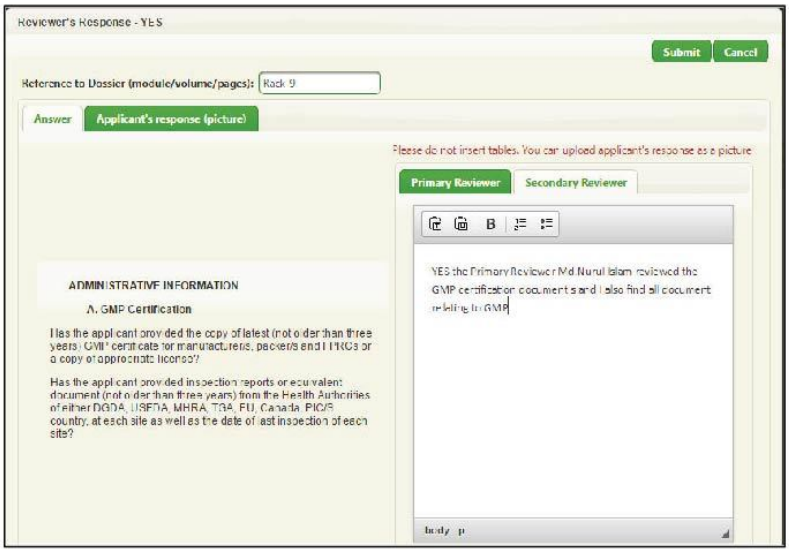
6.2. Secondary Review of Module-1

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



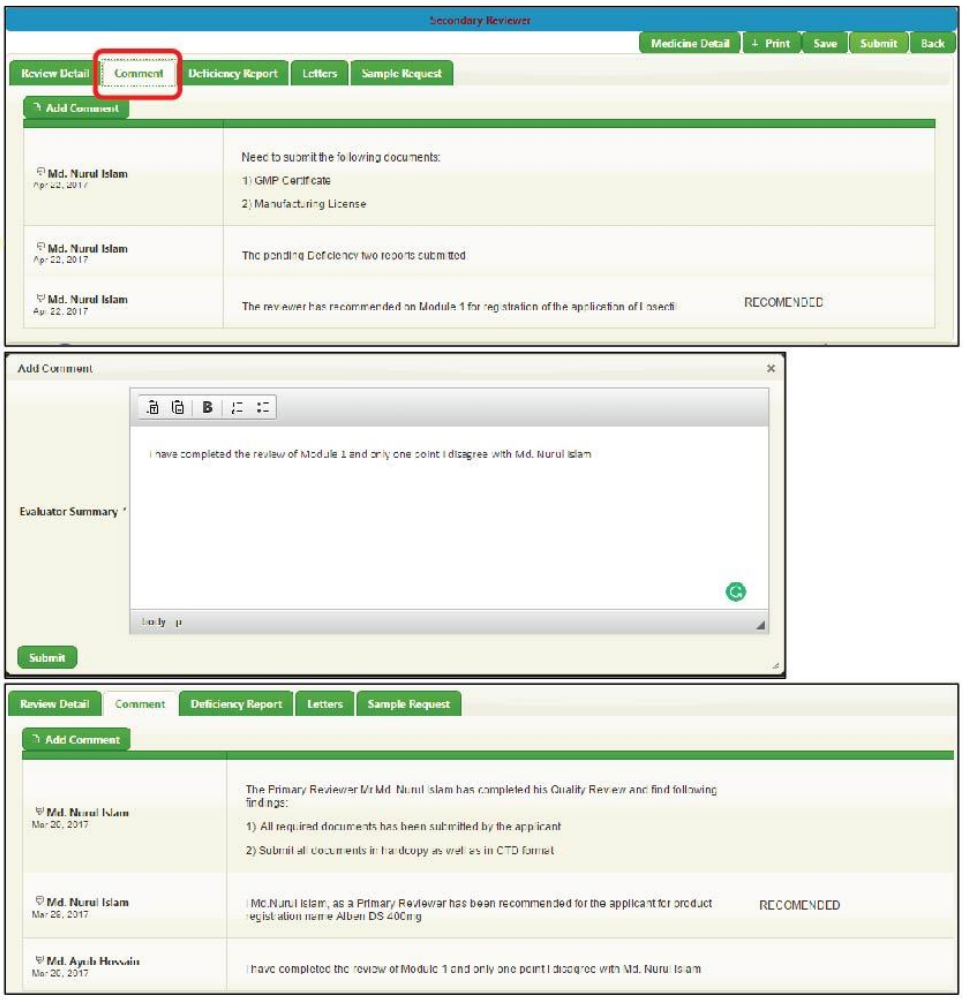
- In the same way as the Primary Reviewer has completed review, the Secondary Reviewer also need to follow all the steps to review Module 1 and same question set under Administrative Information will appear before the reviewer for review and the secondary reviewer will have to complet review accordingly.

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



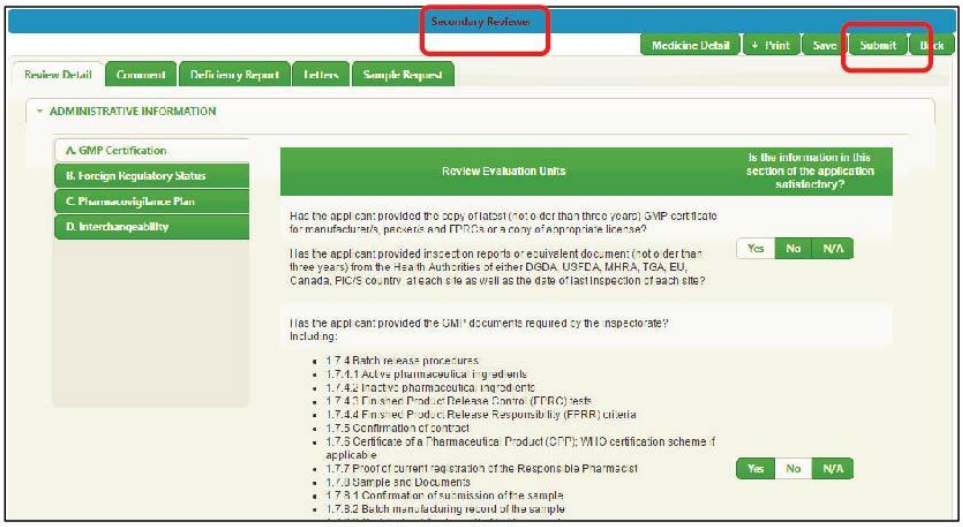
6.3. Comments by Secondary Reviewer

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

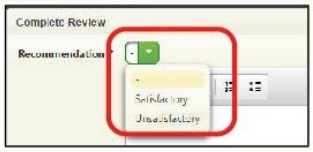


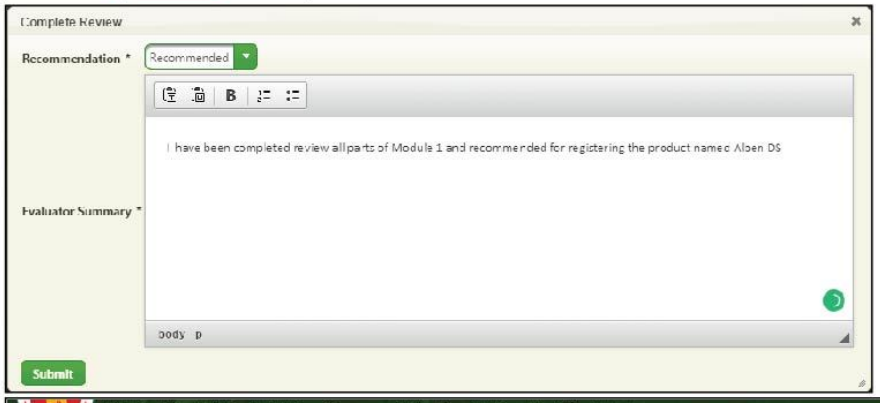
6.4. Submit Recommendation by Secondary Reviewer on Module-1

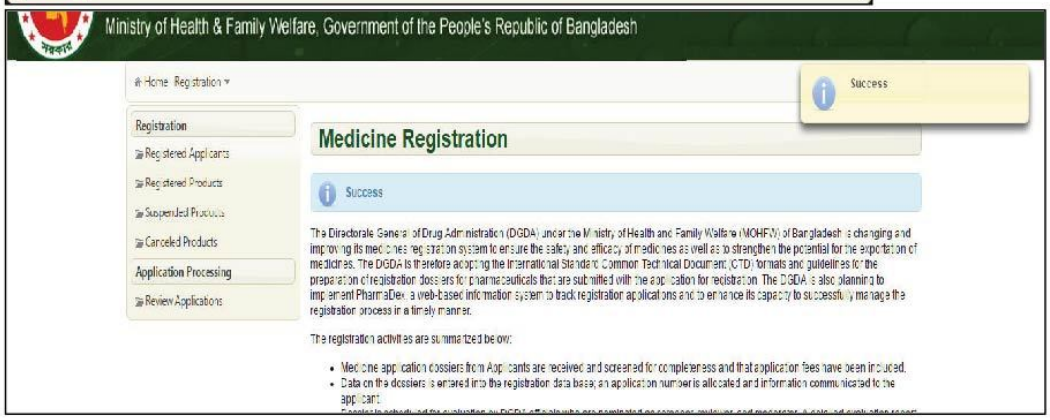
- After completing review (answering all the questions), the secondary reviewer also needs to click on the **"Submit"** button.



- 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:







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

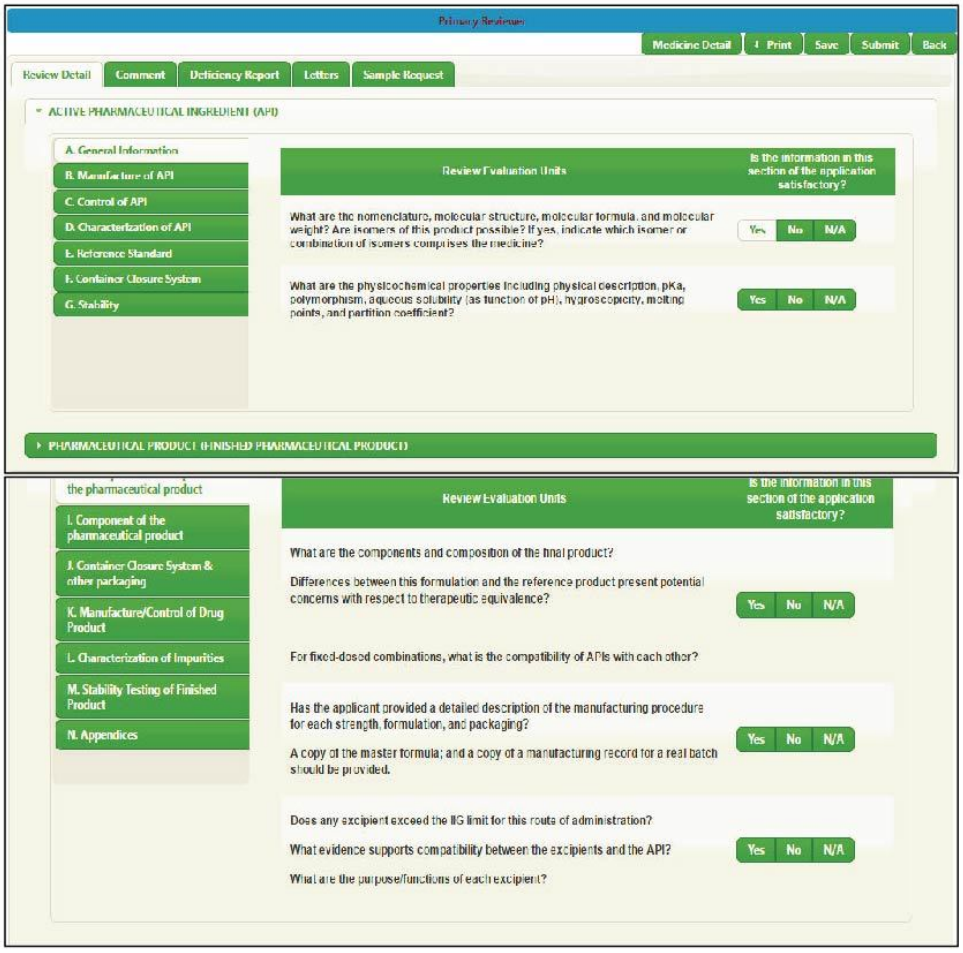
- Write your user id and password like (User: Reviewer2, PW: *******)

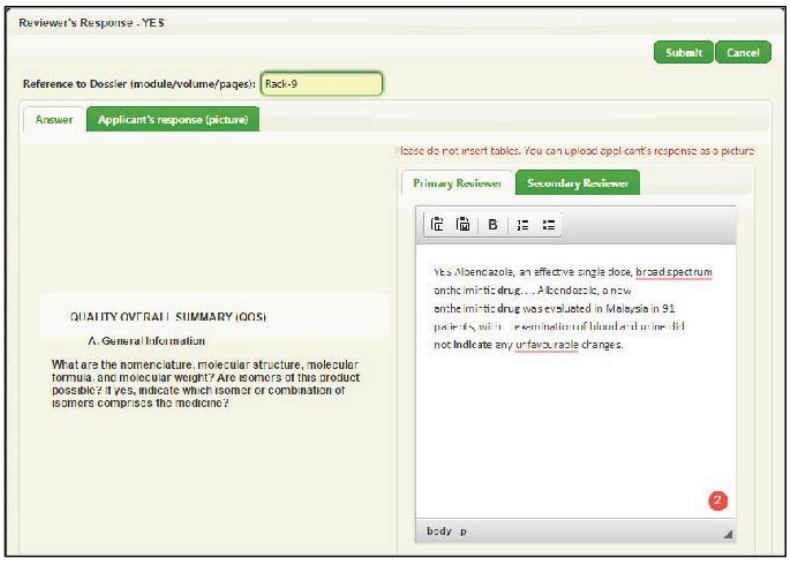
- After logging in, go to **Registration > Review Applications** menu
- The Review Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is “ACE PLUS”

- 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)** questionaries. The QoS questionaries are divided into two sections -

  1) Active Pharmacutical Ingrediants (API) - A to G question set
  2) Pharmacutical Products (Finishned Pharmacutical Products) - H to N question set

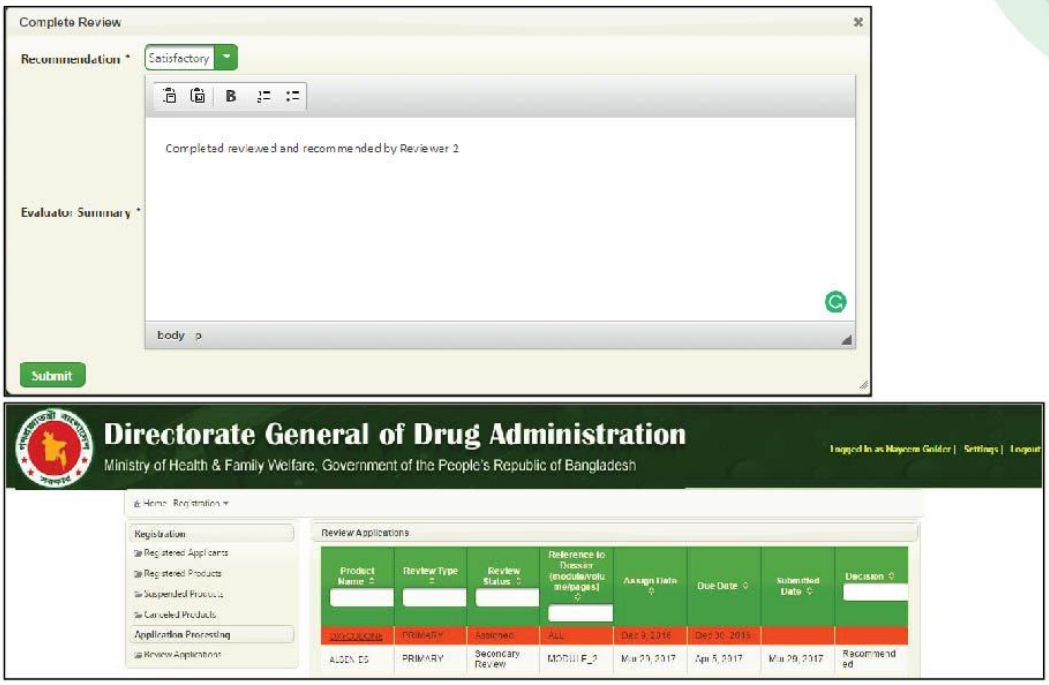
- The Primary Reviewer needs to comple all these questionaries one by one as described in the earlier section.





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:



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

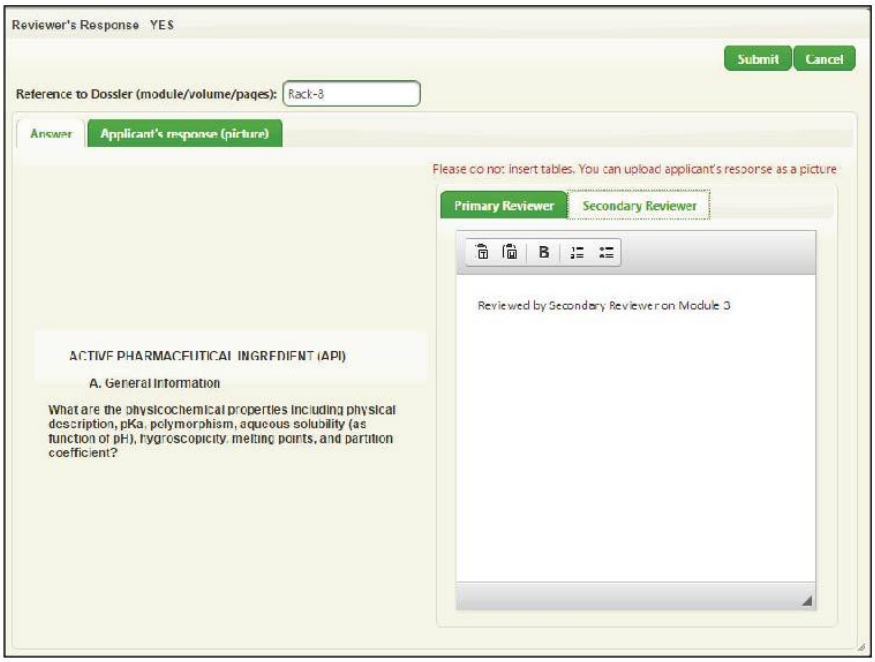
- Write your user id and password like (User: Reviewer1, PW: *******)

- 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"

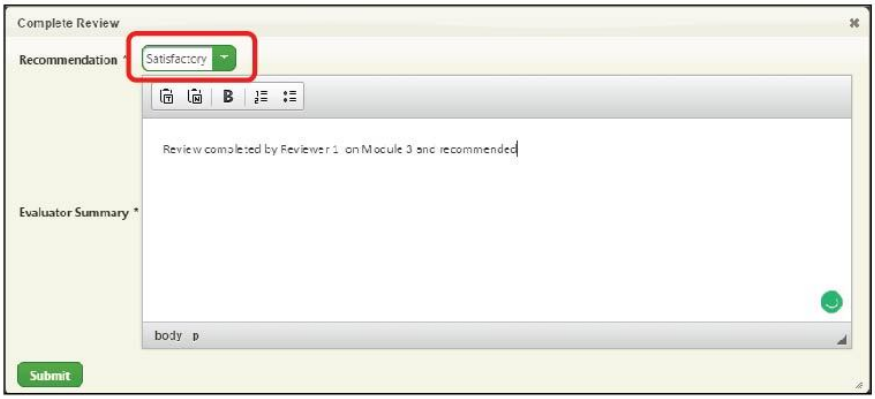
- In the same way, the Secodary Reviewer have to complete the review of Module-3 of QoS questionaries.

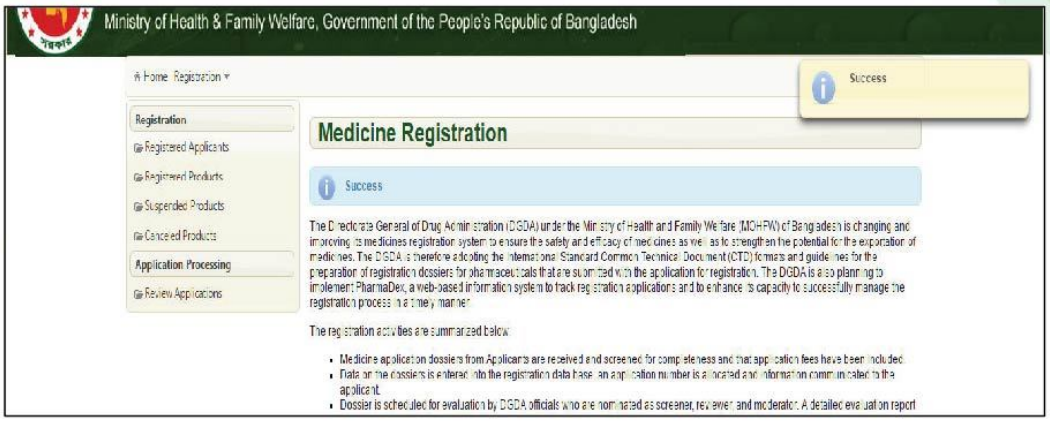
- The Secondary Reviewer of Module-3 will be reviwered all these questionnaires one by one same as described in the earlier section.



8.2. Submit Recommendation by Secondary Reviewer on Module-3

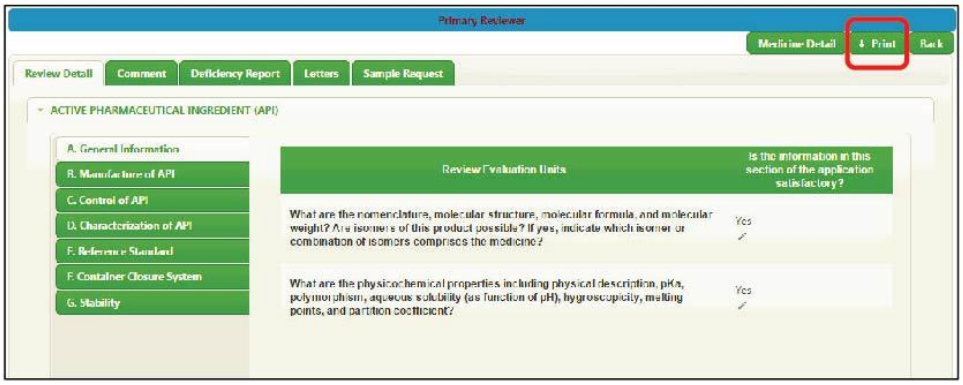
- Same as Primary Review, the Secondary Reviewer of Module-3 also need to follow the same procedure to recommend for product registration as shown in the following section:





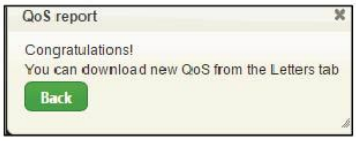
8.3. QoS Report

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



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

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



- 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:

- 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:	6133/NMR/2017
APPLICATION DATE:	20/04/2017
APPROVED TRADE NAME:	LOSECTIL
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)
- [x] GENERIC (Existing Product in Bangladesh)
- [x] 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 I/A Dhaka 1208 Bangladesh
APPLICANT POINT OF CONTACT/POSITION:	SoftWorks
APPLICANT TELEPHONE/FAX NUMBER:	880288891688 - 703 / 880288891190
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:	Nayeem Golder	OVERALL QUALITY REVIEW RESULT:
DATE:	22/04/2017	SATISFACTORY
QUALITY REVIEWER:	Dr. Manshin	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: 8802886 1688 - 703 Fax: 8802886 1190 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

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? [X] 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? [X] 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

Quality Review-Module 3, Version 1 Page 4

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:

s the information in this section of the application satisfactory? ☐ Yes ☐ No

Other Comments:

E. Reference Standard

Has the applicant provided full details of the reference standards or materials of the API? Source?

- **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:

s the information in this section of the application satisfactory? ☐ Yes ☐ No

Other Comments:

F. Container Closure System

Has the applicant provided full details of the container closure system?

- **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:

s the information in this section of the application satisfactory? ☐ Yes ☐ No

Other Comments:

G. Stability

Has the applicant provided full details of the stability data of the API? Including;

- **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:

s the information in this section of the application satisfactory? ☐ Yes ☐ 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? [X] 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 Page 7

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 Page 8

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 physiochemical 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

Quality Review Module 3, Version 1 Page 10

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

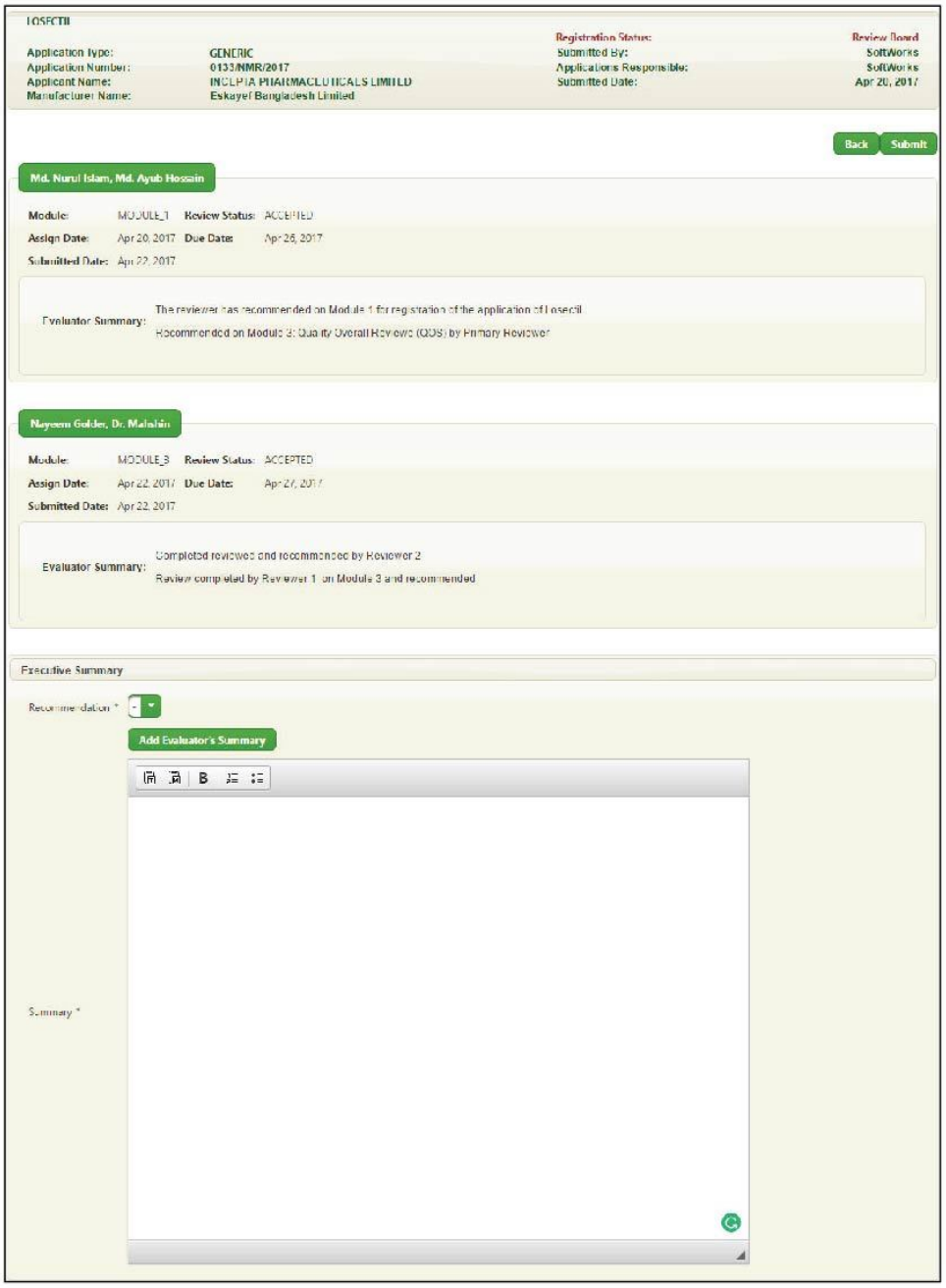
- The Received Application list form will be displayed. From the list you need to click on the hyperlink of the newly added Application - for example Product name is "ACE PLUS"

9.2. Recommendation of Moderator

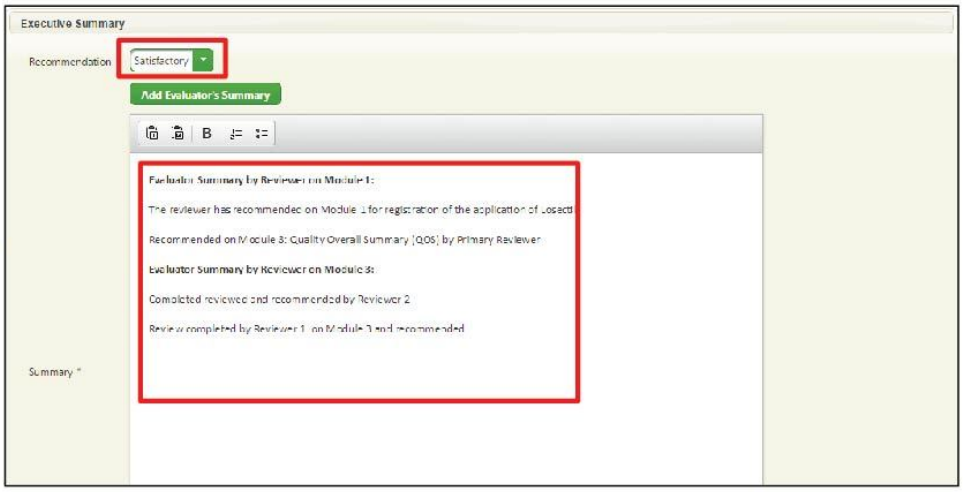
- Based on the Reviewers' recommendations and his/her own observations, the Moderator can now either recommend or not recommend the product.

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

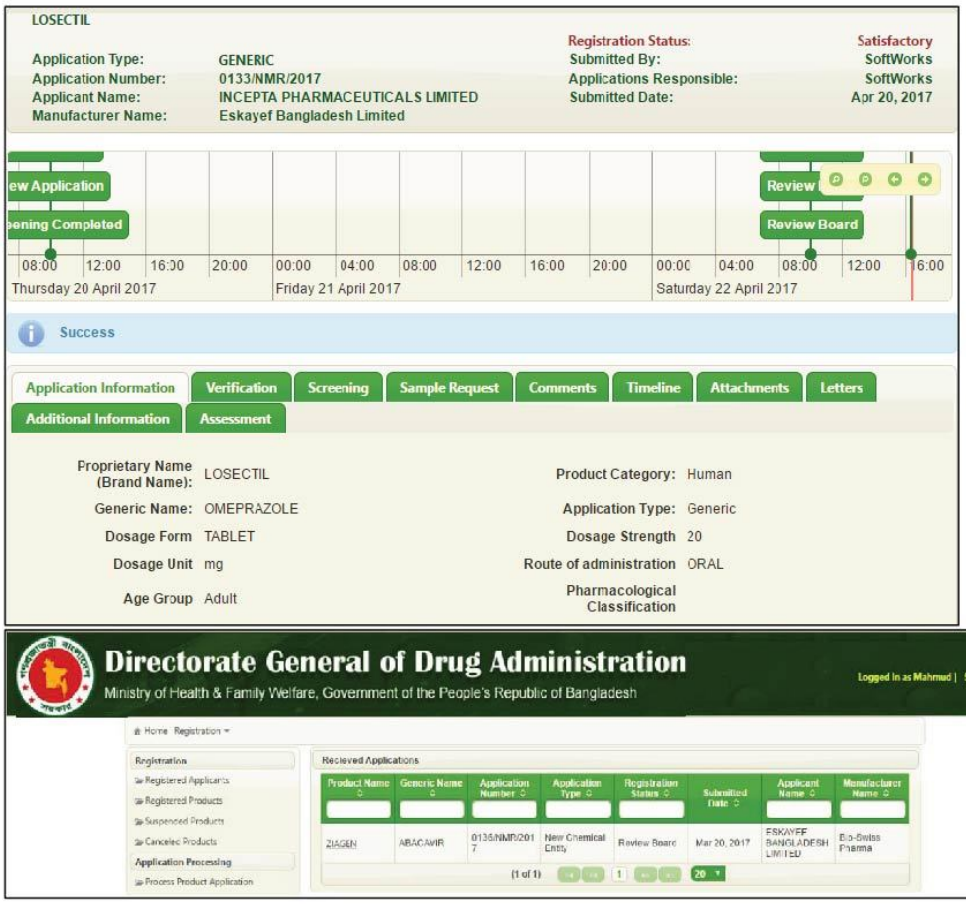
- Click on **"Executive Summary"** from the Assessment tab. After clicking on Executive Summary button the following screen will arrive:



- 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:



- Make the appropriate selection from the dropdown menu and click on **"Submit"** button.



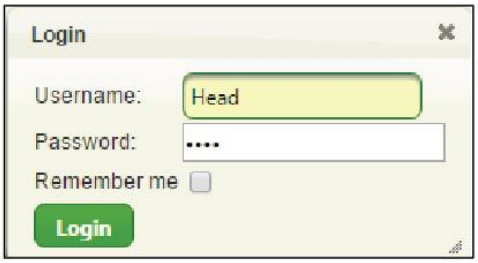
- The registration status will change accordingly.

10. REGISTER PRODUCT BY HEAD

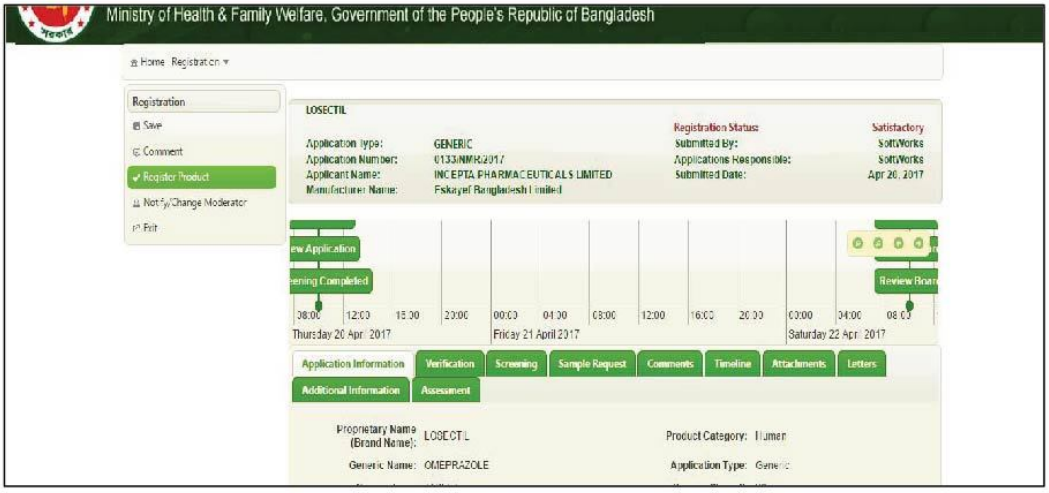
- Once the **Moderator** makes his/her last recommendation, the **Head** is the one who can finally register or reject the product. To login as Head, go to the homepage and click on the door on the upper right corner.

10.1. Log on as Head

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

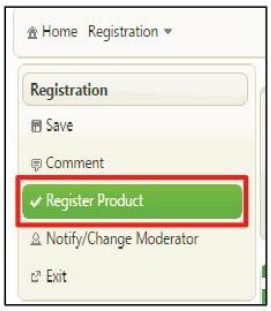


- The **Head** has access to all the same tabs of the Screener, Reviewer and Moderator.
- Click on the **"Product Name"** hyperlink which product you want to give registration to and after clicking the following screen will arrive –

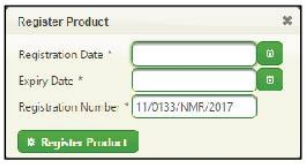


10.2. Product Registration

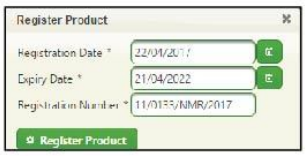
- Go to **Registration > Register Product** menu.



- 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:

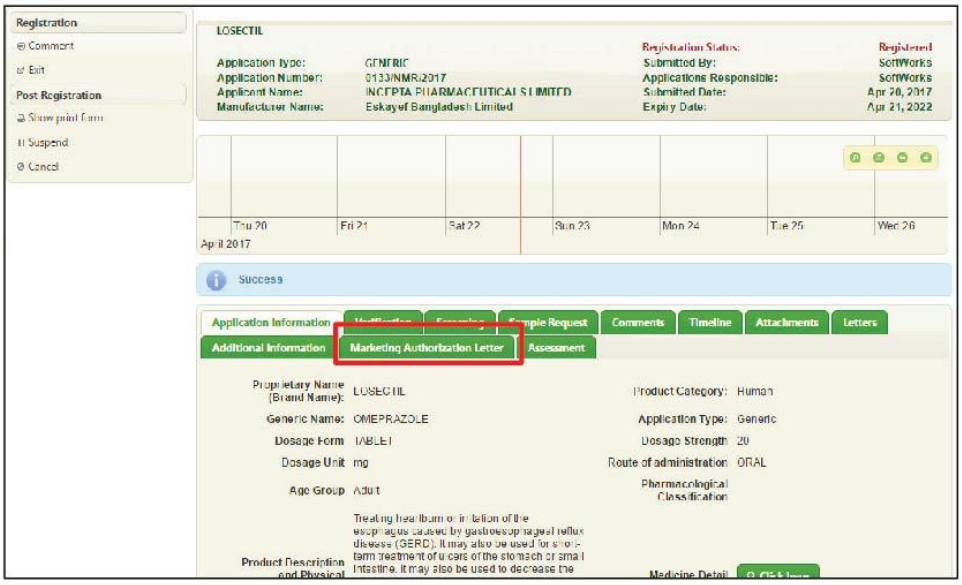


1. **Registration Date:** Select the date from which the registration will be effective.

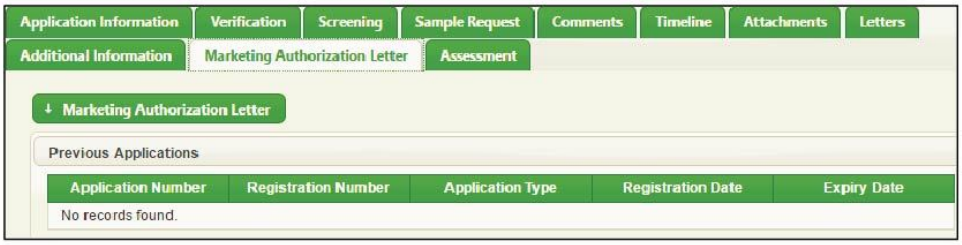
2. **Expiry Date:** After putting the registration date, the date of expiry will be calculated automatically and displayed which may be edited if required.

3. **Registration Number:** Also generated automatically.

- Then you need to press "**Register Product**" button and the following screen will arrive -



- 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.



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 Tejgaon I/A
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	TABLET
Presentation	10

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.

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	API 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	Toll/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	100 Squibb Road, Tongi I/A, Tongi, Gazipur, Bangladesh, 1711, Bangladesh	24 months	Normal

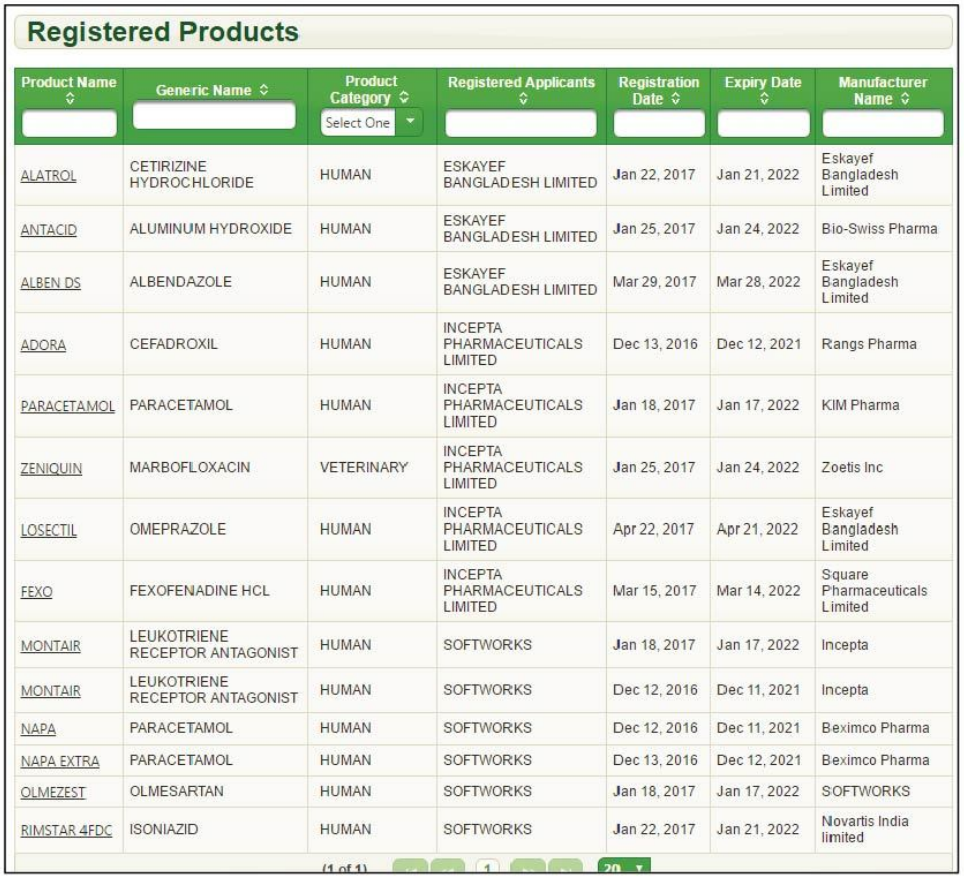
Government of the People's Republic of Bangladesh
Directorate General of Drug Administration (DGDA)
Aushad Bhaban, Mohakhali, Dhaka-1212

Attachment 3

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

Indication, contraindication, side effect, pregnancy.

- The following screen show the Registered Product list –



Registered Products

Product Name	Generic Name	Product Category	Registered Applicants	Registration Date	Expiry Date	Manufacturer Name
		Select One				
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

(1 of 1) 1 20

- END -

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msh Management Sciences for Health

http://www.dgda.gov.bd

https://pharmadexbd.org