New Product Registration Procedure

Applicant User Guide

April 27, 2017

Contents

1. Introduction

Ensuring the quality, safety, and effectiveness of health products is a complex task for national medicine regulatory authorities (NRAs), as is ensuring that these products meet and comply with international standards and guidelines. Regulation of medicines, vaccines, medical devices, and other health products involves pre-marketing evaluation, marketing authorization, and post-marketing surveillance, all of which require effective management of information systems.

Despite efforts to improve regulatory information management in low- and middle-income countries, many countries still face challenges in developing an information system (IS) for the entire pharmaceutical regulatory process, including registration, licensing, inspection, quality control, pharmacovigilance, and medicine information. Implementation of an information management system that supports regulatory business processes and information flow can lead to improved efficiency and transparency by making NRA databases available and by providing timely information to stakeholders.

2. What is PharmaDex?

PharmaDex is a web-based integrated IS solution that facilitates management, documentation, dissemination, and sharing of regulatory information. Key features include—

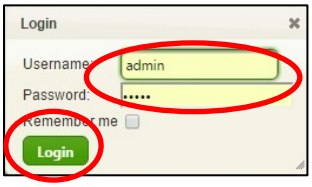
- **Designed as a web-based system**—allows for online application and information sharing with the regulated industry and consumers
- **Provides modular structure**—helps NRA departments integrate and coordinate their work, from product registration, licensing, pre- and post-marketing inspections, to quality control, pharmacovigilance, and administration
- **Includes built-in document tracking and management system**—facilitates archival, documentation, management, and retrieval of dossiers; and provides a platform to develop electronic document management systems
- **Supports submission in Common Technical Document (CTD) format**—allows dossiers to be submitted as non-eCTD electronic submissions
- **Uses international standard dictionaries**—provides standard terminologies and dictionaries with built-in International Nonproprietary Names (INN), Anatomical Therapeutic Chemical (ATC) classification system, and the Medical Dictionary for Regulatory Activities (MedDRA)
- **Provides one-stop access to regulatory approval package**—enables access to product approval history, approval letter, and approved product information.
- **Enhances performance monitoring**—monitors built-in key performance metrics and generates activity reports for the NRA
- **Provided as an open source platform and non-proprietary database** — PharmaDex is freely available for NRAs in developing countries.

3. Accessing PharmaDex

3.1. Applicant Login

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

- Enter in your username and password that was emailed to you and then click **"Login"**.

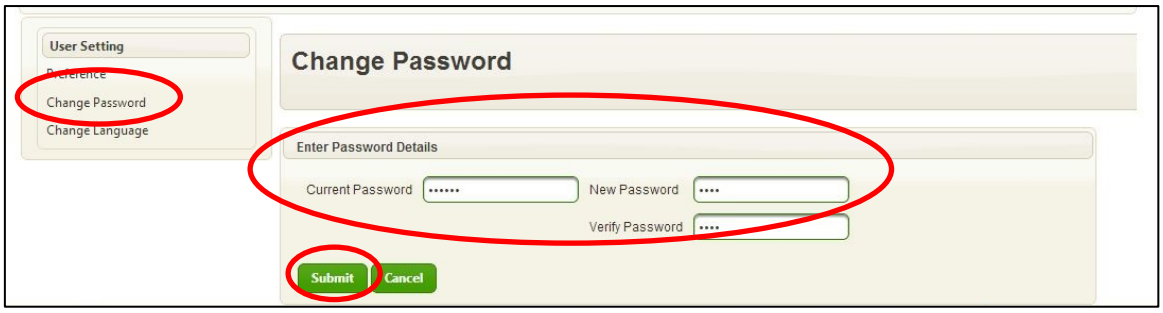


- Once you login, you will see your username in the upper right corner.

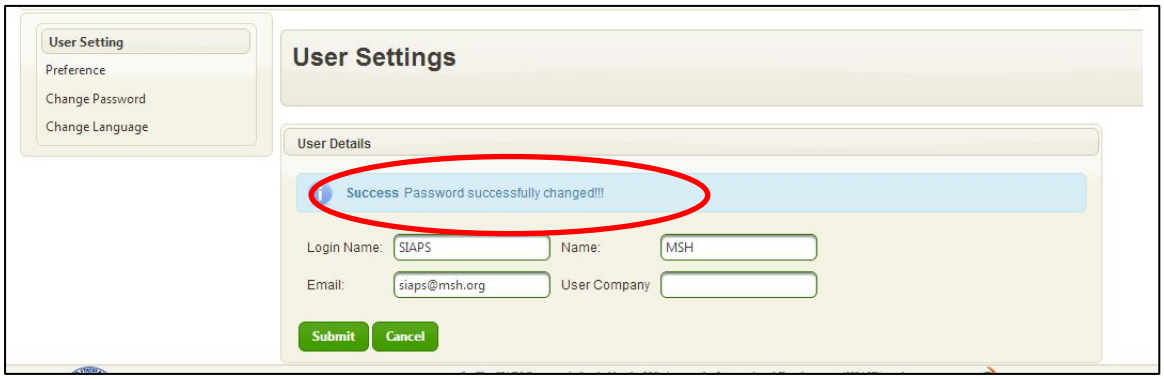
3.2. Changing User Settings

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

- Enter in your current password (the one that was emailed to you) and a new password. Click on **"Submit"** once finished.



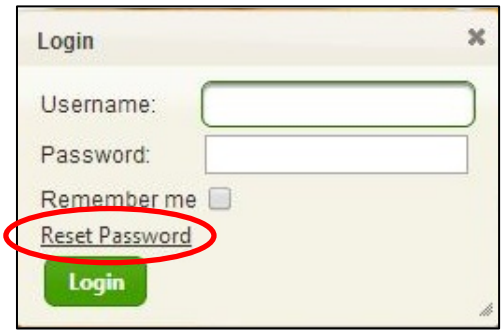
- A message will displaying that your password has been successfully changed.



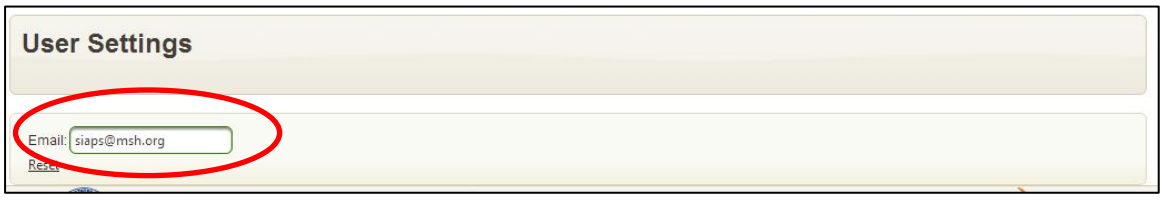
3.3. Resetting Password

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

- Click on "Reset Password".



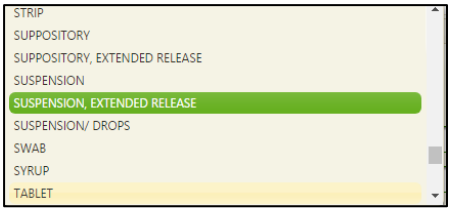
- Enter in the email address you used when you registered for PharmaDex and click on **"Reset"**. A new password will be emailed to you. To change your password, follow the instructions in the above section on changing passwords.



4. Common Feature

4.1. Search Option

- You need to write first alphabet of the word which you need to search:

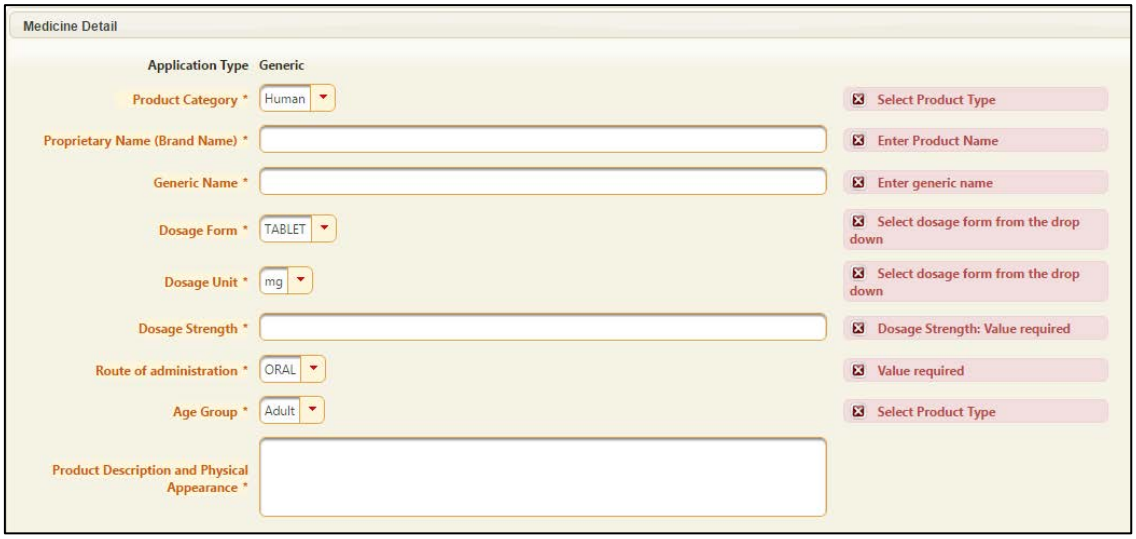


4.2. Success Messages

- The system show success message after saving any new records as shown in the following screen:

4.3. Error Messages

- If you try to go without fill-in up any mandatory fields the following kind of message will arrive:

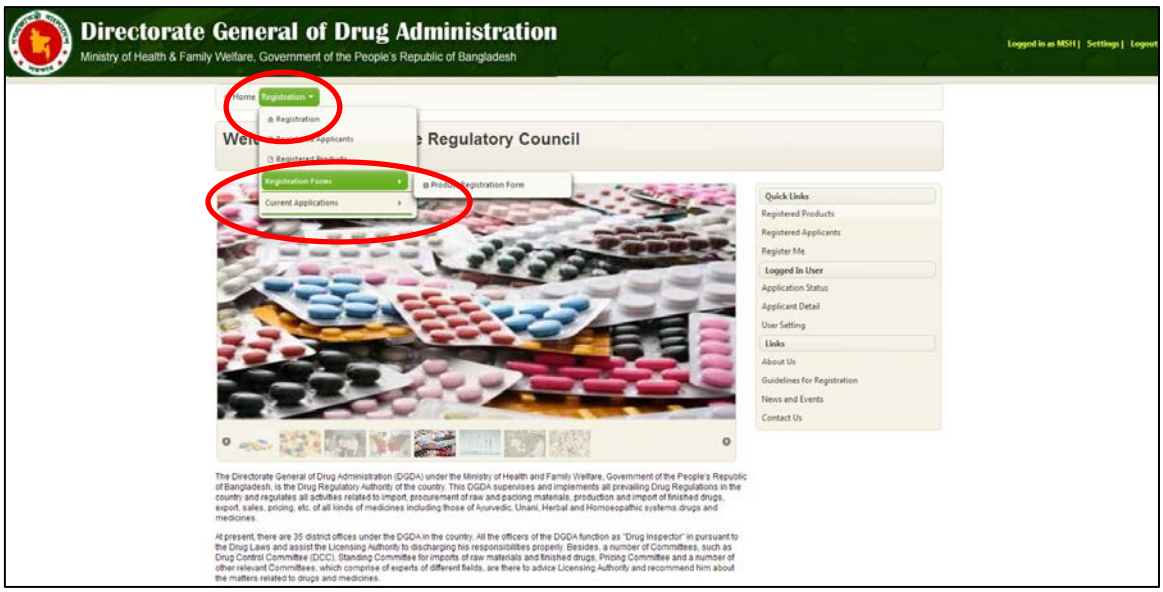


4.4. Timeline View of the Status

- A status bar always visible on to your screen showing the status of the application:

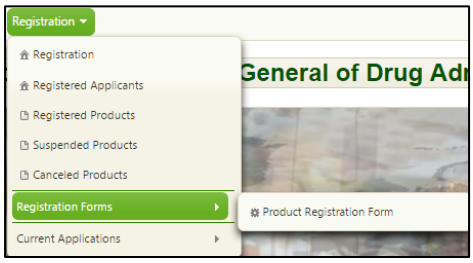
5. Registering Products

- In order to register a product, you must have a valid user name to access the system and you must be the person responsible for the applicant. After registering an applicant, you can begin to register products.
- To do so, go to the following menu options show below click on **“Registration” > “Registration Forms” > “Product Registration Form.”**

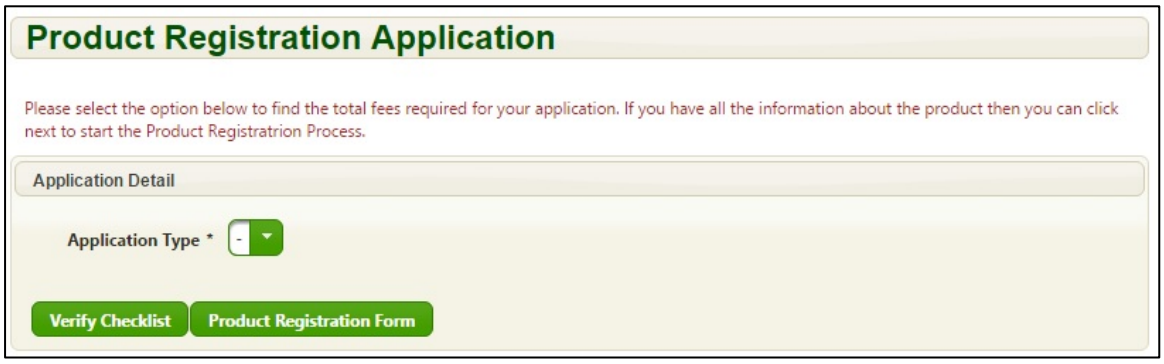


5.1. New Application Submission

- Need to log in as **“Applicant”** user -
- After putting your username and password the following screen has shown your logged in status on right side of the screen -
- Go to **Registration > Registration Forms > Product Registration Form** -

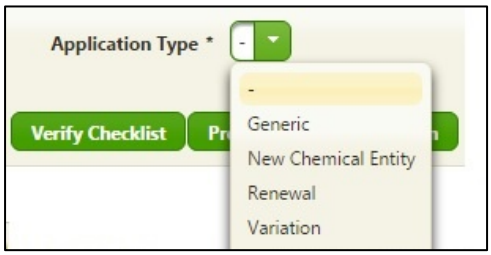


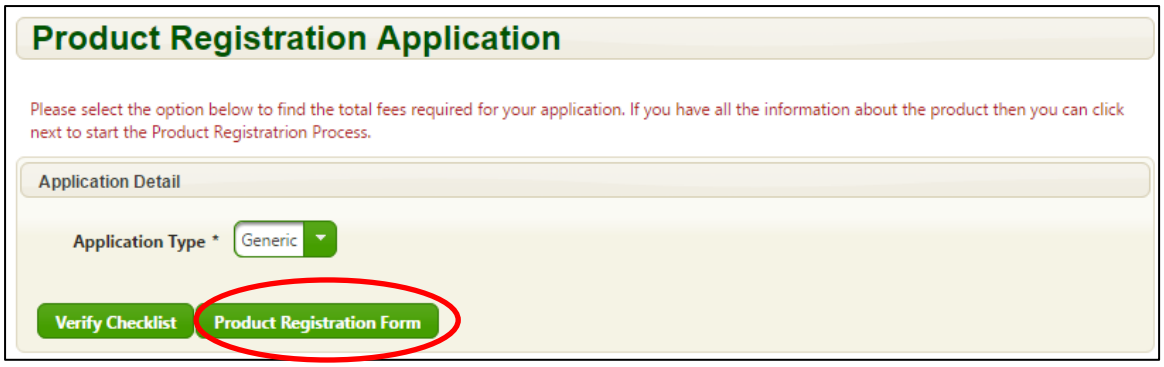
And the following screen will arrive –



5.2. Product Registration Application Entry Form

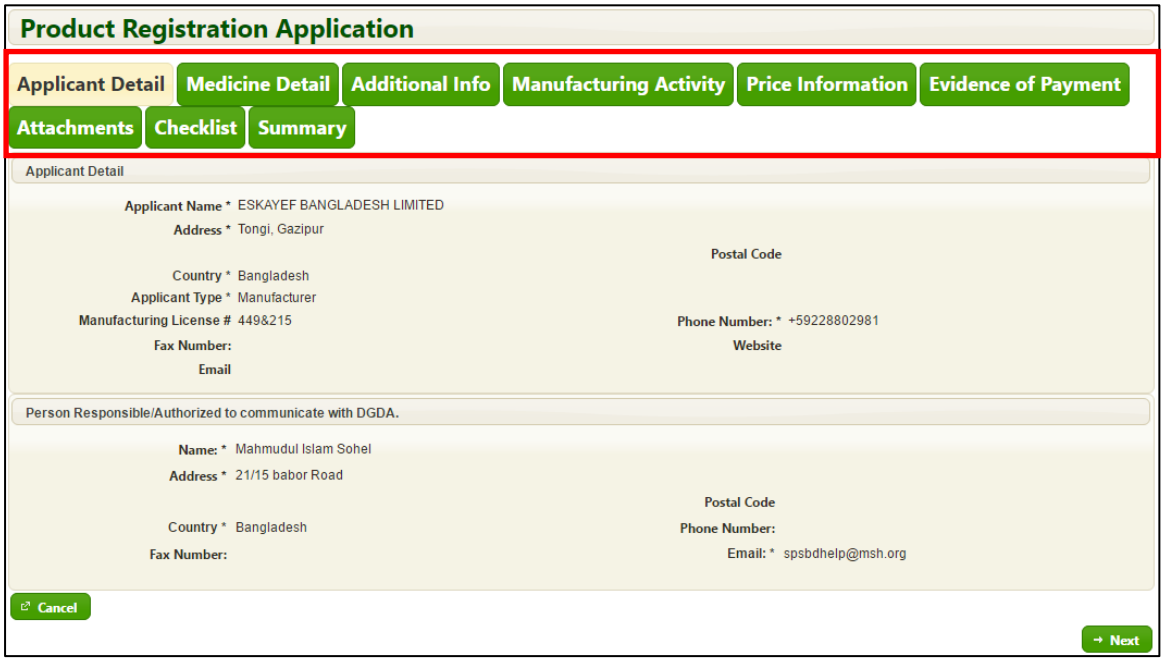
- You need to select one of the Application Type from the following combo – Generic/New Chemical Entity/Renewal or Variation





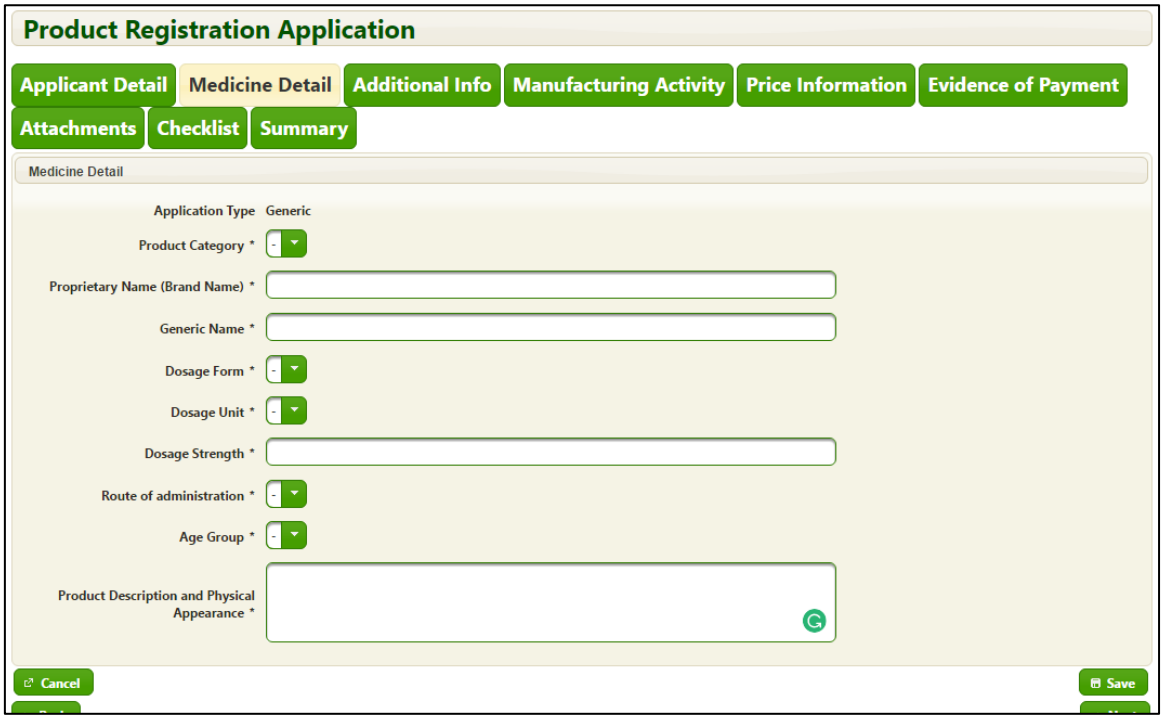
5.2.1. Application Detail

- After pressing Product Registration Form the following window will appear.
- Here you can see the applicant company's basic information only for viewing. Nothing need to do in this tab.



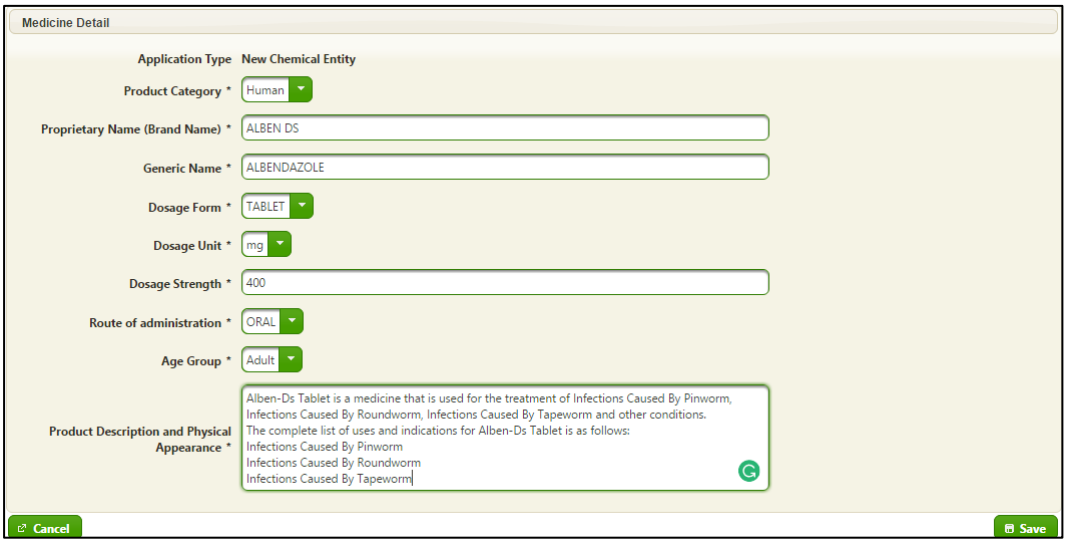
- The following window will appear and you need to press "Next" button for going to next **"Medicine Detail"** tab.

5.2.2. Medicine Detail



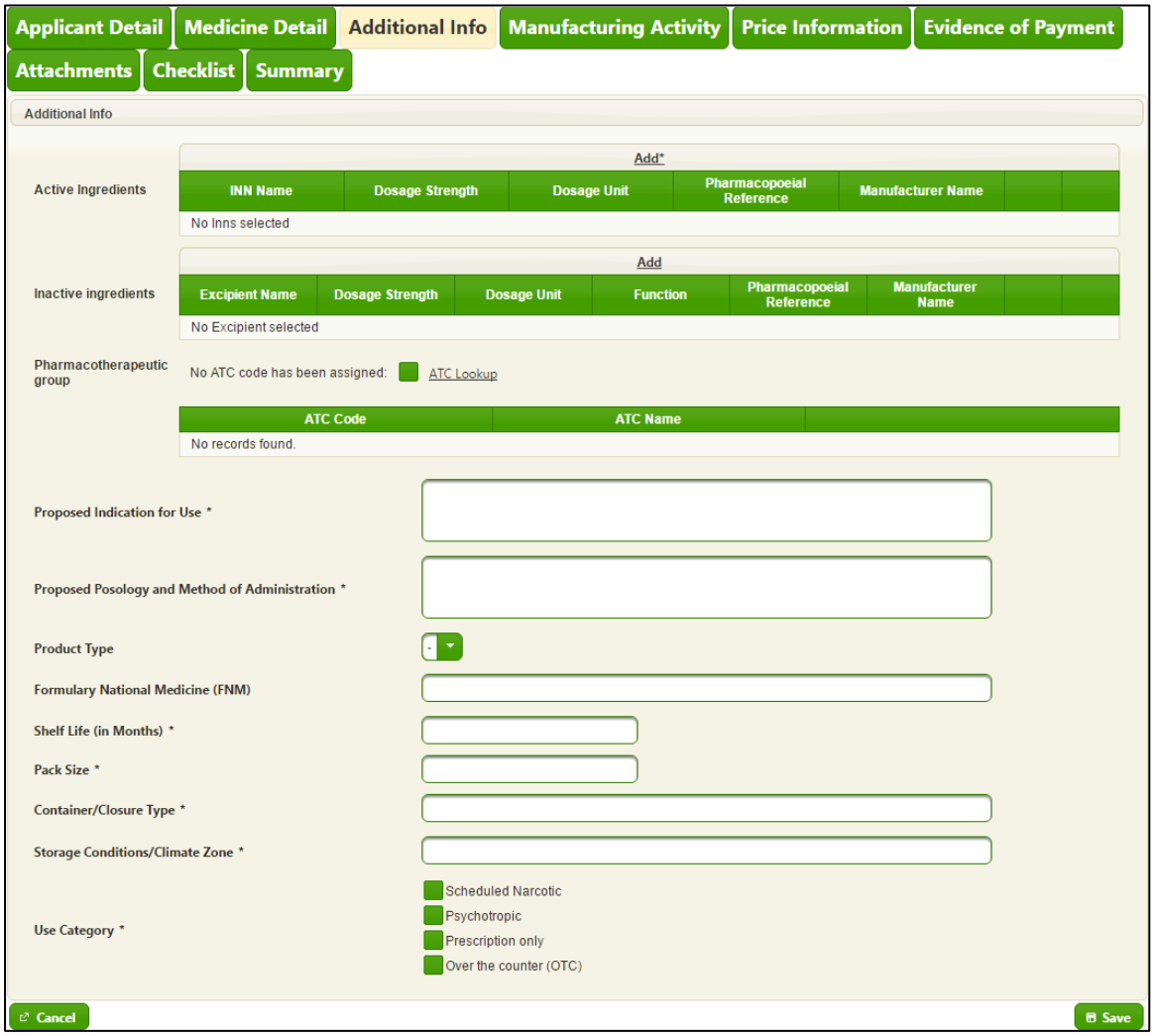
- On the **"Medicine Detail"** tab, fill in the required fields describe below as much information as possible and click **"Next"** to continue.
- Select the following fields from the combos - Product Category*/Dosage Form*/Dosage Unit*/Route of Administration* and Age Group*
- You also need to fill in up the following fields - Proprietary Name (Brand Name)*/Generic Name*/Dosage Strength*/Product Description and Physical Appearance*

- After filing the above fields Medicine Detail tab look like as follows:

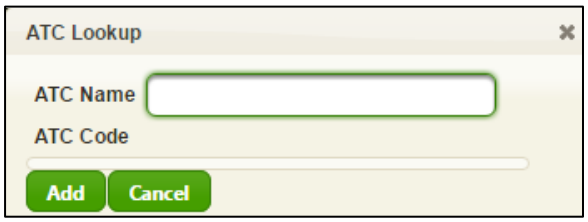


5.2.3. Additional Info

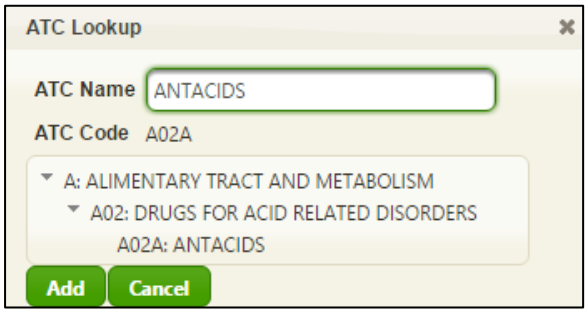
- After pressing "Next" button the following window will appear:



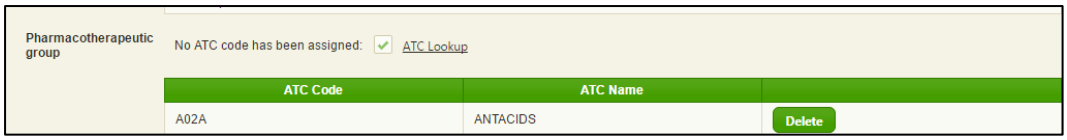
- If you want to assign ATC code, press "ATC Lookup" check box.



- After searching the ATC Name, the ATC Code will have displayed as shown in the following window. Then you need to click on "Add" to add the ATC Code.

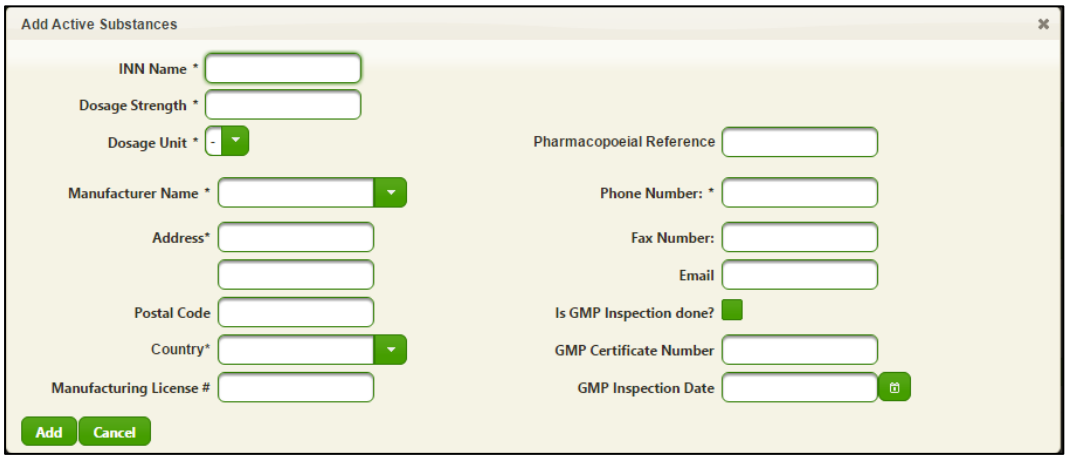


- After added the ATC Code the ATC Lookup window will look like as follows:

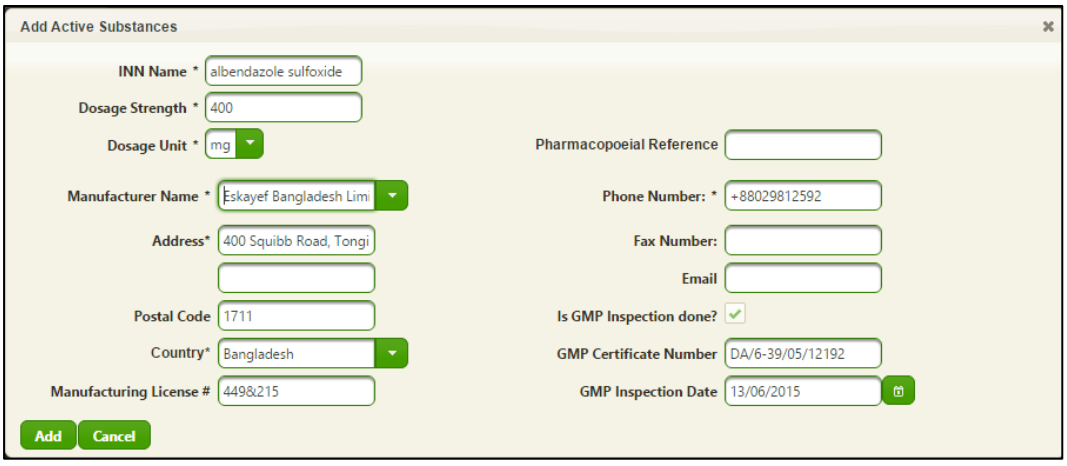


5.2.4. Add Active Ingredients

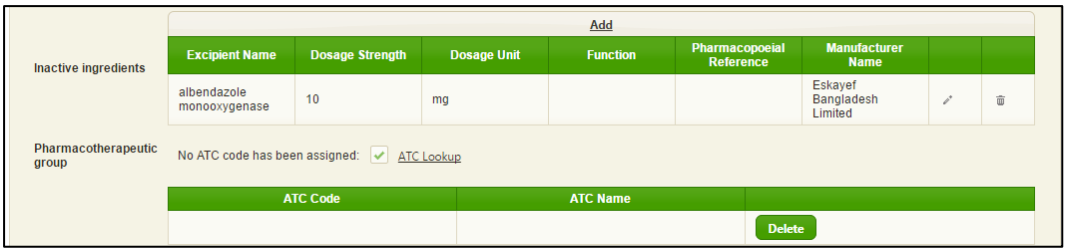
- To add active ingredients you need to click on **"Add"** button and the following window will arrive -



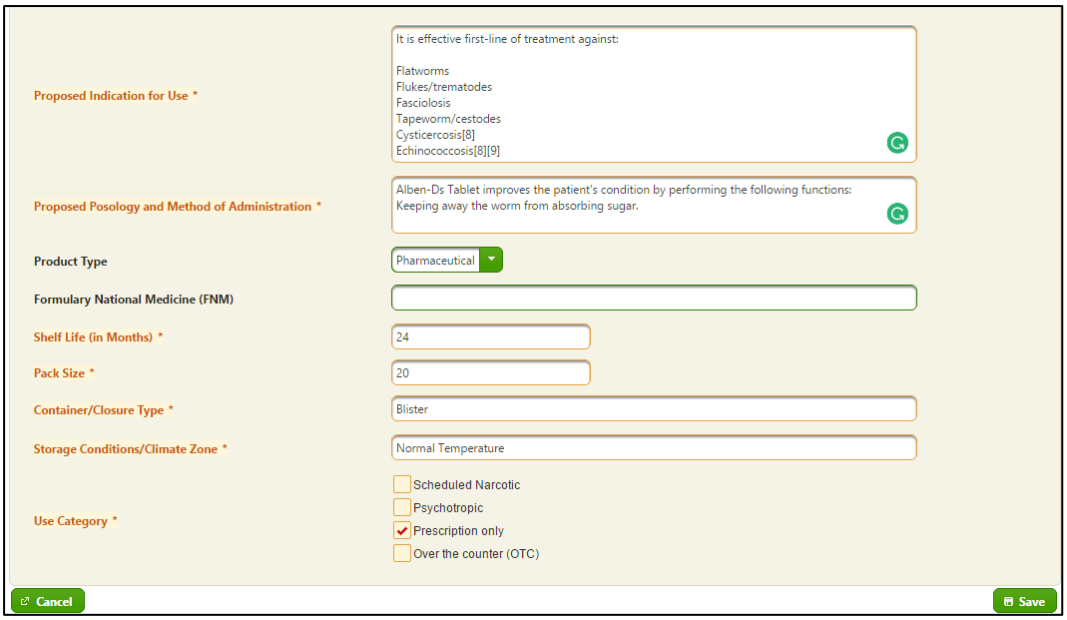
- Begin typing in the INN, and a list will automatically populate based on what you type. Select the correct INN name, and enter in the strength (i.e. how much of that active substance), followed by the dosage unit (g, mg, etc.) and the pharmacopeia reference that was used (USP, BP, etc.).
- Fill in the details of Manufacturer of the active substance. If GMP inspection is done for the manufacturing facility, provide the GMP details also.
- After filled in you need to press **"Add"** button and the pop-up screen will go off and information saved.



- You can add more INN using the **"Add"** button.
- In the same way you can also add Inactive Ingredients.



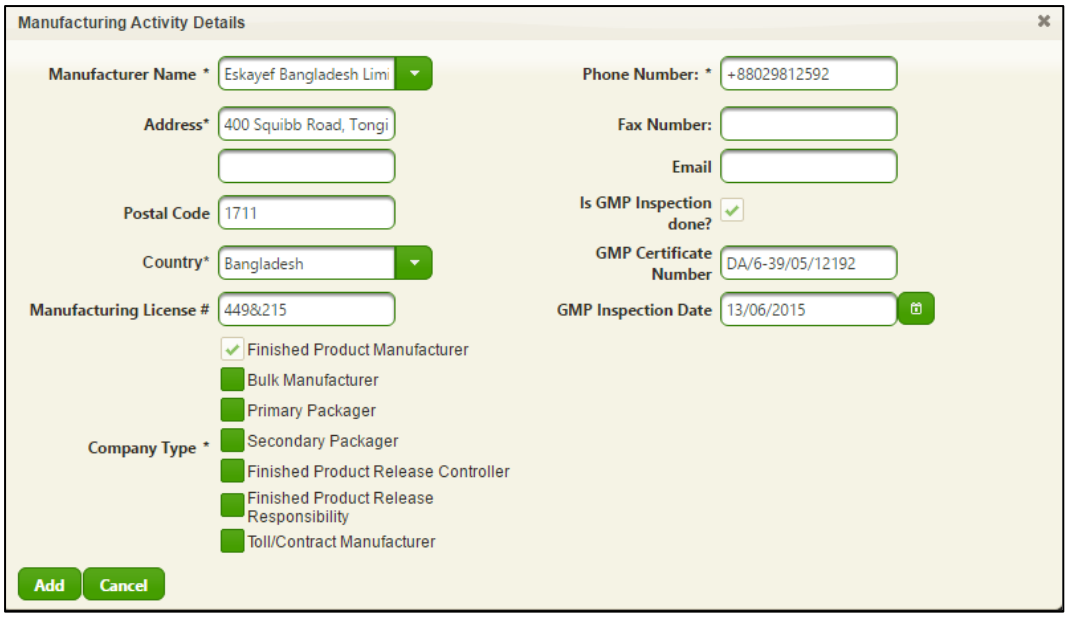
- After that you need to fill in up other fields:



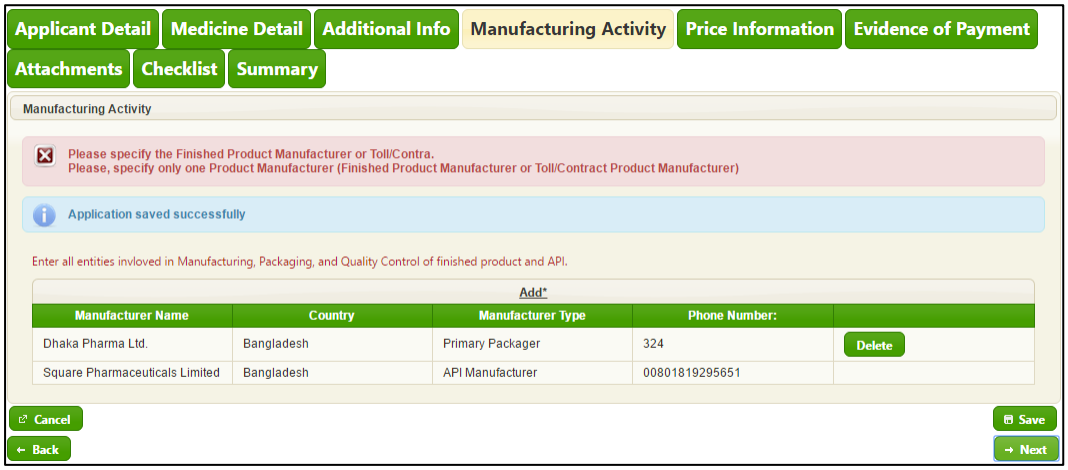
- After adding Active Ingredients, Inactive Ingredients and other fields you need to press **"Save"** button to save data then press **"Next"** button to for going to next "**Manufacturing Activity"** tab.

5.2.5. Manufacturing Activity

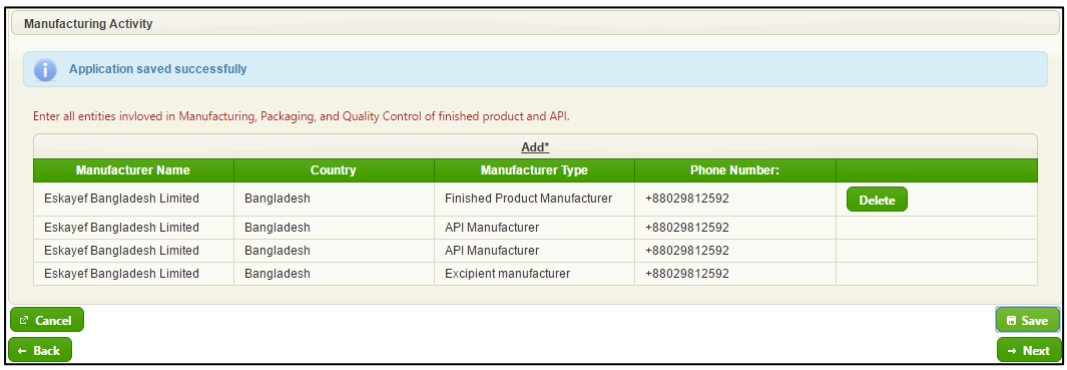
- You can add Manufacturing, Packaging, Quality Control, Finished Product or API manufacturer details in this tab.
- Press the **"Add"** button and fill the all necessary fields as shown in the following window:



- You have to enter at least one record containing **"Company Type"** of **"Finished Product Manufacturer"** or **"Toll/Contract Manufacturer".**
- Without selecting one of these two **"Finished Product Manufacturer"** or **"Toll Contractor Manufacturer"** if you try to save the following error will show:



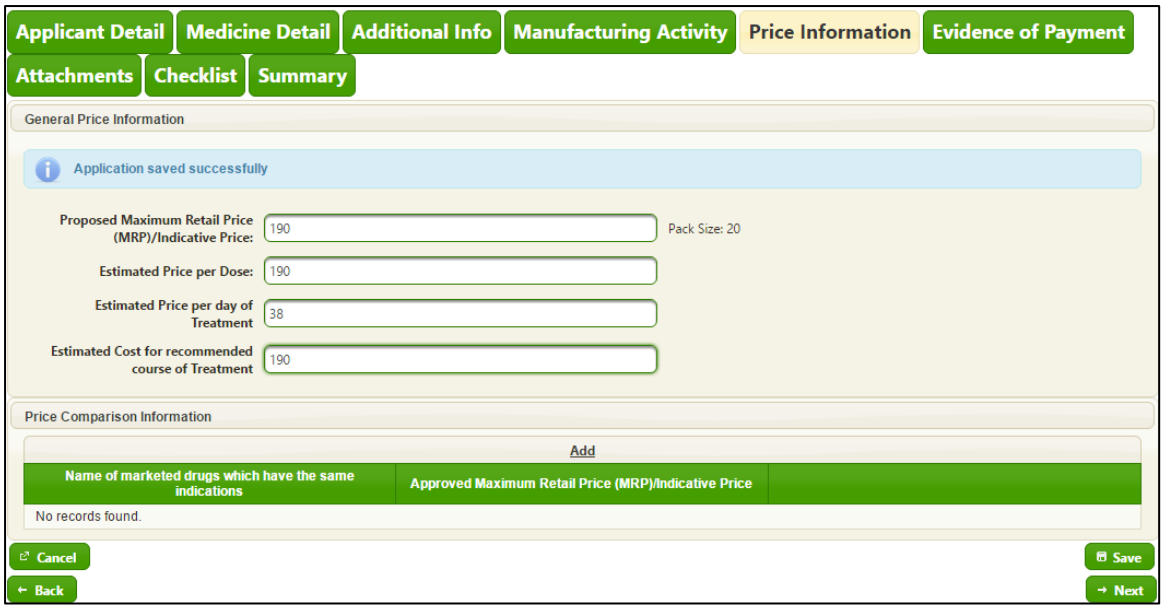
- After selection of **"Manufacturing Activity"** the following screen will arrive:



- If the applicant company have multiple manufacturing activities need to add those types as shown in the above screen.
- Need to press **"Save"** button to save data then press "Next" for going to next "**Price Information"** tab.

5.2.6. Price Information

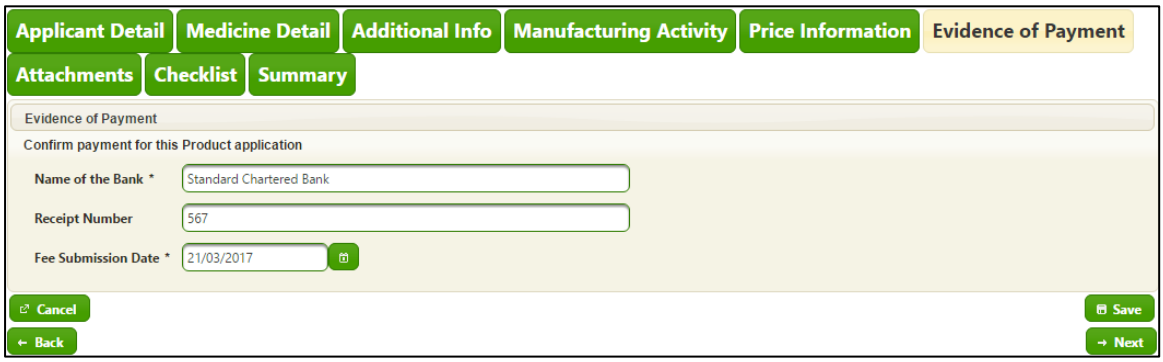
- After pressing to **"Next"** the following window will appear:



- Here you need to put all new Products pricing information as shown in the above screen.
- Need to press **"Save"** button to save data then press "Next" for going to next **"Evidence of Payment"** tab.

5.2.7. Evidence of Payment

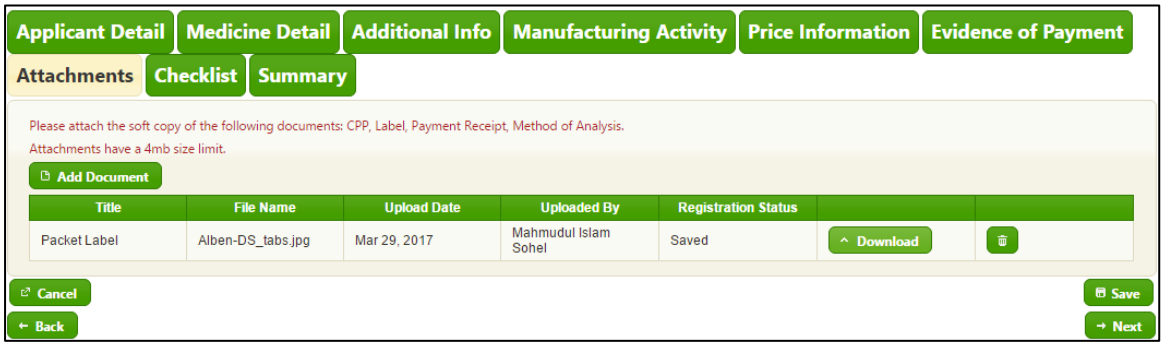
- After pressing to **"Next"** the following window will appear:



- Here you need to put payment details as shown in the above screen.
- Need to press **"Save"** button to save data then press "Next" for going to next "**Attachment"** tab.

5.2.8. Attachments

- Here you need to attach necessary files like label of the product, Images of the product using "Add Document" button. .



- Need to press **"Save"** button to save data then press "Next" for going to next **"Checklist"** tab.

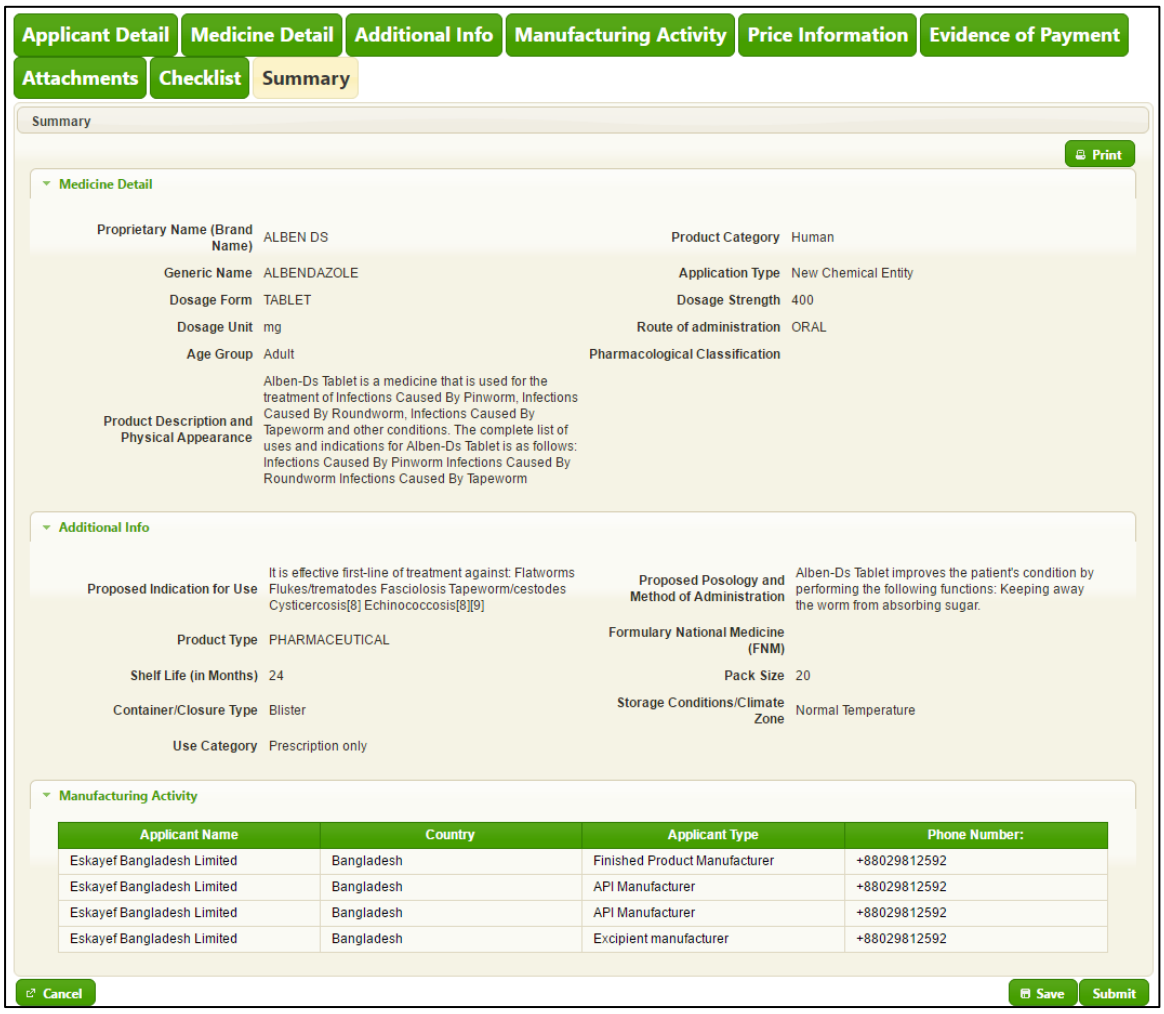
5.2.9. Checklist

- After pressing to **"Next"** the following window will appear:

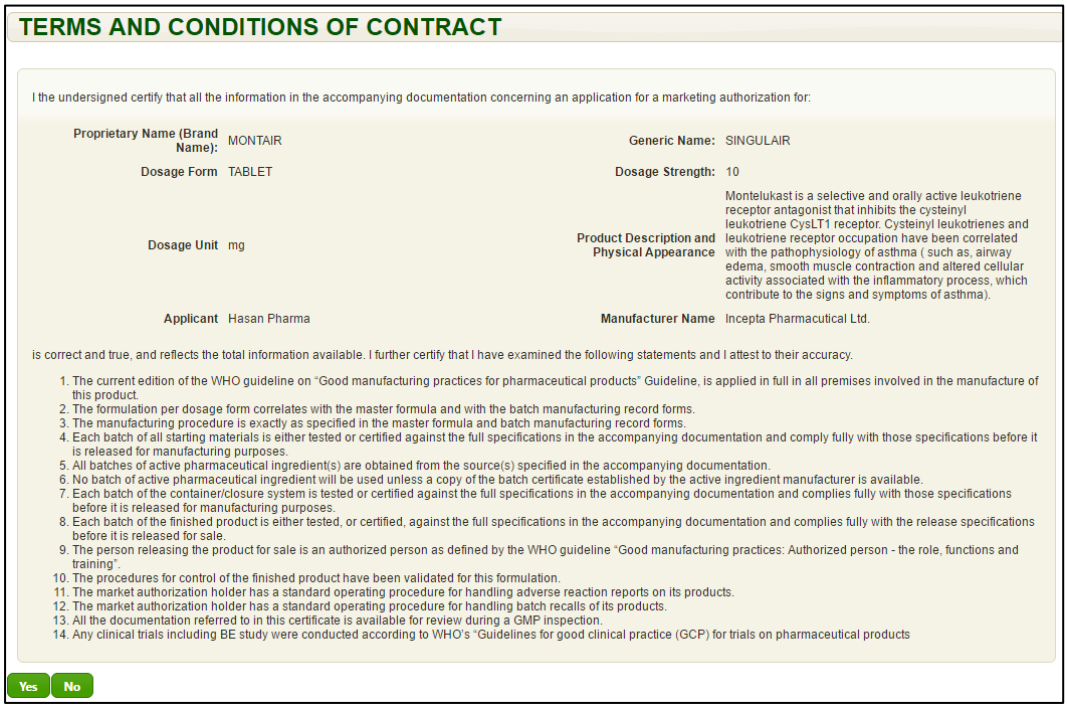
- Here you have to select any of the 3 options against each checklist item- **Yes, No or N/A**. Each checklist item represents one item from the application submitted physically. If you have submitted the document, select Yes, if you have not select No. If the checklist item does not apply for your application – select N/A.
- Need to press **"Save"** button to save data then press "Next" for going to next **"Summary"** tab.

5.2.10. Summary

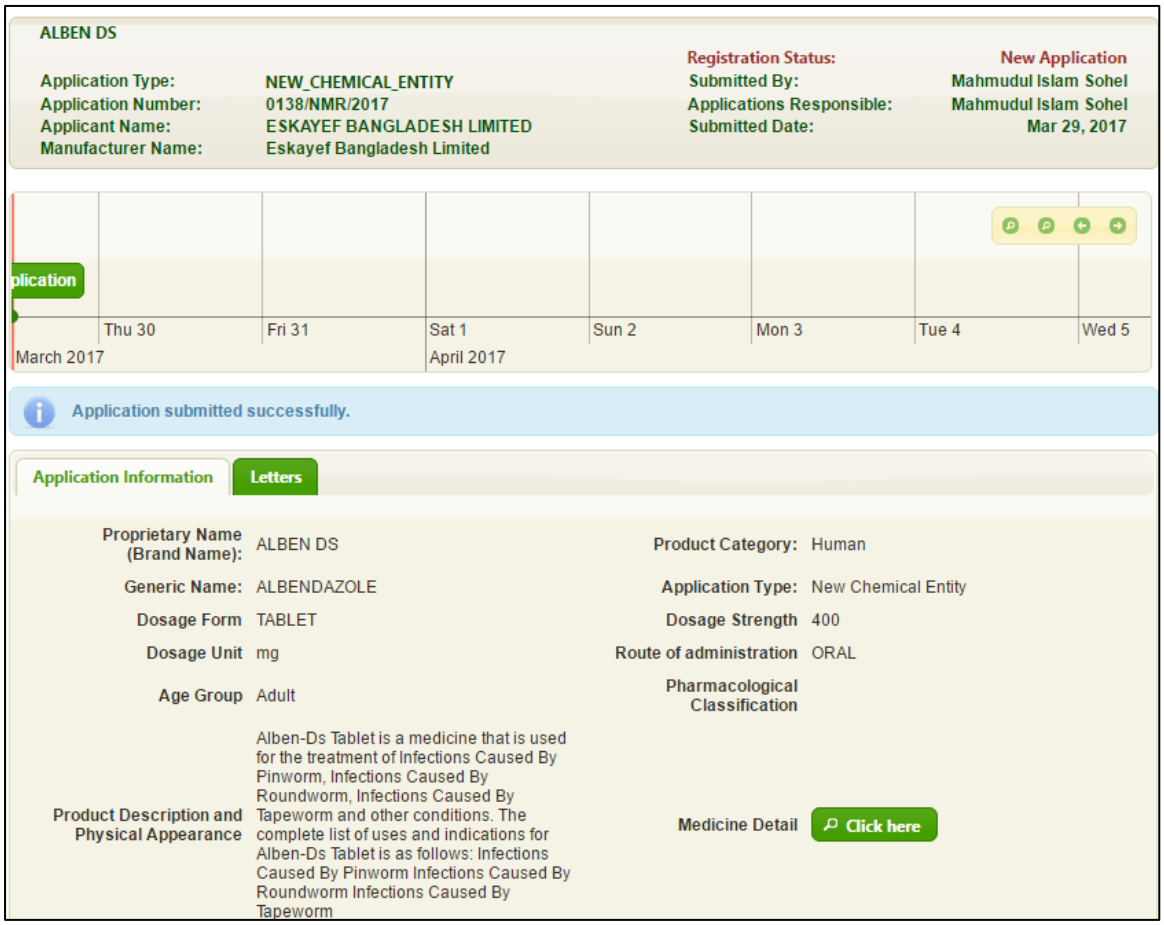
- On the **"Summary"** tab, you can view all of the information you have provided. After checking all entered information here you need to press **"Save"** button to save and press **"Submit"** button to submit the new application.



- After pressing **"Submit"** button the following **"Terms and Conditions"** window will appear:

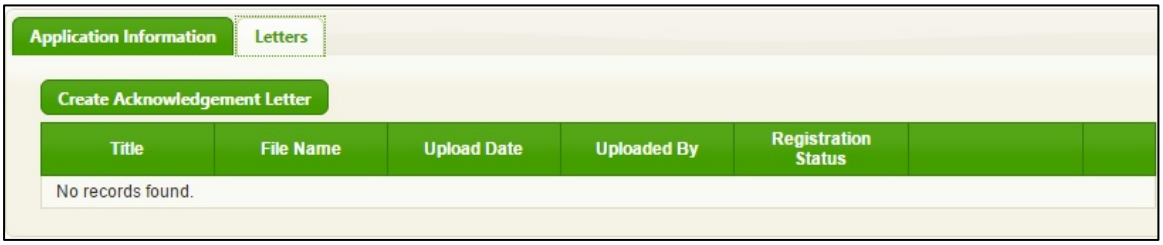


- After pressing **"Yes"** button the submitted **"New Application"** will appear in the screen:

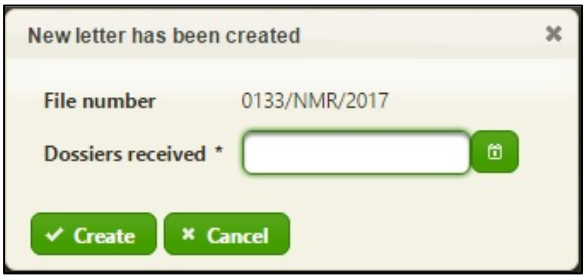


5.2.11. Generate Acknowledgement Letter

- After submitting the application the system give you option to generate Acknowledgement Letter under **Letters** tab.
- To generate Acknowledgement Letter you need to click on **"Create Acknowledgement Letter"** under Letters tab.

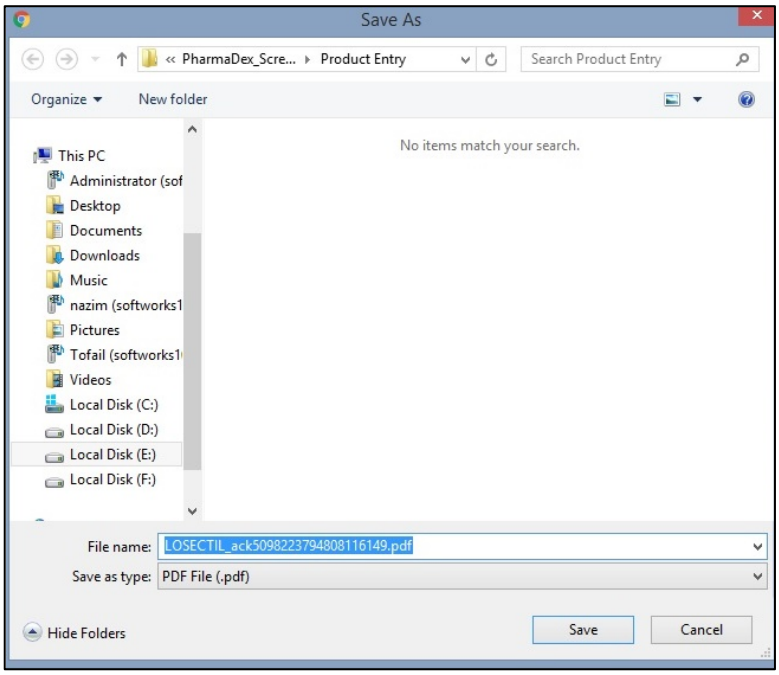


- A pop-up window will arrive to put Dossiers submission date. After putting the date click on **"Create"** button.



- You will see the following screen –

- To print the Acknowledgement Letter you need to click on **"Download"** button and save the file in a drive of your computer -



- The following printable view will generated as PDF format –

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

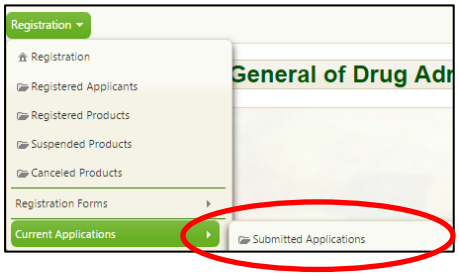
Director General,
Directorate General of Drug Administration
&
Licencing Authority (Drugs)
Government of the People's Republic of Bangladesh

6. Viewing Status of Applications

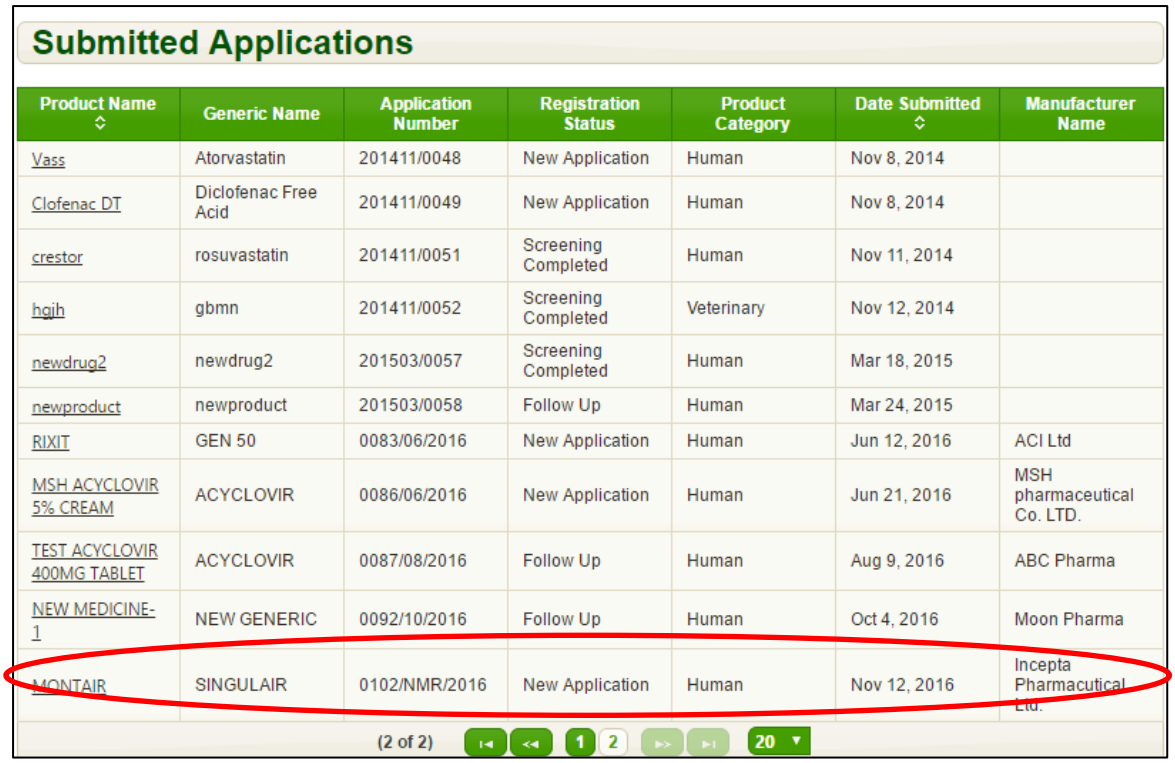
- To view the status of applications you have submitted, log in and click on **"Application Status".** From here, you can view submitted and saved applications as well as any products that have already been registered.

6.1. Submitted Product Application View

- After that you can view your submitted application by going to submitted applications from the menu **Registration > Current Application > Submitted Application**



- The submitted **"New Application"** will appear in the screen:



Submitted Applications

Product Name	Generic Name	Application Number	Registration Status	Product Category	Date Submitted	Manufacturer Name
Vass	Atorvastatin	201411/0048	New Application	Human	Nov 8, 2014	
Clofenac DT	Diclofenac Free Acid	201411/0049	New Application	Human	Nov 8, 2014	
crestor	rosuvastatin	201411/0051	Screening Completed	Human	Nov 11, 2014	
hgjh	gbmn	201411/0052	Screening Completed	Veterinary	Nov 12, 2014	
newdrug2	newdrug2	201503/0057	Screening Completed	Human	Mar 18, 2015	
newproduct	newproduct	201503/0058	Follow Up	Human	Mar 24, 2015	
RIXIT	GEN 50	0083/06/2016	New Application	Human	Jun 12, 2016	ACI Ltd
MSH ACYCLOVIR 5% CREAM	ACYCLOVIR	0086/06/2016	New Application	Human	Jun 21, 2016	MSH pharmaceutical Co. LTD.
TEST ACYCLOVIR 400MG TABLET	ACYCLOVIR	0087/08/2016	Follow Up	Human	Aug 9, 2016	ABC Pharma
NEW MEDICINE-1	NEW GENERIC	0092/10/2016	Follow Up	Human	Oct 4, 2016	Moon Pharma
MONTAIR	SINGULAIR	0102/NMR/2016	New Application	Human	Nov 12, 2016	Incepta Pharmaceutical Ltd.

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- You can continue to register other products by repeating the same steps above.

6.2. Viewing Saved Applications

- During the process of filling out the product registration information you can save the information and access it at a later point. You will have to login to the system and go to the registration page or access the menu **Registration > Current Application > Saved Application**