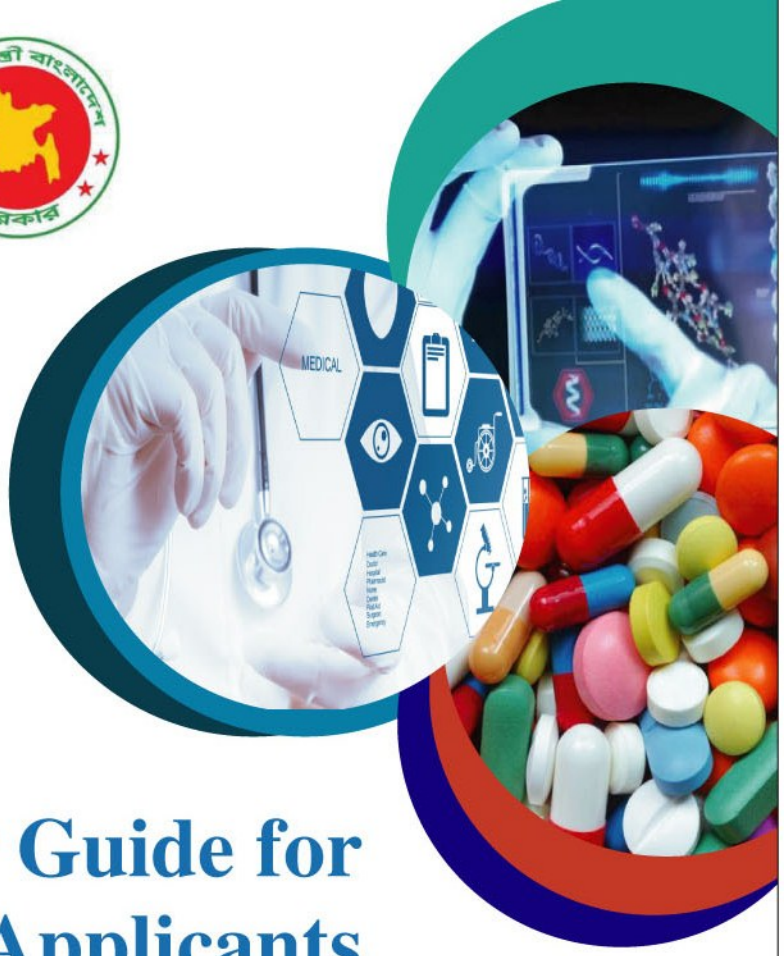

Pharmadex: User Guide for Applicants

April 2017

USAID FROM THE AMERICAN PEOPLE

SIAPS Systems for Improved Access to Pharmaceuticals and Services

DGDA

Pharmadex: User Guide for Applicants

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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. Introduction

Registering pharmaceutical products in alignment with international standards for medicine registration is critical to improving health and saving lives during the Sustainable Development Goals era. When countries have weak medicine registration systems—backlogs and inefficient tracking of drug registration applications, inefficient drug testing systems, and incomplete data on suppliers and products—money is wasted and millions of people are put at risk of using unsafe and low-quality medicines.

The Directorate General of Drug Administration (DGDA), Bangladesh's national regulatory authority, approves pharmaceuticals for sale in the country along with the specifics of the products and suppliers. Therefore, collecting product-related scientific data, recording that information, and the details of where a product's application is in the registration process are important for DGDA to ensure that the manufactured drugs are safe, effective, and of good quality. Currently, processing and tracking the registration of medicines and suppliers in Bangladesh is a time-consuming and detail-oriented task. Clearly, DGDA needed an efficient procedure for processing pharmaceutical and supplier applications so that timely decisions can be made and supported.

Acknowledging the existing gaps, the DGDA requested that the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program develop an online drug registration system, Pharmadex (https://pharmadexbd.org), to determine data elements for each function and the real-time decision-making process within the DGDA. SIAPS is funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH). Responding to that request, SIAPS worked with DGDA through a task force to adapt Pharmadex to a Bangladesh-specific medicine registration system and work flow. The existing database of DGDA's registered drugs, manufacturers, and pharmacies for both local producers and importers was also validated for an effective drug-registration process flow within the online system. To make sure that encrypted data was transferred and that valuable information provided by pharmaceutical companies was safeguarded, SIAPS assisted the DGDA in establishing a data center that included Pharmadex. Simultaneously, SIAPS installed a dedicated file network-attached storage device within DGDA to provide local-area network nodes with file-based shared storage through a standard Ethernet connection to protect the confidentiality and privacy of the submitted dossiers.

2. What is PharmaDex?

Pharmadex is an integrated information system that facilitates the submission, review, and evaluation of applications and dossiers. It can capture and track whether the dossier requirements for medicine registration submitted by a pharmaceutical company are based on common technical document (CTD)[1]

Key Features of Pharmadex

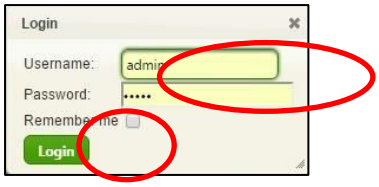
- Designed as a web-based system—allows for online application and information sharing with the regulated industry and consumers
- Provides a modular structure—helps DGDA integrate and coordinate their work, from product registration, licensing, and pre- and post-marketing inspections to quality control, pharmacovigilance, and administration
- Built-in document tracking and management system—facilitates archiving, documentation, management, and retrieval of dossiers and provides a platform for developing electronic document management systems
- Uses international standard dictionaries—provides standard terminologies and dictionaries with built-in international nonproprietary names, the Anatomical Therapeutic Chemical classification system, and the Medical Dictionary for Regulatory Activities
- Provides one-stop access to a regulatory approval package—enables access to product approval history, approval letter, and approved product information
- Provides administrative capabilities—allows for automatic printing of acknowledgment letters and registration certificates
- Enhances performance monitoring—monitors built-in key performance metrics and generates activity reports for the DGDA

3. Accessing PharmaDex

3.1. Applicant Login

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

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

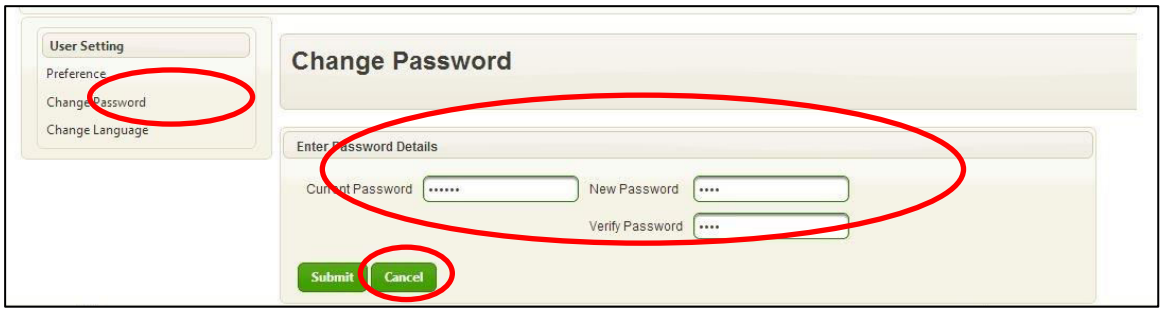


- Once you login, you will see your username in the upper right corner.

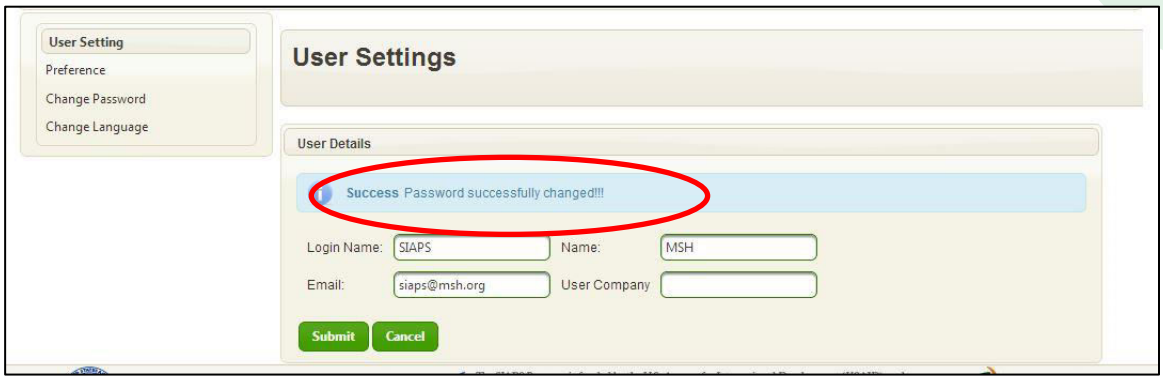
3.2. Changing User Settings

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

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



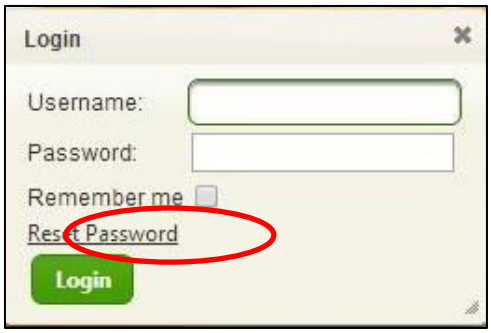
- A message will appear displaying that your password has been successfully changed.



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 on the upper right corner.

- Click on "Reset Password".

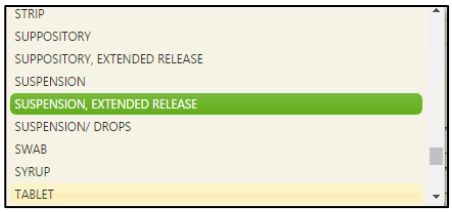


- Enter the email address you used when you registered for Pharmadex and click on the **"Reset"** button. A new password will be emailed to you. To change your password, follow the instructions in the above section for changing passwords.

4. Common Feature

4.1. Search Option

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

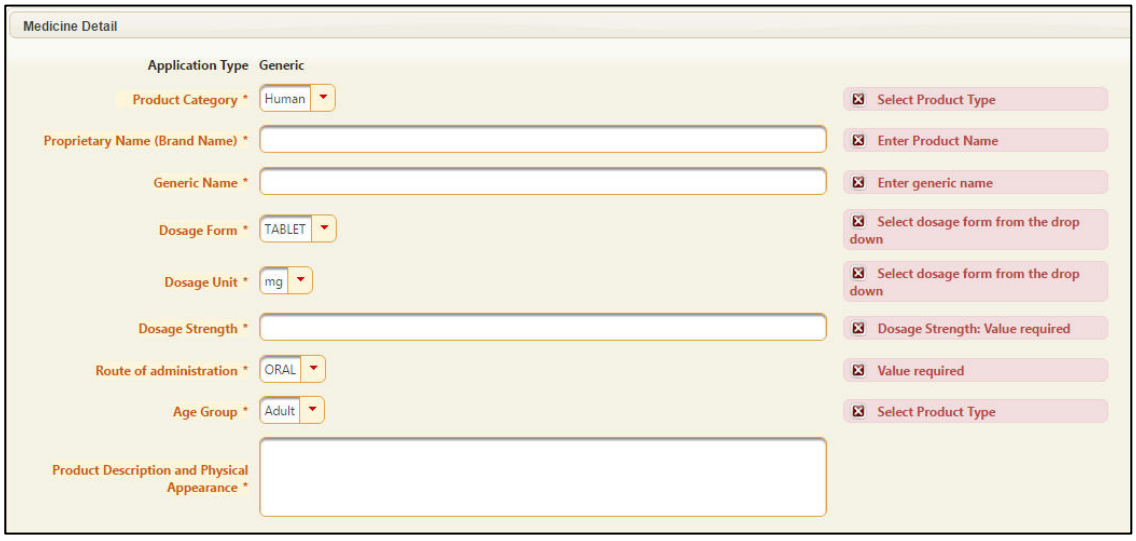


4.2. Success Messages

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

4.3. Error Messages

- If you try to leave the page without filling up any mandatory field, the following error message will arrive:



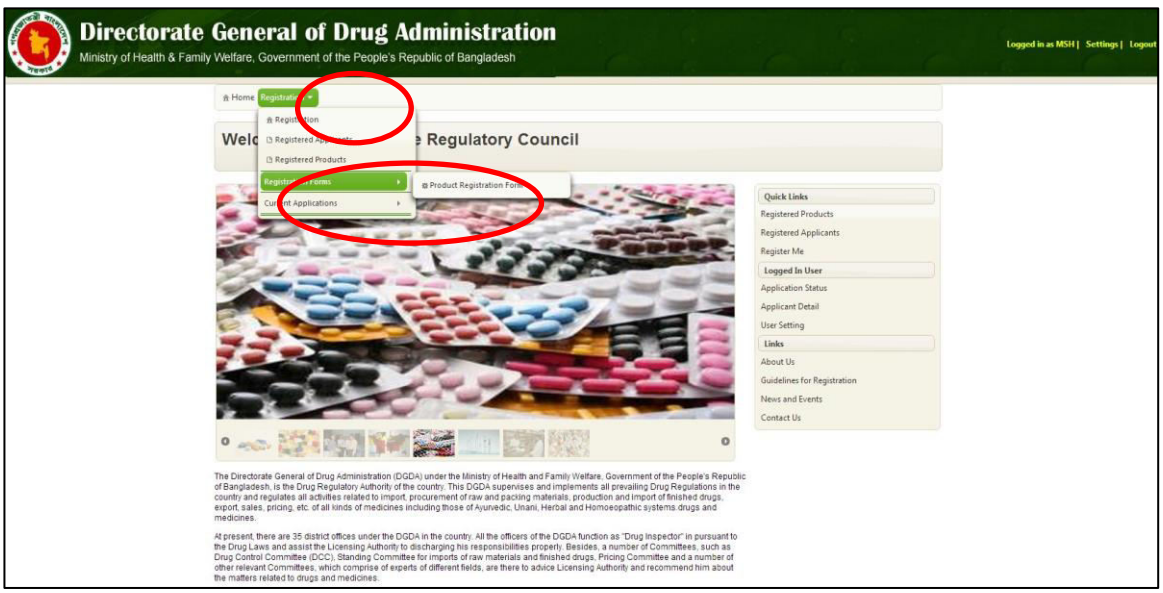
4.4. Timeline View of the Status

- A status bar is always visible on 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 application. After registering as an applicant, you can begin to register products.

- To do so, go to the following menu options shown below and click on **"Registration" > "Registration Forms" > "Product Registration Form."**



5.1. New Application Submission

- Need to log in as **"Applicant"** user –

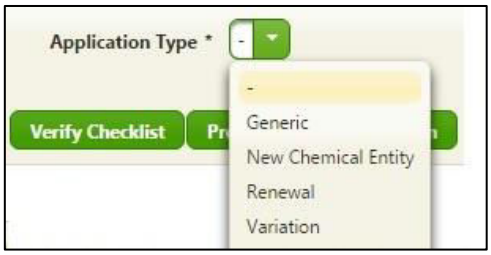
- After putting your username and password the following screen has shown your logged in status on right side of the screen –

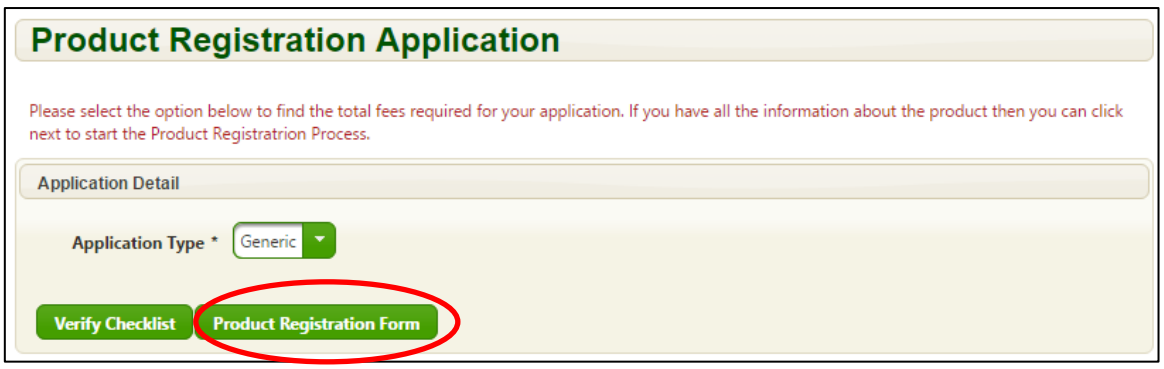
- Go to **Registration > Registration Forms > Product Registration Form** -

And the following screen will arrive –

5.2. Product Registration Application Entry Form

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

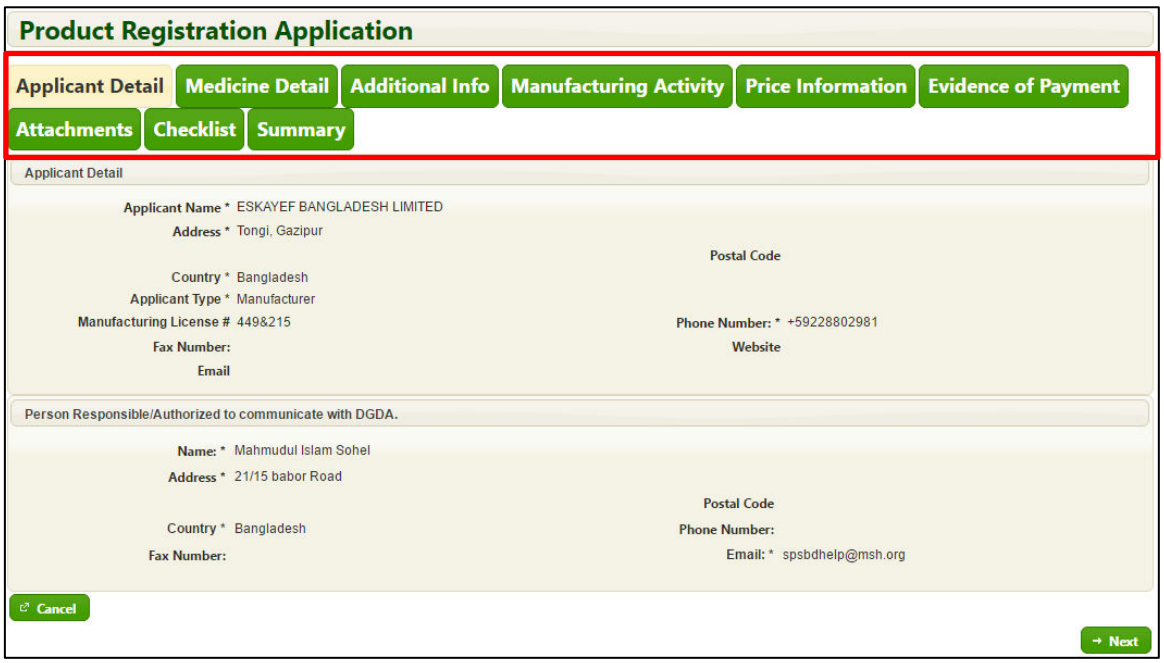




5.2.1. Application Detail

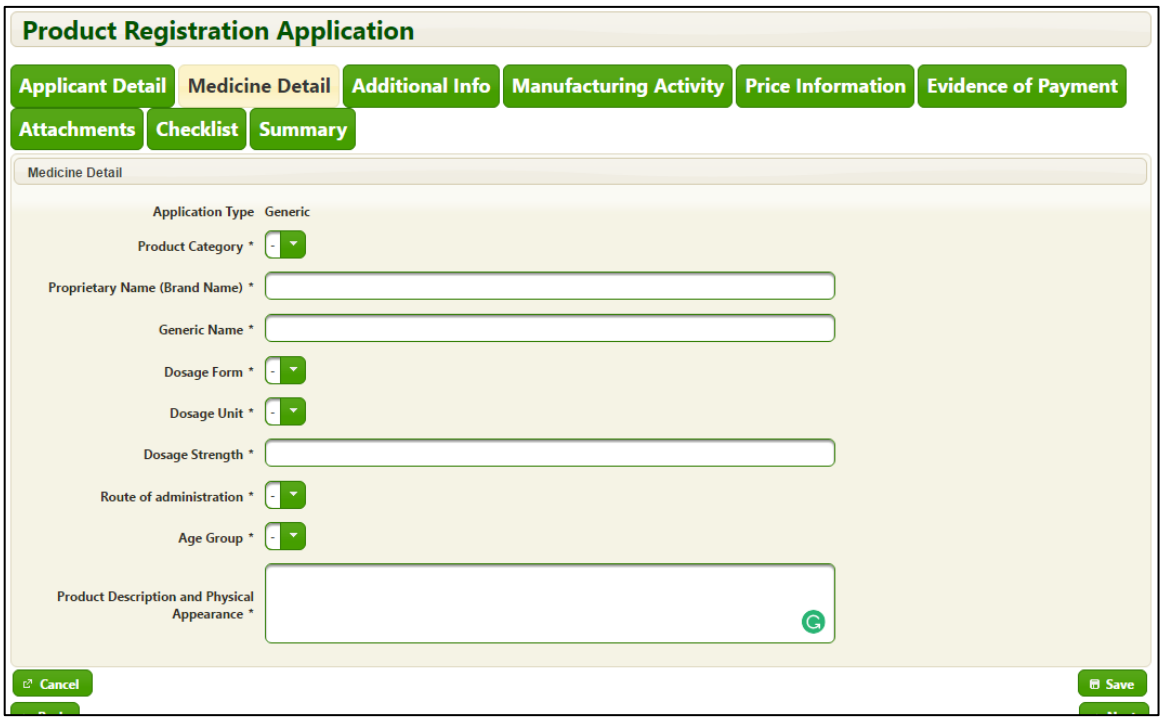
- After pressing Product Registration Form the following window will appear.

- Here you can see the applicant company's basic information only for viewing. Nothing needs to be done in this tab.

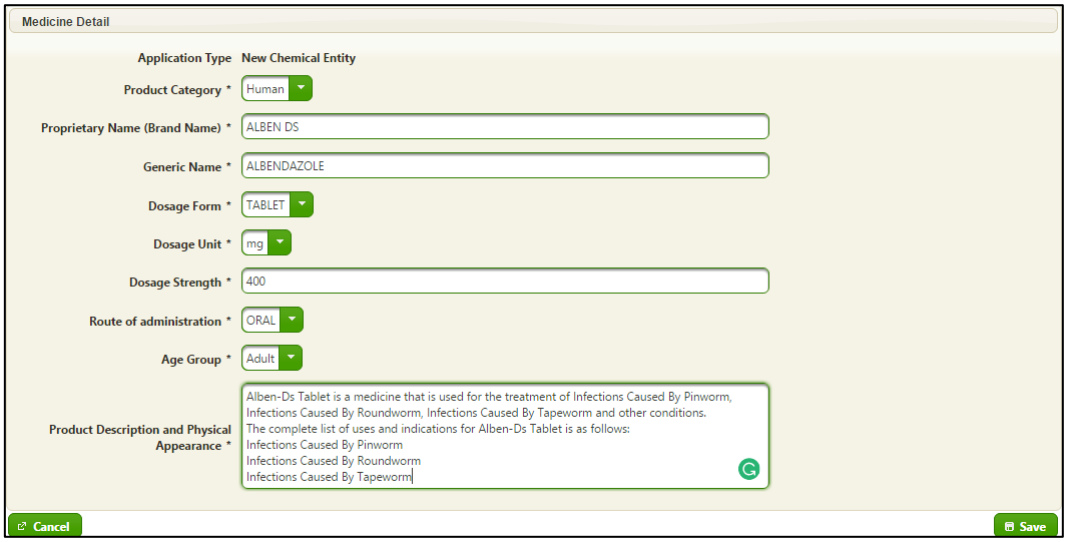


- The following window will appear and you need to press "Next" button for going to the next **"Medicine Detail"** tab.

5.2.2. Medicine Detail

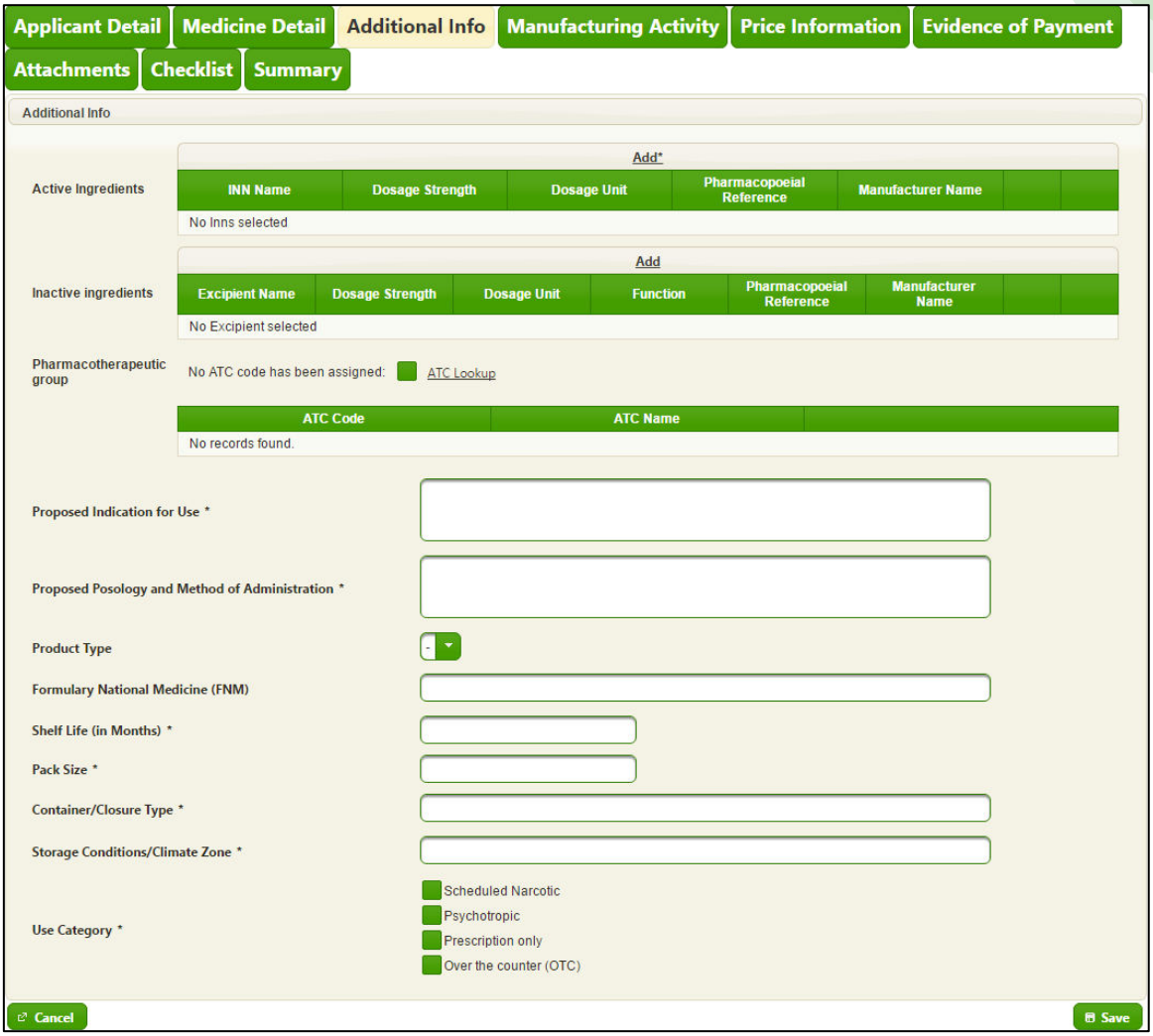


- On the **"Medicine Detail"** tab, fill in the required fields described below by giving as many information as possible and click **"Next"** to continue.
- Select the following fields from the combos - Product Category*/Dosage Form*/Dosage Unit*/Route of Administration* and Age Group*
- You also need to fill 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 will look like as follows:

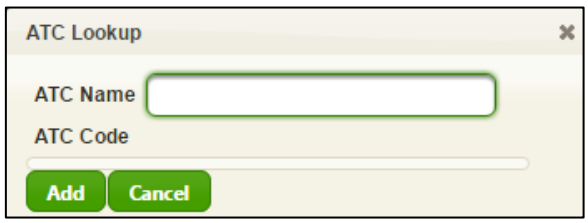


5.2.3. Additional Info

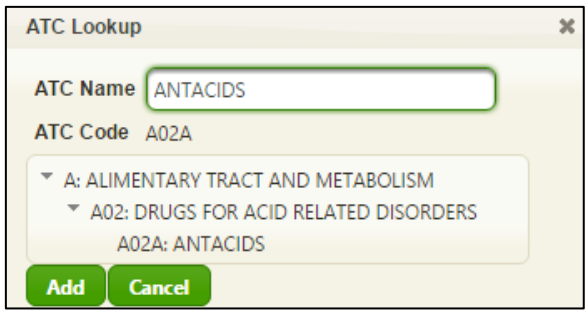
- After pressing "Next" button the following window will appear:



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



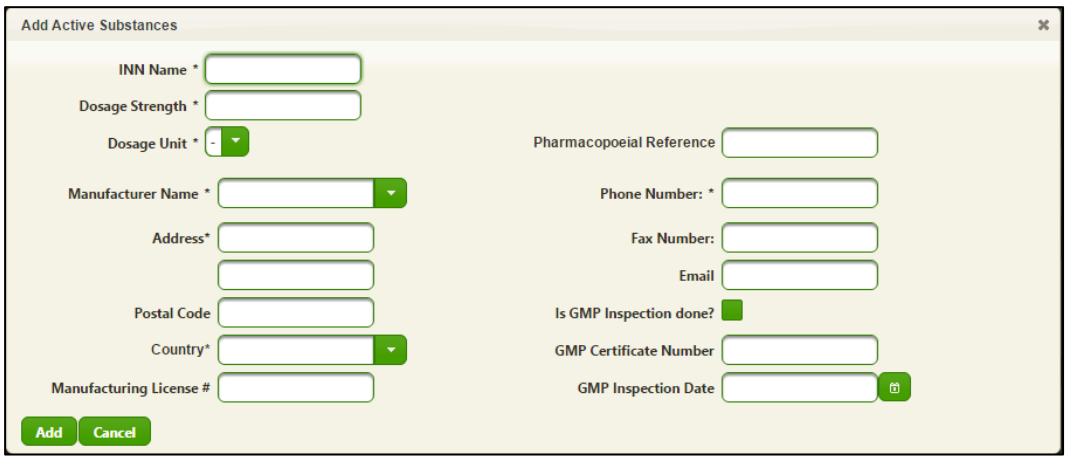
- After searching the ATC Name, the ATC Code will be displayed as shown in the following window. Then you need to click on "Add" to add the ATC Code.



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

5.2.4. Add Active Ingredients

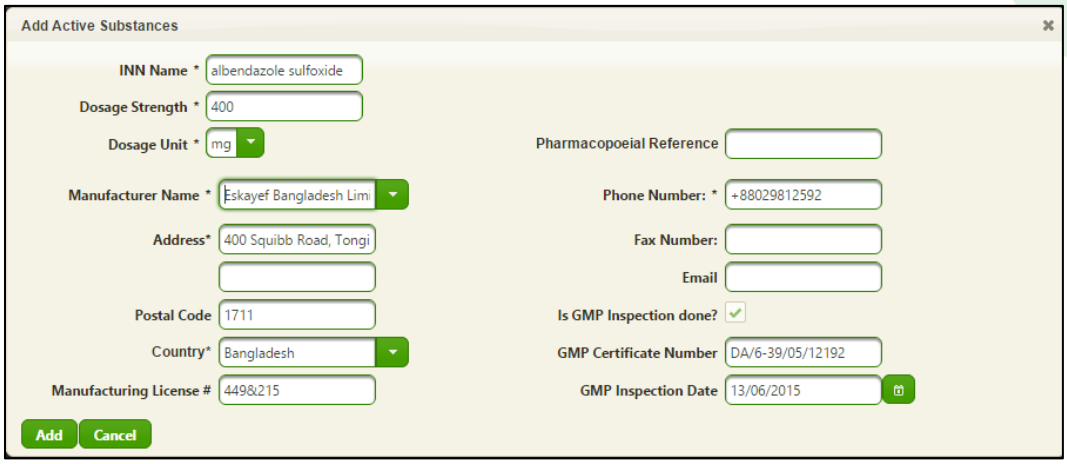
- To add active ingredients you need to click on **"Add"** button and the following window will arrive –



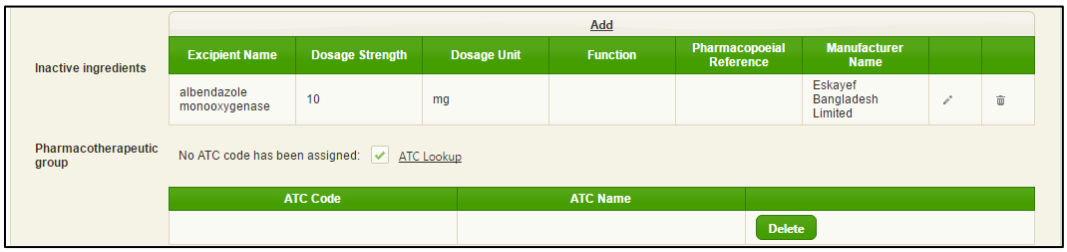
- Begin typing in the INN, and a list will be automatically populated based on what you type. Select the correct INN name, and enter in the strength (i.e. how much of that active substance), followed by the dosage unit (g, mg, etc.) and the pharmacopeia reference that was used (USP, BP, etc.).

- Fill in the details of Manufacturer of the active substance. If GMP inspection is done for the manufacturing facility, provide the GMP details also.

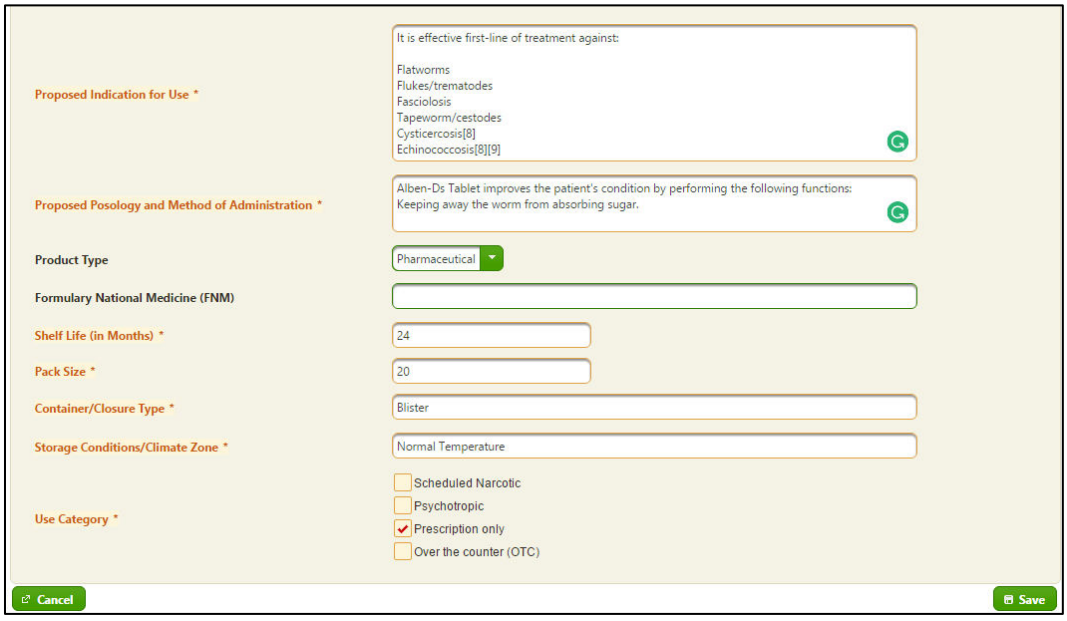
- After filling in you need to press **"Add"** button and the pop-up screen will go off and information will be saved.



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



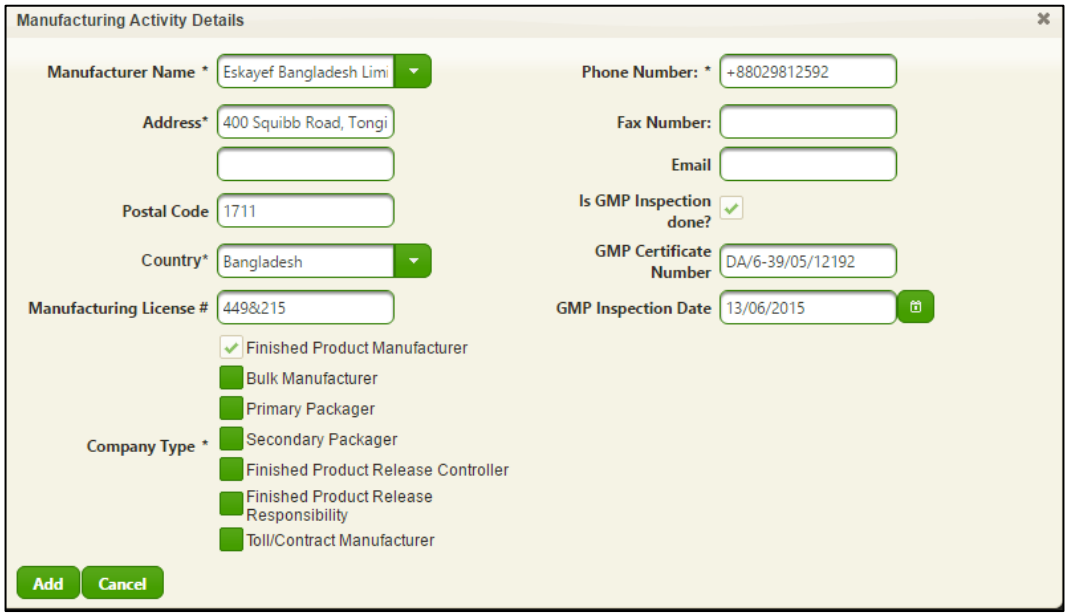
- After that you need to fill up other fields:



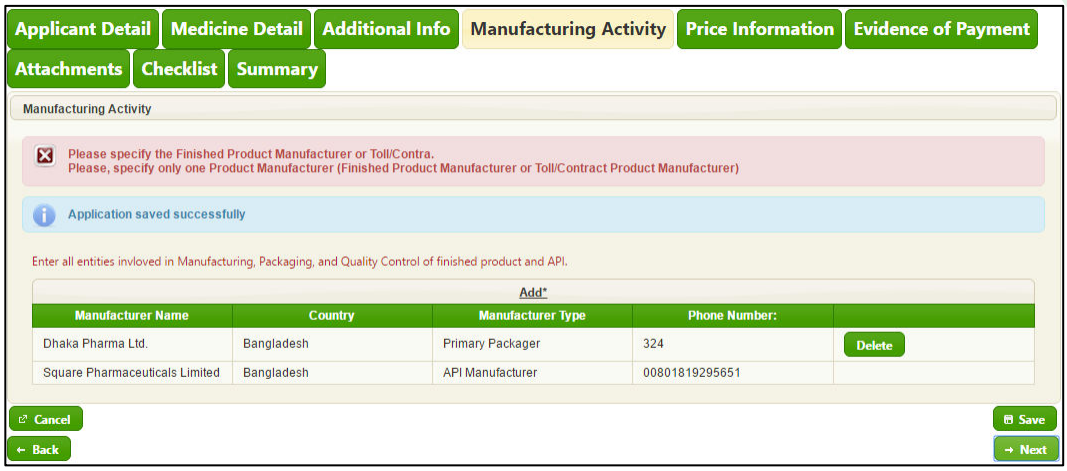
- After adding Active Ingredients, Inactive Ingredients and other fields you need to press **"Save"** button to save data then press **"Next"** button for going to next "**Manufacturing Activity"** tab.

5.2.5. Manufacturing Activity

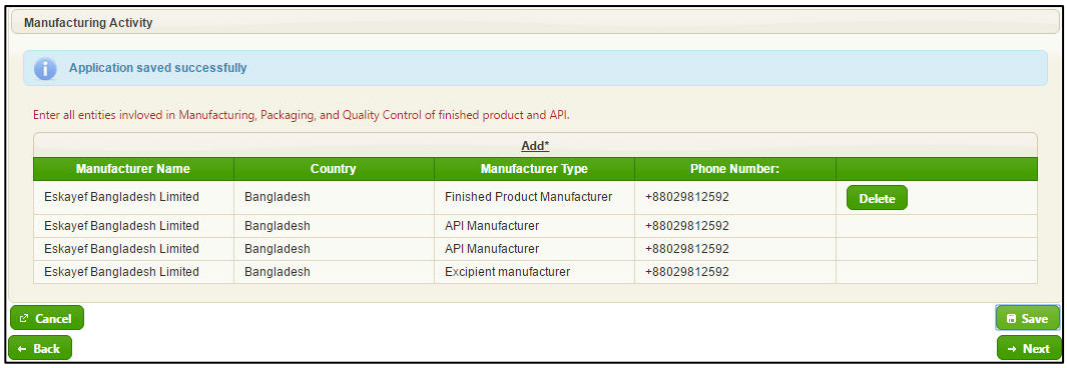
- You can add Manufacturing, Packaging, Quality Control, Finished Product or API manufacturer details in this tab.
- Press the **"Add"** button and fill all the necessary fields as shown in the following window:



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



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

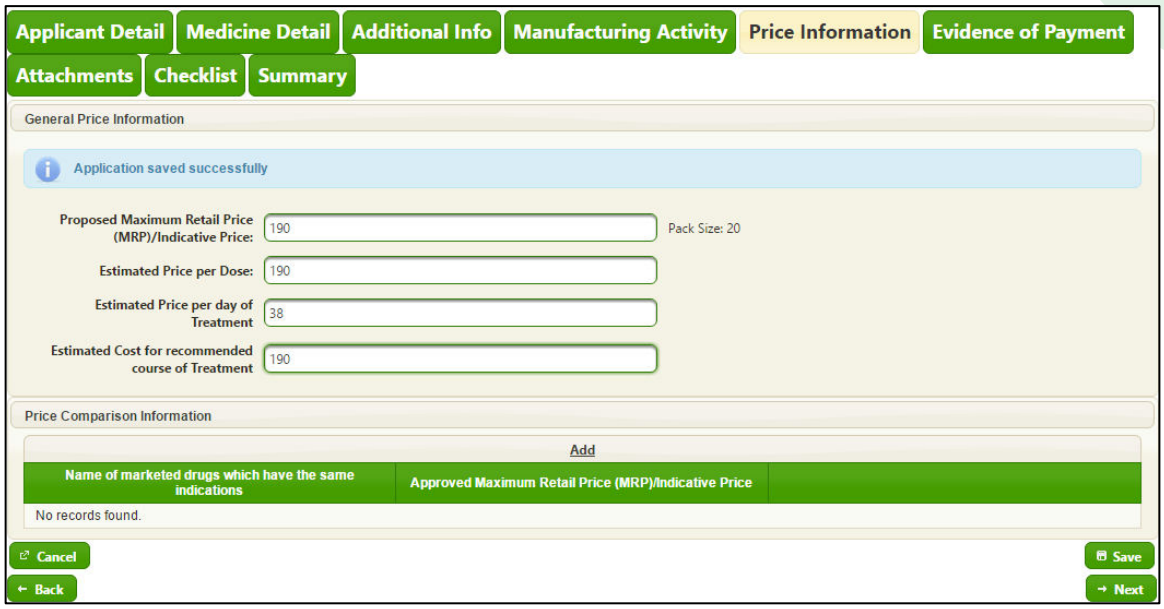


- If the applicant company hasmultiple manufacturing activities you need to add those types as shown in the above screen.

- 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:

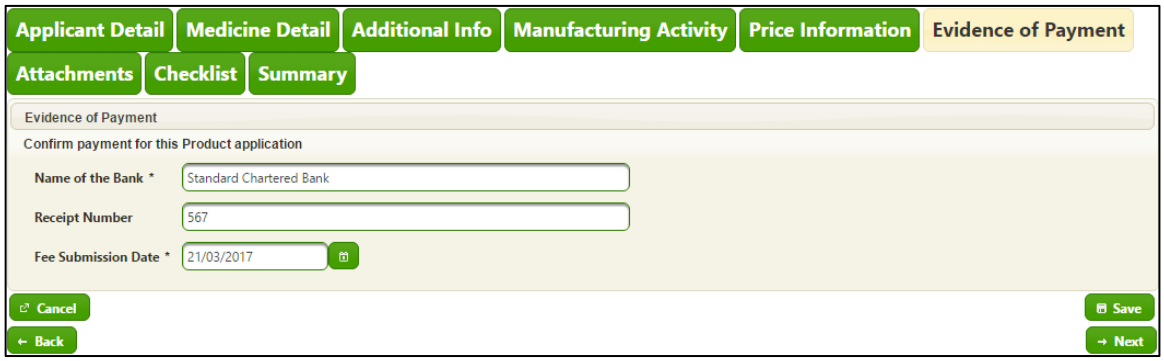


- Here you need to put all new Products pricing information as shown in the above screen.

- 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.

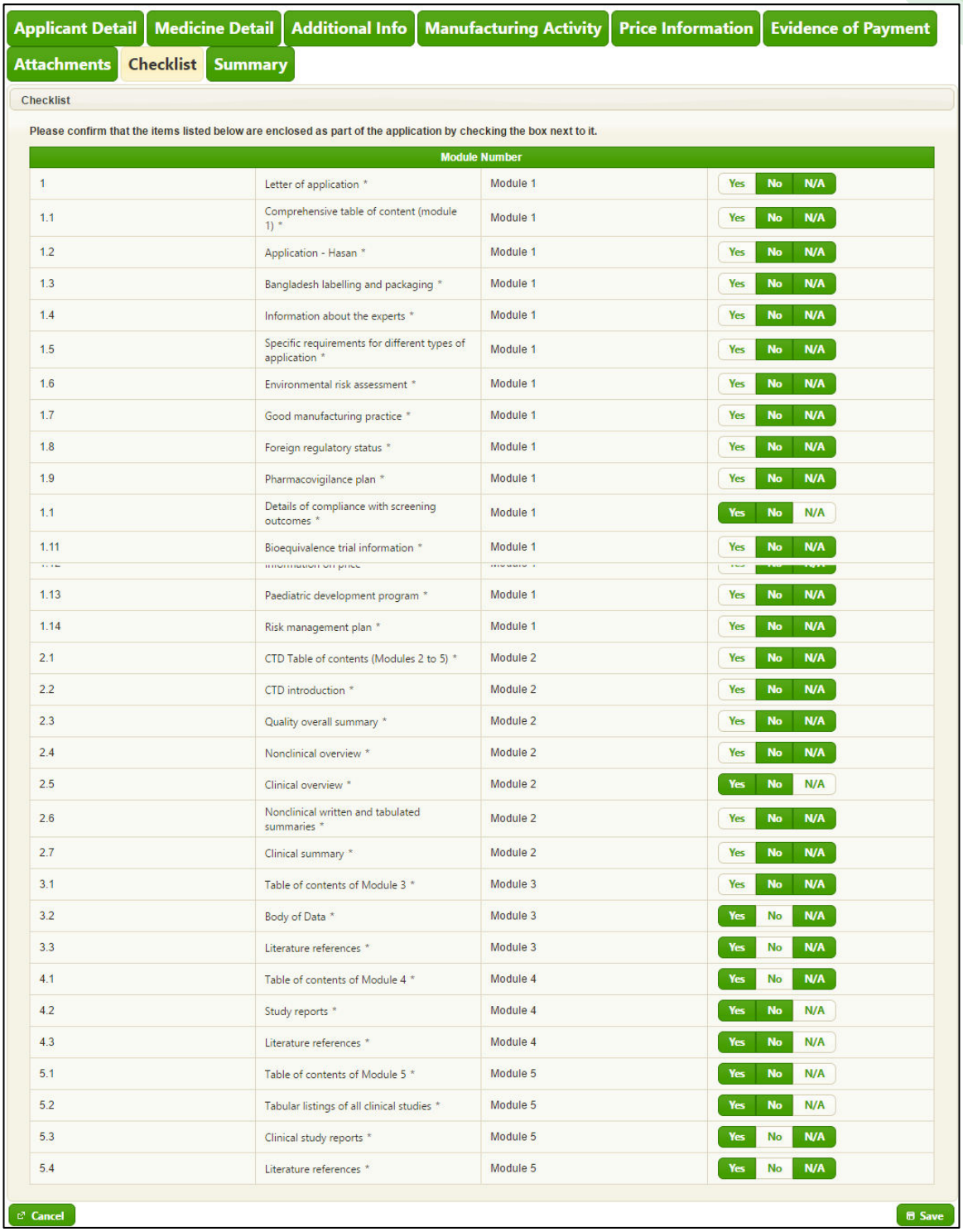
5.2.8. Attachments

- 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:

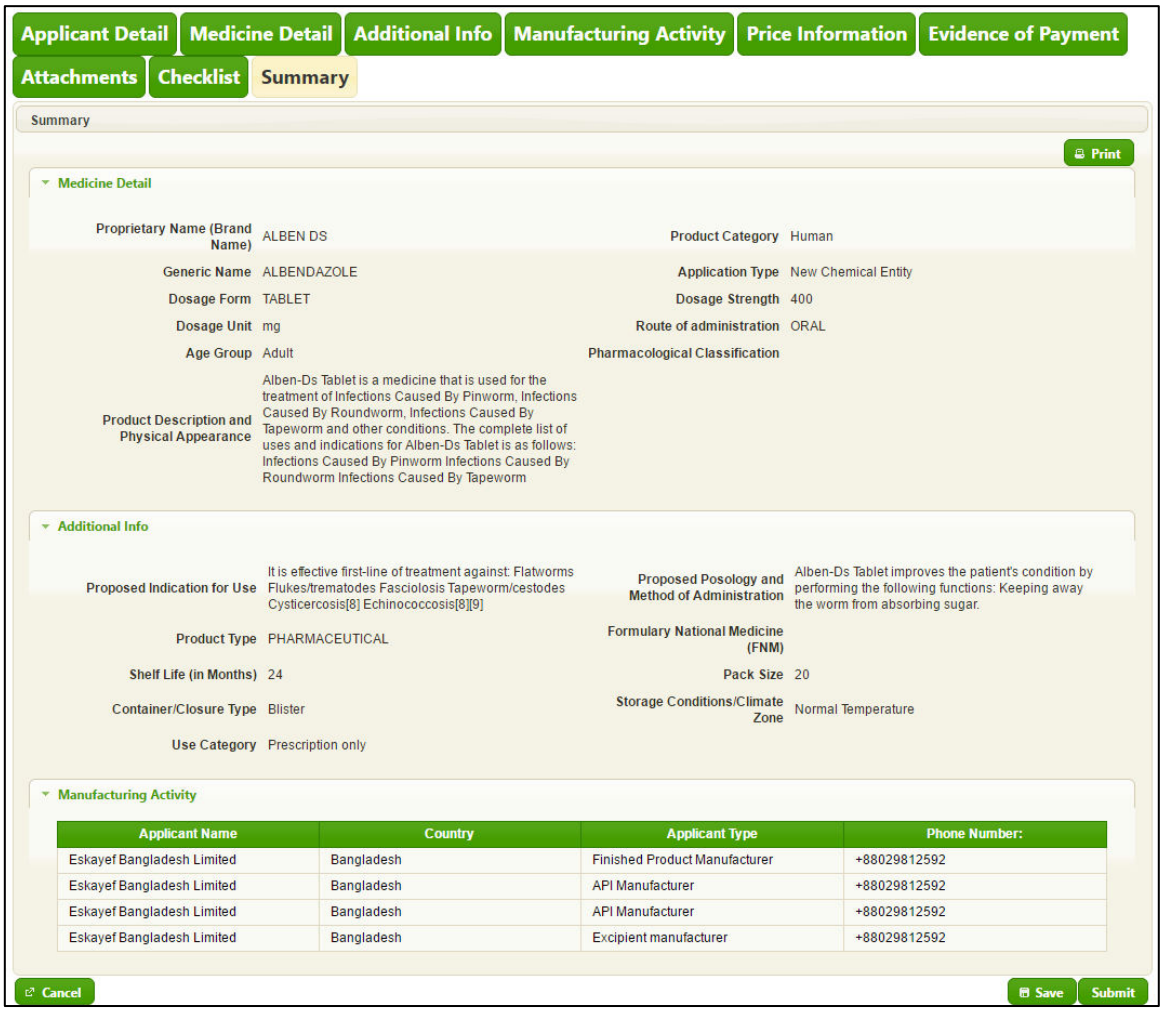


- Here you have to select any of the 3 options against each checklist item- **Yes, No or N/A**. Each checklist item represents one item from the application submitted physically. If you have submitted the document, select Yes; if you have not then select No. If the checklist item does not apply for your 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 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:

TERMS AND CONDITIONS OF CONTRACT

I the undersigned certify that all the information in the accompanying documentation concerning an application for a marketing authorization for:

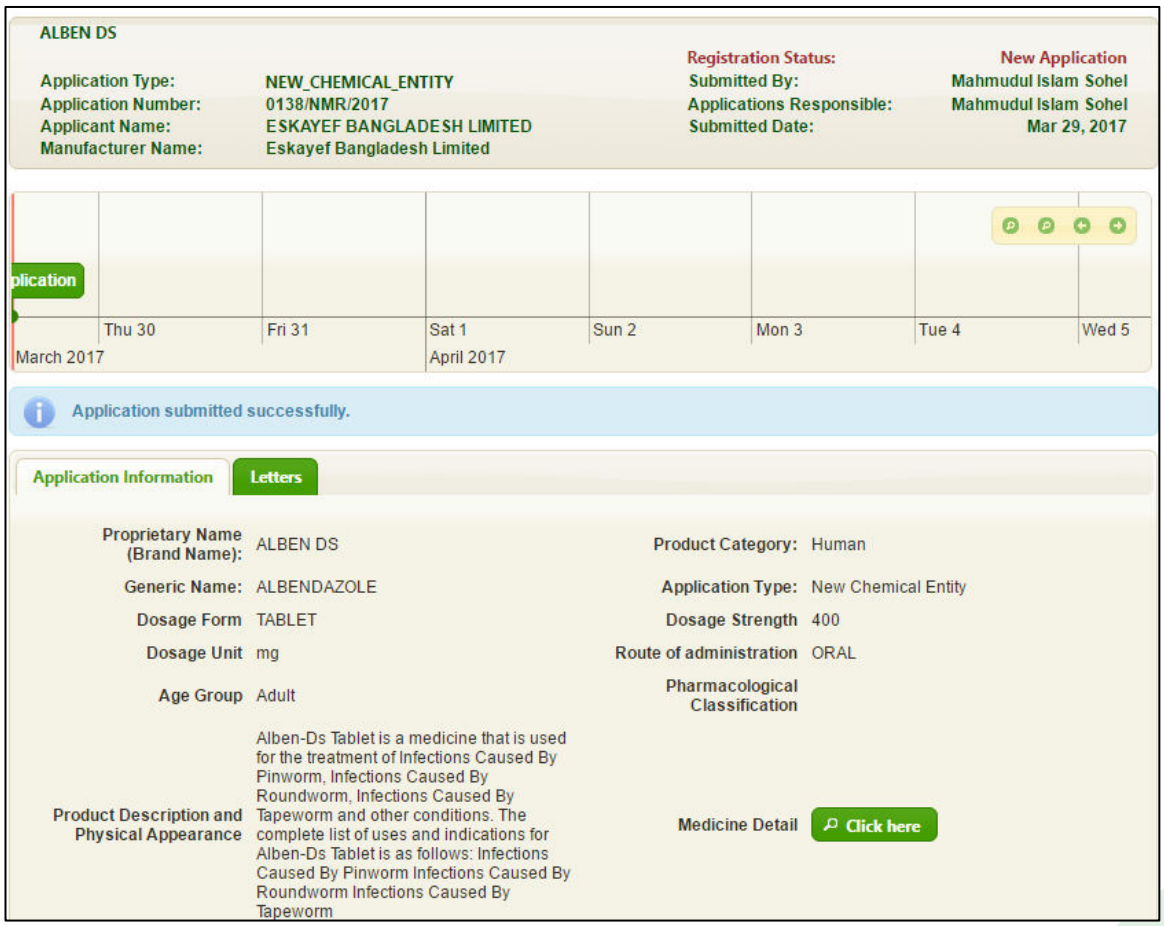
Proprietary Name (Brand Name):	MONTAIR	**Generic Name:**	SINGULAIR
Dosage Form	TABLET	**Dosage Strength:**	10
Dosage Unit	mg	**Product Description and Physical Appearance**	Montelukast is a selective and orally active leukotriene receptor antagonist that inhibits the cysteinyl leukotriene CysLT1 receptor. Cysteinyl leukotrienes and leukotriene receptor occupation have been correlated with the pathophysiology of asthma (such as, airway edema, smooth muscle contraction and altered cellular activity associated with the inflammatory process, which contribute to the signs and symptoms of asthma).
Applicant	Hasan Pharma	**Manufacturer Name**	Incepta Pharmacutical Ltd.

is correct and true, and reflects the total information available. I further certify that I have examined the following statements and I attest to their accuracy.

1. The current edition of the WHO guideline on "Good manufacturing practices for pharmaceutical products" Guideline, is applied in full in all premises involved in the manufacture of this product.
2. The formulation per dosage form correlates with the master formula and with the batch manufacturing record forms.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record forms.
4. Each batch of all starting materials is either tested or certified against the full specifications in the accompanying documentation and comply fully with those specifications before it is released for manufacturing purposes.
5. All batches of active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.
6. No batch of active pharmaceutical ingredient will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
7. Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before it is released for manufacturing purposes.
8. Each batch of the finished product is either tested, or certified, against the full specifications in the accompanying documentation and complies fully with the release specifications before it is released for sale.
9. The person releasing the product for sale is an authorized person as defined by the WHO guideline "Good manufacturing practices: Authorized person - the role, functions and training".
10. The procedures for control of the finished product have been validated for this formulation.
11. The market authorization holder has a standard operating procedure for handling adverse reaction reports on its products.
12. The market authorization holder has a standard operating procedure for handling batch recalls of its products.
13. All the documentation referred to in this certificate is available for review during a GMP inspection.
14. Any clinical trials including BE study were conducted according to WHO's "Guidelines for good clinical practice (GCP) for trials on pharmaceutical products

Yes No

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



ALBEN DS

		Registration Status:	**New Application**
Application Type:	**NEW_CHEMICAL_ENTITY**	**Submitted By:**	**Mahmudul Islam Sohel**
Application Number:	**0138/NMR/2017**	**Applications Responsible:**	**Mahmudul Islam Sohel**
Applicant Name:	**ESKAYEF BANGLADESH LIMITED**	**Submitted Date:**	**Mar 29, 2017**
Manufacturer Name:	**Eskayef Bangladesh Limited**		

plication | Thu 30 | Fri 31 | Sat 1 | Sun 2 | Mon 3 | Tue 4 | Wed 5

March 2017 | April 2017

Application submitted successfully.

Application Information | Letters

Proprietary Name (Brand Name):	ALBEN DS	**Product Category:**	Human
Generic Name:	ALBENDAZOLE	**Application Type:**	New Chemical Entity
Dosage Form	TABLET	**Dosage Strength**	400
Dosage Unit	mg	**Route of administration**	ORAL
Age Group	Adult	**Pharmacological Classification**	
Product Description and Physical Appearance	Alben-Ds Tablet is a medicine that is used for the treatment of Infections Caused By Pinworm, Infections Caused By Roundworm, Infections Caused By Tapeworm and other conditions. The complete list of uses and indications for Alben-Ds Tablet is as follows: Infections Caused By Pinworm Infections Caused By Roundworm Infections Caused By Tapeworm	**Medicine Detail**	Click here

5.2.11. Generate Acknowledgement Letter

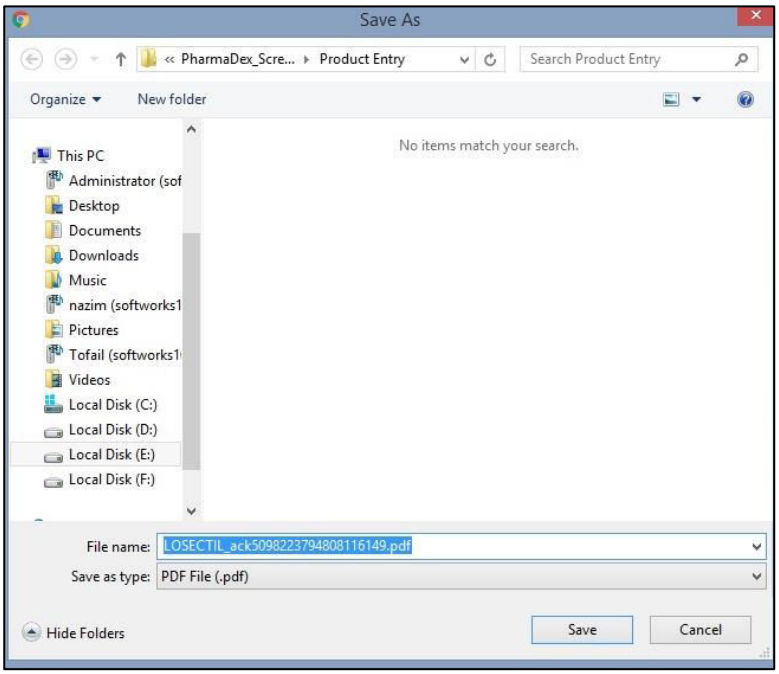
- Once you submit the application, the system will give you option to generate Acknowledgement Letter under **Letters** tab.

- 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 be 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

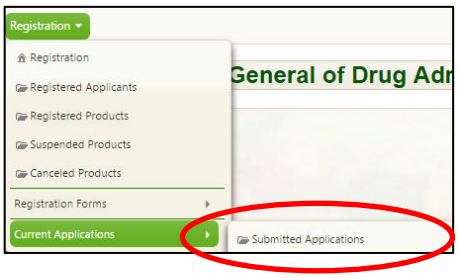
Director General,
Directorate General of Drug Administration
&
Licencing Authority (Drugs)
Government of the People's Republic of Bangladesh

6. Viewing Status of Applications

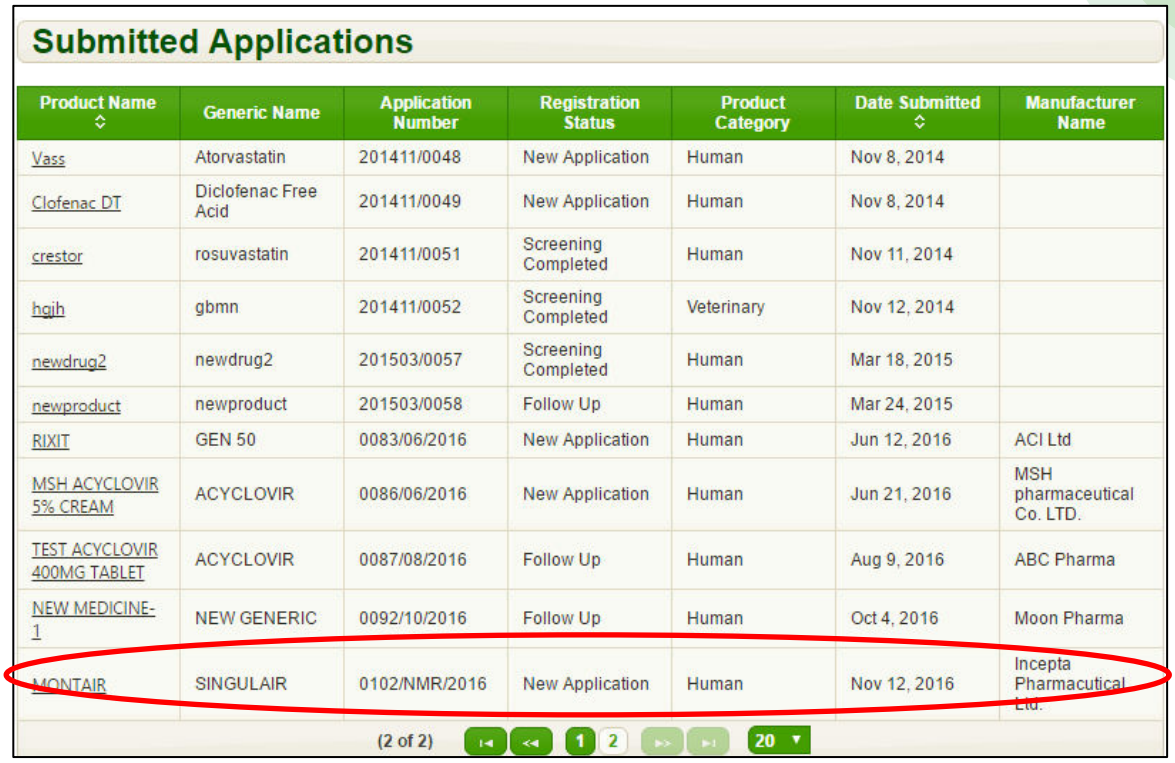
- To view the status of applications you have submitted, log in and click on **"Application Status".** From here, you can view submitted and saved applications as well as any products that have already been registered.

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 on 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 Pharmacutical Ltd.

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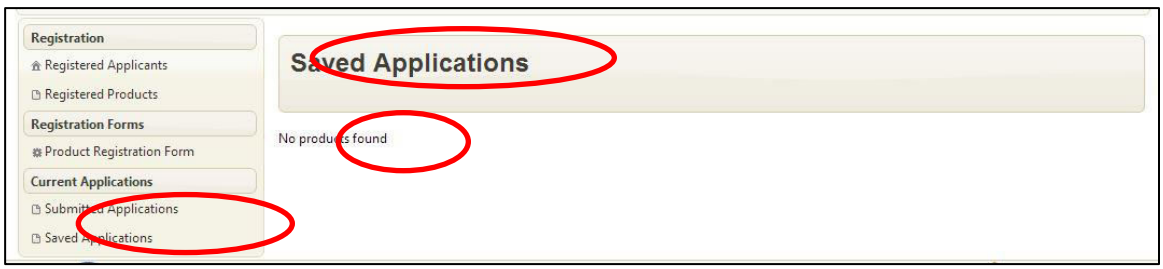
- You can continue to register other products by repeating the same steps above.

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**



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http://www.dgda.gov.bd

https://pharmadexbd.org