

Pharmadex: User Guide for Applicants

April 2017



USAID
FROM THE AMERICAN PEOPLE

SIAPS
Systems for Improved Access
to Pharmaceuticals and Services





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About SIAPS

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

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Key Words

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

Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Web: www.siapsprogram.org

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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

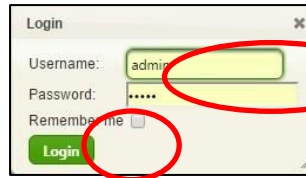
3. Accessing PharmaDex

3.1. Applicant Login

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



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



A screenshot of a web browser window showing a 'Login' form. The form has three input fields: 'Username:' with the text 'admin', 'Password:' with masked characters '*****', and a 'Remember me' checkbox. Below the fields is a green 'Login' button. Red circles are drawn around the 'Username' field, the 'Password' field, and the 'Login' button.

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



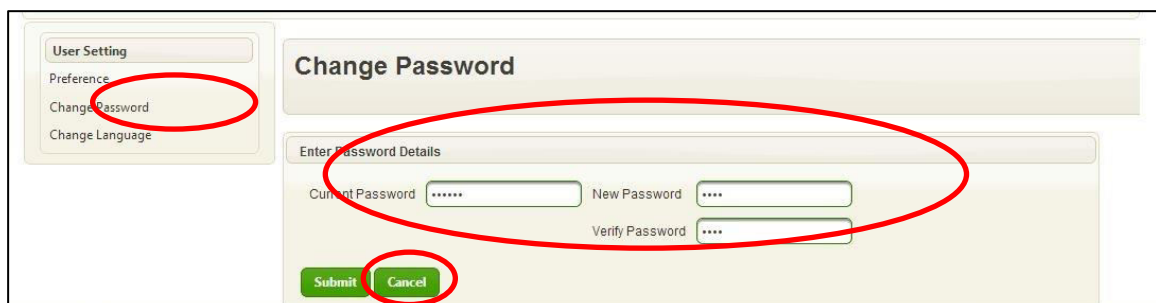
3.2. Changing User Settings

- 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.



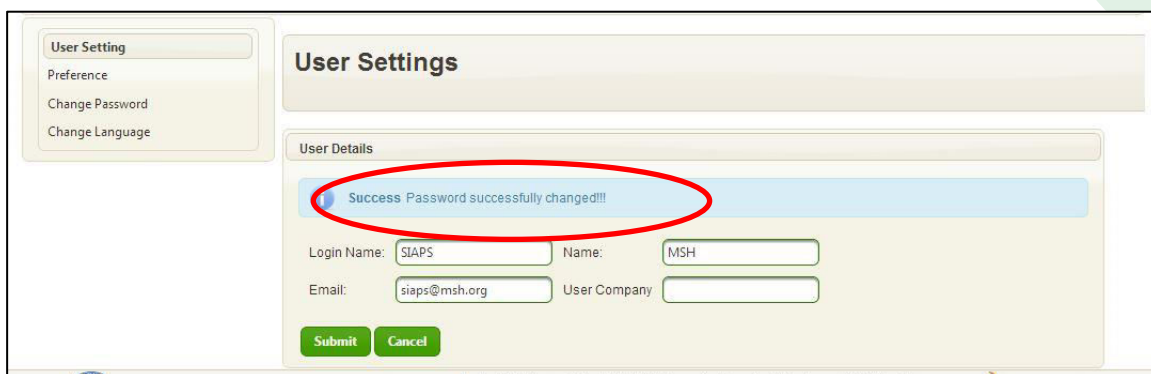
A screenshot of the 'User Settings' page. On the left is a sidebar with 'User Setting' and its sub-items: 'Preference', 'Change Password', and 'Change Language'. The main area is titled 'User Settings' and contains a 'User Details' section with input fields for 'Login Name' (SIAPS), 'Name' (MSH), 'Email' (siaps@msh.org), and 'User Company'. At the bottom of this section are 'Submit' and 'Cancel' buttons. A red circle highlights the 'Submit' button.

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



A screenshot of the 'Change Password' page. The sidebar on the left has 'Change Password' highlighted with a red circle. The main area is titled 'Change Password' and contains an 'Enter Password Details' section with input fields for 'Current Password', 'New Password', and 'Verify Password'. At the bottom are 'Submit' and 'Cancel' buttons. A large red circle highlights the entire 'Enter Password Details' section, and another red circle highlights the 'Submit' button.

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



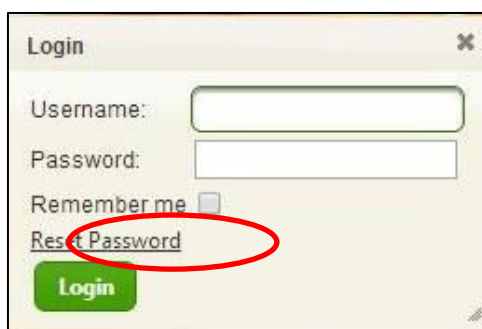
The screenshot shows the 'User Settings' page. On the left, there is a sidebar with links: 'User Setting', 'Preference', 'Change Password', and 'Change Language'. The main content area is titled 'User Settings' and contains a 'User Details' section. A blue success message 'Success Password successfully changed!!!' is displayed at the top of the details section, circled in red. Below the message are input fields for 'Login Name' (SIAPS), 'Name' (MSH), 'Email' (siaps@msh.org), and 'User Company'. At the bottom are 'Submit' and 'Cancel' buttons.

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 icon on the upper right corner.



- Click on "Reset Password".



The screenshot shows a 'Login' dialog box. It contains input fields for 'Username' and 'Password', a 'Remember me' checkbox, and a 'Reset Password' link. The 'Reset Password' link is circled in red. At the bottom is a green 'Login' button.

- 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.



The screenshot shows the 'User Settings' page. The 'Email' input field, containing 'siaps@msh.org', is circled in red. Below the email field is a 'Reset' button.

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

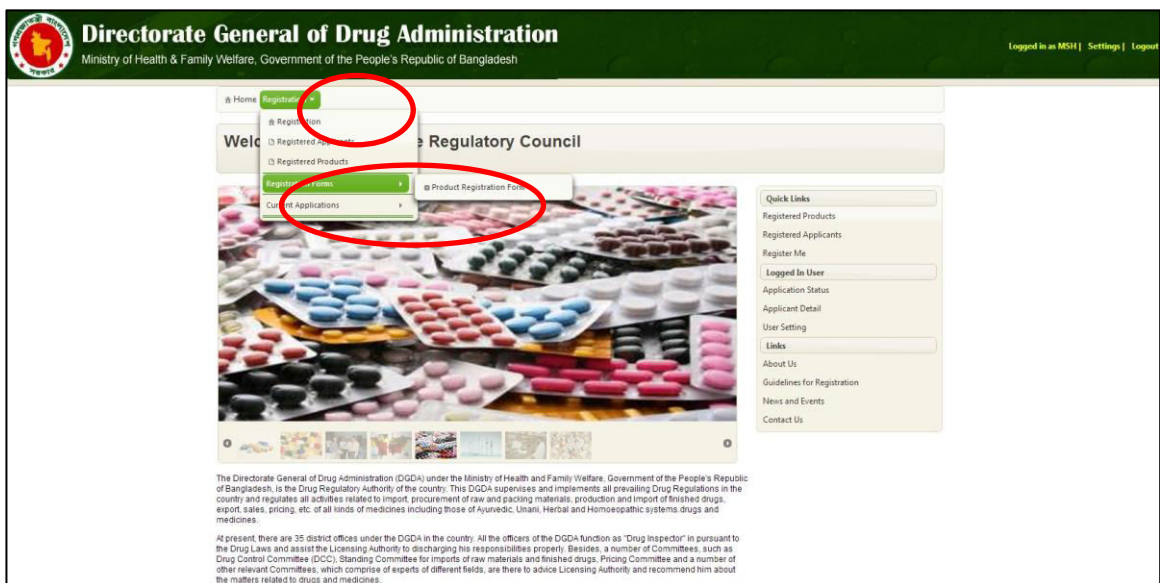
- A status bar is always visible on your screen showing the status of the application:

MONTAIR		Registration Status: Screening Completed	
Application Type:	GENERIC	Submitted By:	Hasan Mahmud
Application Number:	0102/NMR/2016	Applications Responsible:	Hasan Mahmud
Applicant Name:	Hasan Pharma	Submitted Date:	Nov 12, 2016
Manufacturer Name:	Incepta Pharmaceutical Ltd.		

Application						
Completed						
November 2016	Sun 13	Mon 14	Tue 15	Wed 16	Thu 17	Fri 18
						Sat 19

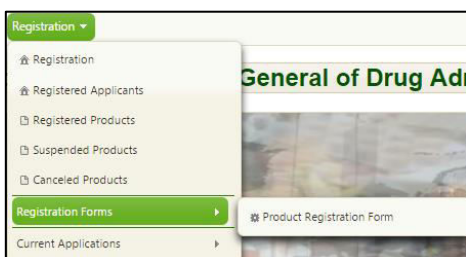
5. Registering Products

- 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

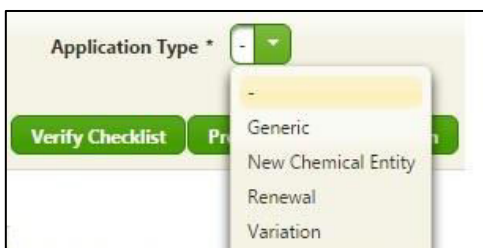
- Need to log in as **“Applicant”** user –
- After putting your username and password the following screen has shown your logged in status on right side of the screen –
- Go to **Registration > Registration Forms > Product Registration Form** -



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.

Product Registration Application

Applicant Detail **Medicine Detail** Additional Info Manufacturing Activity Price Information Evidence of Payment

Attachments Checklist Summary

Applicant Detail

Applicant Name * ESKAYEF BANGLADESH LIMITED
Address * Tongi, Gazipur
Country * Bangladesh
Applicant Type * Manufacturer
Manufacturing License # 4498215
Fax Number:
Email

Postal Code
Phone Number: * +59228802981
Website

Person Responsible/Authorized to communicate with DGDA.

Name: * Mahmudul Islam Sohel
Address * 21/15 babor Road
Country * Bangladesh
Fax Number:

Postal Code
Phone Number:
Email: * spsbdhelp@msh.org

Cancel Next

- 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

Product Registration Application


Applicant Detail **Medicine Detail** Additional Info Manufacturing Activity Price Information Evidence of Payment

Attachments Checklist Summary

Medicine Detail

Application Type Generic
Product Category * -

Proprietary Name (Brand Name) *
Generic Name *
Dosage Form * -
Dosage Unit * -
Dosage Strength *
Route of administration * -
Age Group * -

Product Description and Physical Appearance * 

Cancel Save

- 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:

The screenshot shows the 'Medicine Detail' form with the following fields and values:

- Application Type:** New Chemical Entity
- Product Category *:** Human
- Proprietary Name (Brand Name) *:** ALBEN DS
- Generic Name *:** ALBENDAZOLE
- Dosage Form *:** TABLET
- Dosage Unit *:** mg
- Dosage Strength *:** 400
- Route of administration *:** ORAL
- Age Group *:** Adult
- 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

At the bottom of the form, there are 'Cancel' and 'Save' buttons.

5.2.3. Additional Info

- After pressing **“Next”** button the following window will appear:

Applicant Detail	Medicine Detail	Additional Info	Manufacturing Activity	Price Information	Evidence of Payment
Attachments	Checklist	Summary			

Additional Info

Active Ingredients

INN Name	Dosage Strength	Dosage Unit	Pharmacopoeial Reference	Manufacturer Name
No Inns selected				

Inactive Ingredients

Excipient Name	Dosage Strength	Dosage Unit	Function	Pharmacopoeial Reference	Manufacturer Name
No Excipient selected					

Pharmacotherapeutic group

No ATC code has been assigned: ☐ ATC Lookup

ATC Code	ATC Name
No records found.	

Proposed Indication for Use *

Proposed Posology and Method of Administration *

Product Type

Formulary National Medicine (FNM)

Shelf Life (in Months) *

Pack Size *

Container/Closure Type *

Storage Conditions/Climate Zone *

Use Category *

☐ Scheduled Narcotic
☐ Psychotropic
☐ Prescription only
☐ Over the counter (OTC)

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

ATC Lookup

ATC Name

ATC Code

- 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.

ATC Lookup

ATC Name

ATC Code

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

Pharmacotherapeutic group	No ATC code has been assigned: <input checked="" type="checkbox"/> ATC Lookup		
	ATC Code	ATC Name	
	A02A	ANTACIDS	Delete

5.2.4. Add Active Ingredients

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

Add Active Substances

INN Name *

Dosage Strength *

Dosage Unit *

-

Manufacturer Name *

Address*

Postal Code

Country*

Manufacturing License #

Pharmacopoeial Reference

Phone Number: *

Fax Number:

Email

Is GMP Inspection done?

☐

GMP Certificate Number

GMP Inspection Date

Add

Cancel

- 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.

Add Active Substances

INN Name *

Dosage Strength *

Dosage Unit *

Manufacturer Name *

Address*

Postal Code

Country*

Manufacturing License #

Pharmacopoeial Reference

Phone Number: *

Fax Number:

Email

Is GMP Inspection done? ☒

GMP Certificate Number

GMP Inspection Date

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

Add

Excipient Name	Dosage Strength	Dosage Unit	Function	Pharmacopoeial Reference	Manufacturer Name
albendazole monooxygenase	10	mg			Eskayef Bangladesh Limited

Pharmacotherapeutic group No ATC code has been assigned: ☒ [ATC Lookup](#)

ATC Code	ATC Name

- After that you need to fill up other fields:

Proposed Indication for Use *

It is effective first-line of treatment against:

Flatworms
Flukes/trematodes
Fasciolosis
Tapeworm/cestodes
Cysticercosis[8]
Echinococcosis[8][9]

Proposed Posology and Method of Administration *

Alben-Ds Tablet improves the patient's condition by performing the following functions:
Keeping away the worm from absorbing sugar.

Product Type

Formulary National Medicine (FNM)

Shelf Life (in Months) *

Pack Size *

Container/Closure Type *

Storage Conditions/Climate Zone *

Use Category *

☐ Scheduled Narcotic
☐ Psychotropic
☒ Prescription only
☐ Over the counter (OTC)

- 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

Manufacturing Activity

Application saved successfully

Enter all entities involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Add*

Manufacturer Name	Country	Manufacturer Type	Phone Number:	
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592	

Cancel Back Save Next

- 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:

Manufacturing Activity Details

Manufacturer Name * Eskayef Bangladesh Limi

Address* 400 Squibb Road, Tongi

Postal Code 1711

Country* Bangladesh

Manufacturing License # 4498215

Phone Number: * +88029812592

Fax Number:

Email:

Is GMP Inspection done? ☒

GMP Certificate Number DA/6-39/05/12192

GMP Inspection Date 13/06/2015

Company Type *

☒ Finished Product Manufacturer

☐ Bulk Manufacturer

☐ Primary Packager

☐ Secondary Packager

☐ Finished Product Release Controller

☐ Finished Product Release Responsibility

☐ Toll/Contract Manufacturer

Add Cancel

- 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:

Manufacturing Activity

Please specify the Finished Product Manufacturer or Toll/Contra.
Please, specify only one Product Manufacturer (Finished Product Manufacturer or Toll/Contract Product Manufacturer)

Application saved successfully

Enter all entries involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Manufacturer Name	Country	Manufacturer Type	Phone Number:	
Dhaka Pharma Ltd.	Bangladesh	Primary Packager	324	Delete
Square Pharmaceuticals Limited	Bangladesh	API Manufacturer	00801819295651	

Cancel Back Save Next

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

Manufacturing Activity

Application saved successfully

Enter all entries involved in Manufacturing, Packaging, and Quality Control of finished product and API.

Manufacturer Name	Country	Manufacturer Type	Phone Number:	
Eskayef Bangladesh Limited	Bangladesh	Finished Product Manufacturer	+88029812592	Delete
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592	
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592	

Cancel Back Save Next

- If the applicant company has multiple 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:

General Price Information

Application saved successfully

Proposed Maximum Retail Price (MRP)/Indicative Price: 190 Pack Size: 20

Estimated Price per Dose: 190

Estimated Price per day of Treatment: 38

Estimated Cost for recommended course of Treatment: 190

Price Comparison Information

Add

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

Cancel Back Save Next

- 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:

Evidence of Payment

Confirm payment for this Product application

Name of the Bank * Standard Chartered Bank

Receipt Number 567

Fee Submission Date * 21/03/2017

Cancel Back Save Next

- 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. .

Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Price Information
Evidence of Payment

Attachments
Checklist
Summary

Please attach the soft copy of the following documents: CPP, Label, Payment Receipt, Method of Analysis.
Attachments have a 4mb size limit.

Add Document

Title	File Name	Upload Date	Uploaded By	Registration Status		
Packet Label	Alben-DS_tabs.jpg	Mar 29, 2017	Mahmudul Islam Sohel	Saved	Download	

Cancel
Back
Save
Next

- 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:

Applicant Detail **Medicine Detail** **Additional Info** **Manufacturing Activity** **Price Information** **Evidence of Payment**

Attachments **Checklist** **Summary**

Checklist

Please confirm that the items listed below are enclosed as part of the application by checking the box next to it.

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

Cancel Save

- 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.

The screenshot displays the 'Summary' tab of the Pharmadex application form. The interface includes a top navigation bar with tabs: Applicant Detail, Medicine Detail, Additional Info, Manufacturing Activity, Price Information, Evidence of Payment, Attachments, Checklist, and Summary. The 'Summary' tab is active, showing a detailed overview of the application data.

Medicine Detail

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

Additional Info

Proposed Indication for Use	It is effective first-line of treatment against: Flatworms Flukes/trematodes Fasciolosis Tapeworm/cestodes Cysticercosis[8] Echinococcosis[8][9]	Proposed Posology and Method of Administration	Alben-Ds Tablet improves the patient's condition by performing the following functions: Keeping away the worm from absorbing sugar.
Product Type	PHARMACEUTICAL	Formulary National Medicine (FNM)	
Shelf Life (in Months)	24	Pack Size	20
Container/Closure Type	Blister	Storage Conditions/Climate Zone	Normal Temperature
Use Category	Prescription only		

Manufacturing Activity

Applicant Name	Country	Applicant Type	Phone Number:
Eskayef Bangladesh Limited	Bangladesh	Finished Product Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	API Manufacturer	+88029812592
Eskayef Bangladesh Limited	Bangladesh	Excipient manufacturer	+88029812592

At the bottom of the form, there are buttons for 'Cancel', 'Save', and 'Submit'.

- 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 Pharmaceutical 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:
Submitted By: **Mahmudul Islam Sohel**
Applications Responsible: **Mahmudul Islam Sohel**
Submitted Date: **Mar 29, 2017**

New Application
Mahmudul Islam Sohel
Mar 29, 2017

Application Type: **NEW_CHEMICAL_ENTITY**
Application Number: **0138/NMR/2017**
Applicant Name: **ESKAYEF BANGLADESH LIMITED**
Manufacturer Name: **Eskayef Bangladesh Limited**

	Thu 30	Fri 31	Sat 1	Sun 2	Mon 3	Tue 4	Wed 5
March 2017			April 17				

i Application submitted successfully.

Application Information Letters

Proprietary Name (Brand Name): **ALBEN DS**
Generic Name: **ALBENDAZOLE**
Dosage Form: **TABLET**
Dosage Unit: **mg**
Age Group: **Adult**

Product Category: **Human**
Application Type: **New Chemical Entity**
Dosage Strength: **400**
Route of administration: **ORAL**
Pharmacological Classification:

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

Medicine Detail [Click here](#)

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.

Title	File Name	Upload Date	Uploaded By	Registration Status
No records found.				

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

New letter has been created

File number 0133/NMR/2017

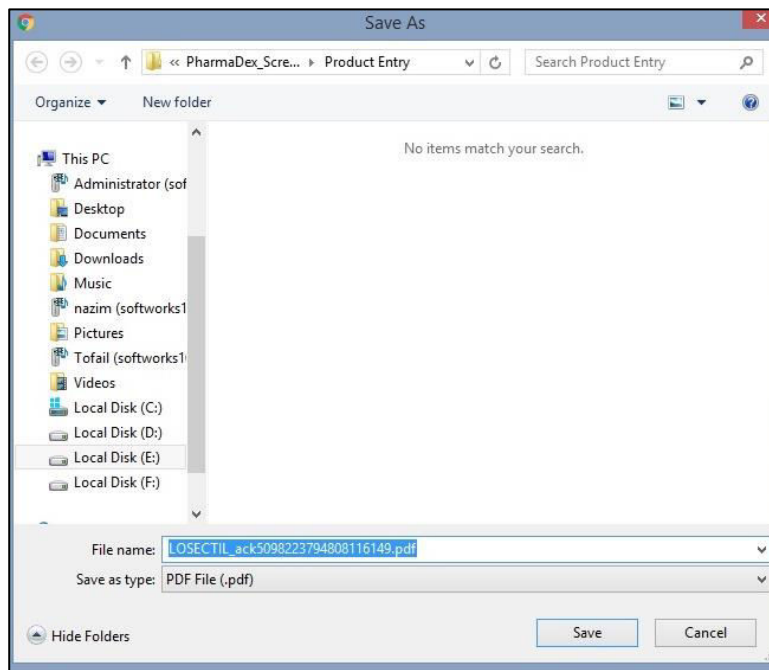
Dossiers received *

- You will see the following screen –

Title	File Name	Upload Date	Uploaded By	Registration Status
Acknowledgment letter	LOSECTIL_ack50 98223794808116 149.pdf	Apr 20, 2017	SoftWorks	New Application

Download

- 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

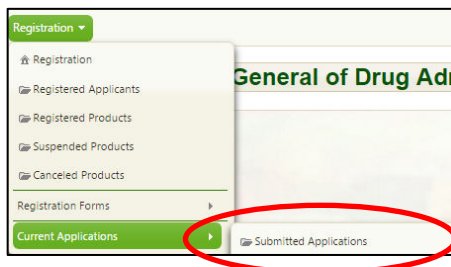
6. Viewing Status of Applications

- 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**



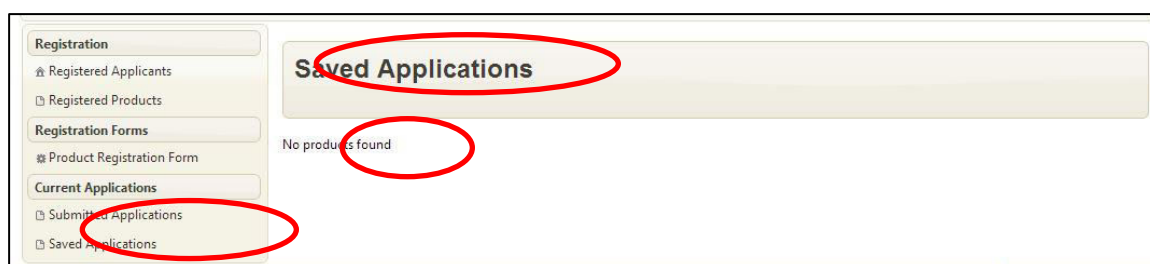
- The submitted **"New Application"** will appear on the screen:

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	
hgih	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.
(2 of 2) < << 1 2 >> > 20 ▾						

- 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**



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

<https://pharmadexbd.org>