

# **PharmaDex Software Applicant User Manual**

**January 2016**

DRAFT

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## Accronyms and Abbreviations

API	Active Pharmaceutical Ingredient
ATC	Anatomical Therapeutic Chemical (Classification)
BP	British Pharmacopeia
CTD	Common Technical Document
DGDA	Directorate General of Drug Administration
INN	International Non-proprietary Name
IS	Information System
MedRA	Medical Dictionary for Regulatory Activities
MSH	Management Sciences for Health
NRA	National Regulatory Authority
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization

## 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.

## 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.

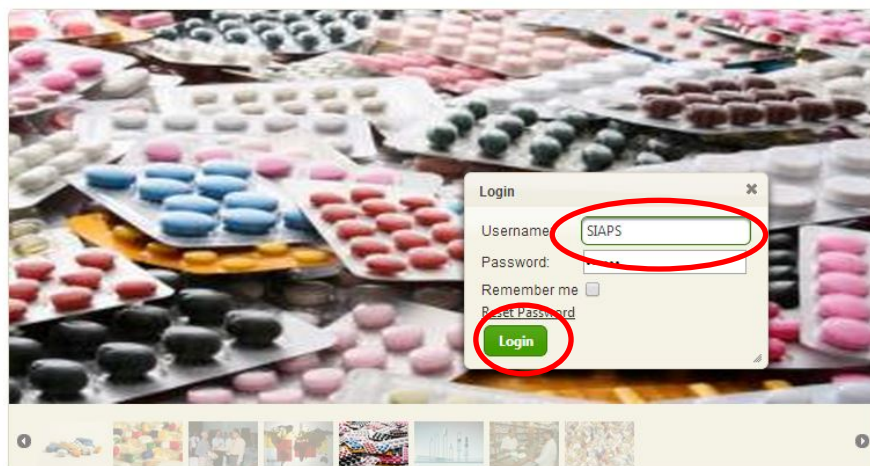
## Accessing PharmaDex

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



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

## Welcome to the Medicine Regulatory Council



### Quick Links

Registered Products  
Registered Applicants  
Register Me

### Links

About Us  
Guidelines for Registration  
News and Events  
Contact Us

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh, is the Drug Regulatory Authority of the country. This DGDA supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc. of all kinds of medicines including those of Ayurvedic, Unani, Herbal and Homoeopathic systems, drugs and medicines.

At present, there are 35 district offices under the DGDA in the country. All the officers of the DGDA function as "Drug Inspector" in pursuant to the Drug Laws and assist the Licensing Authority in discharging his responsibilities properly. Besides, a number of Committees, such as Drug Control Committee (DCC), Standing Committee for imports of raw materials and finished drugs, Pricing Committee and a number of other relevant Committees, which comprise of experts of different fields, are there to advise Licensing Authority and recommend him about the matters related to drugs and medicines.

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





## Changing User Settings

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

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

Logged in as **MSH** | **Settings** | Logout

Welcome to the Medicine Regulatory Council

**Quick Links**

- Registered Products
- Registered Applicants
- Register Me
- Logged In User
- Application Status
- Applicant Detail
- User Setting
- Links
- About Us
- Guidelines for Registration
- News and Events
- Contact Us

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh, is the Drug Regulatory Authority of the country. This DGDA supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc. of all kinds of medicines including those of Ayurvedic, Unani, Herbal and Homeopathic systems drugs and medicines.

At present, there are 35 district offices under the DGDA in the country. All the officers of the DGDA function as "Drug Inspector" in pursuant to the Drug Laws and assist the Licensing Authority to discharging his responsibilities properly. Besides, a number of Committees, such as Drug Control Committee (DCC), Standing Committee for imports of raw materials and finished drugs, Pricing Committee and a number of other relevant Committees, which comprise of experts of different fields, are there to advise Licensing Authority and recommend him about the matters related to drugs and medicines.

**User Setting**

- Preference
- Change Password
- Change Language

**User Settings**

**User Details**

Login Name:  Name:

Email:  User Company:

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



**User Setting**

- Preference
- Change Password**
- Change Language

### Change Password

Enter Password Details

Current Password:  New Password:

Verify Password:

**Submit** **Cancel**

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

**User Setting**

- Preference
- Change Password
- Change Language

### User Settings

User Details

**Success: Password successfully changed!!!**

Login Name:  Name:

Email:  User Company:

**Submit** **Cancel**

## 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 hit “Reset.” A new password will be emailed to you. To change your password, follow the instructions in Chapter 5 on changing passwords.

## Registering Applicants

After logging into PharmaDex, if you are not associated with an applicant you will need to register an applicant before registering any products. To do this, click on “Registration,” “Registration Forms,” and “Applicant Registration Form.”



Fill in the required information and hit “Submit.”

## Applicant Registration

### Applicant Detail

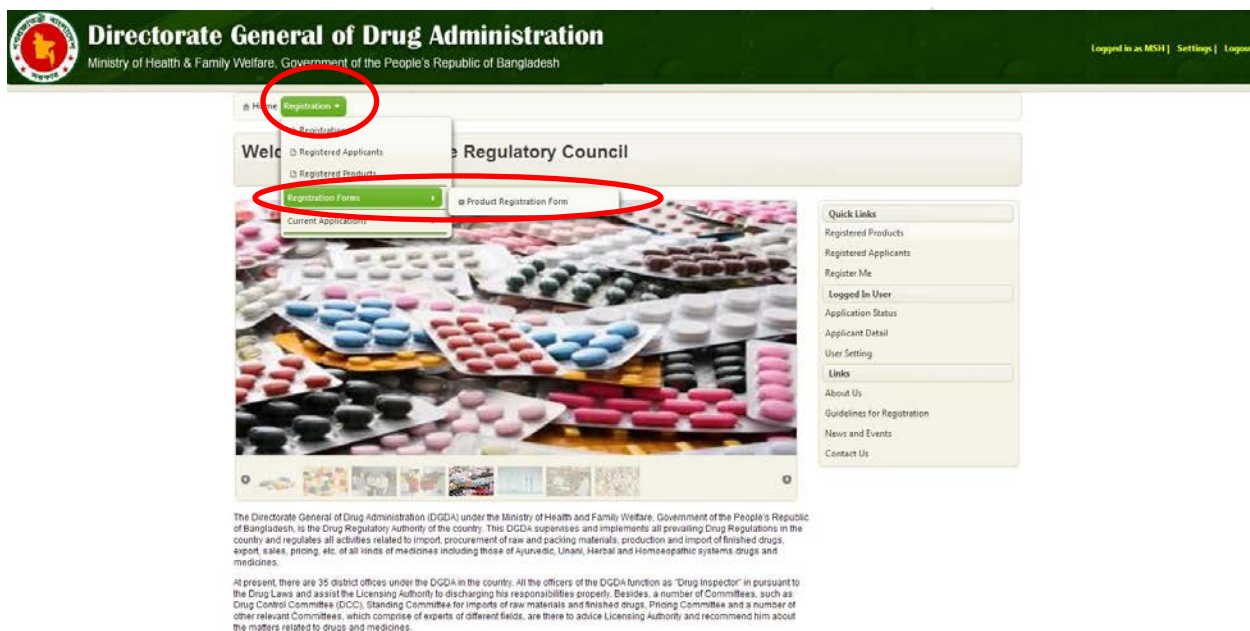
Applicant Name *	<input type="text" value="SIAPS Rx"/>	
Address*	<input type="text" value="4301 N. Fairfax Drive"/>	
	<input type="text" value="Suite 400"/>	
Country*	<input type="text" value="United States of America"/>	
Applicant Type*	<input type="text" value="Manufacturer"/>	
Site/Applicant Master File Number	<input type="text" value="12345"/>	
Fax Number:	<input type="text" value="7035247898"/>	
		Zip Code* <input type="text" value="22203"/>
		Phone Number: <input type="text" value="7035246575"/>
		Website <input type="text" value="siapsprogram.org"/>

### Person Responsible/Authorized to communicate to the council.

Name:	MSH	
Address*	4301 N. Fairfax Drive	
	Suite 400	
Country*		Zip Code* 22203
Fax Number:	7035247898	Phone Number: 7035246575
		Email: siaps@msh.org

## 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.”



The first page you see contains information about the applicant. The system will automatically populate your profile. Click on “Next” to proceed or “Cancel” to cancel.

## Product Registration Application

Applicant Detail

Medicine Detail

Additional Info

Manufacturing Activity

Evidence of Payment

Checklist

Summary

Applicant Detail

Applicant Name \* SIAPS Rx  
Address\* 4301 N. Fairfax Drive  
Suite 400  
Country\* United States of America  
Applicant Type\* Manufacturer  
Site/Applicant Master File Number 12345  
Fax Number: 7035247898  
Zip Code\* 22203  
Phone Number: 7035246575  
Website siapsprogram.org

Person Responsible/Authorized to communicate to the council.

Name: MSH  
Address\* 4301 N. Fairfax Drive  
Suite 400  
Country\*  
Fax Number: 7035247898  
Zip Code\* 22203  
Phone Number: 7035246575  
Email: siaps@msh.org

Cancel Next

## Medicine Detail

On the “Medicine Detail” tab, fill in the required fields with as much information as possible and click “Next” to continue.

## Product Registration Application

Applicant Detail

Medicine Detail

Additional Info

Manufacturing Activity

Evidence of Payment

Checklist

Summary

Medicine Detail

Application Type \* New Chemical Entity  
Product Category \* Human  
Product Type \* Allopathy  
Proprietary Name (Brand Name) \* Nexium  
Generic/Approved Name \* esomeprazole  
Dosage Form \* CAPSULE, DELAYED RELEASE  
Dosage Unit \* mg  
Dosage Strength \* 20  
Route of administration \* ORAL  
Age Group \* Adult  
Pharmacological Classification \* Proton Pump inhibitor  
Product Description and Physical Appearance  
purple pill

Save Cancel Previous Next



## Additional Product Information

On the “Additional Info” tab, if the product is a new chemical entity, check the box and type in the product’s name. If it is not a new chemical entity, leave the box unchecked.

Applicant Detail

Medicine Detail

Additional Info

Manufacturing Activity

Evidence of Payment

Checklist

Summary

Additional Info

Is it new chemical entity

☐

List the Active Substances

Add

Active Substance	Quantity	Dosage Unit	Pharmacopoeial Reference
No Inns selected			

Pharmacotherapeutic group

No ATC code has been assigned: ☐ [ATC Lookup](#)

ATC Code	ATC Name
No records found.	

Shelf Life (in Months)

Product Type

Pack Size

Container/Closure Type

Storage Conditions/Climate Zone

Physical appearance of the product

Registration number (s) in country of origin and other countries where product is registered

Inactive ingredients

Save

Cancel

Previous

Next



## Active Substance

To add the Active Substance(s), click on “Add.”

Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Evidence of Payment
Checklist

Summary

Additional Info

Is it new chemical entity ☒

New Chemical Entity Name

List the Active Substances

Active Substance	Quantity	Dosage unit	Pharmacopoeial Reference
No Inns selected			

Add

Pharmacotherapeutic group

No ATC code has been assigned: ☐ ATC Lookup

ATC Code	ATC Name
No records found.	

Shelf Life (in Months)

Product Type

Pack Size

Container/Closure Type

Storage Conditions/Climate Zone

Physical appearance of the product

Registration number (s) in country of origin and other countries where product is registered

Inactive ingredients

Save

Cancel

Previous

Next

Begin typing in the INN, and a list will automatically populate based on what you type. Select the correct INN code, and enter in the quantity (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.). Click “Add” once finished and the ATC code will appear.

Applicant Detail Medicine Detail Additional Info Manufacturing Activity Evidence of Payment Checklist

Summary

Additional Info

Is it new chemical entity ☐

New Chemical Entity Name

List the Active Substances

Active Substance	Quantity	Dosage Unit	Pharmacopoeial Reference
No Inns selected			

Pharmacotherapeutic group No ATC code

Shelf Life (in Months)

Product Type

Pack Size

Container/Closure Type

Storage Conditions/Climate Zone

Physical appearance of the product

Registration number (s) in country of origin and other countries where product is registered

Inactive ingredients

Save Cancel Previous Next

Add Active Substances

INN Code

Quantity

Dosage Unit

Pharmacopoeial Reference

Add Cancel

[Applicant Detail](#)
[Medicine Detail](#)
[Additional Info](#)
[Manufacturing Activity](#)
[Evidence of Payment](#)
[Checklist](#)

[Summary](#)

Additional Info

Is it new chemical entity ☒

New Chemical Entity Name

List the Active Substances

Active Substance	Quantity	Dosage Unit	Pharmacopoeial Reference	
esomeprazole	20	mg	USP	<a href="#">Delete</a>

Pharmacotherapeutic group

No ATC code has been assigned: ☐ [ATC Lookup](#)

ATC Code	ATC Name	
A02BC05	esomeprazole	<a href="#">Delete</a>

Shelf Life (in Months)

Product Type

Pack Size

Container/Closure Type

Storage Conditions/Climate Zone

Registration number (s) in country of origin and other countries where product is registered

Inactive ingredients

[Save](#)
[Cancel](#)
[Previous](#)
[Next](#)

## ATC Code

If no ATC code has been assigned, then you can click “ATC Lookup” and search that way. Click “Add” once finished.

Additional Info

Is it new chemical entity ☐

List the Active Substances

No Inns selected

Pharmacotherapeutic group

No ATC code has been assigned: ☐ [ATC Lookup](#)

ATC Code	ATC Name
No records found.	

ATC Lookup

ATC Name: esomeprazole

ATC Code: esomeprazole

Add

esomeprazole, amoxicillin and clarithromycin

Fill in the rest of the information on the page and hit “Next” to continue. At any point, you can click “Save” to save your application, but your application will automatically be saved when you advance to the next page.

Applicant Detail Medicine Detail **Additional Info** Manufacturing Activity Evidence of Payment Checklist

Summary

Additional Info

Is it new chemical entity ☒

New Chemical Entity Name: esomeprazole

List the Active Substances

Active Substance	Quantity	Dosage Unit	Pharmacopoeial Reference	
esomeprazole	20	mg	USP	Delete

Pharmacotherapeutic group

No ATC code has been assigned: ☐ ATC Lookup

ATC Code	ATC Name	
A02BC05	esomeprazole	Delete

Shelf Life (in Months): 24

Product Type: Pharmaceutical

Pack Size: 100

Container/Closure Type: white bottle with safety cap

Storage Conditions/Climate Zone: room temperature

Registration number (s) in country of origin and other countries where product is registered: 12345

Inactive ingredients: colorants

Save Cancel Previous **Next**

## Manufacturing Activity

To add a manufacturer, click “Add” and fill in the information in the required fields. Check the appropriate company type(s) and if a GMP inspection was performed, check the box and enter in the GMP certificate number and date of inspection.

**Note: You need to have at least one Finished Product Manufacturer specified in order to submit the application.**

Applicant Detail Medicine Detail Additional Info **Manufacturing Activity** Evidence of Payment Checklist

Summary

Manufacturing Activity

Application saved successfully

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

**Add**

Applicant Name	Country	Applicant Type	Phone Number:
No records found.			

Save Cancel Previous Next

Manufacturing Activity Details

Applicant Name \*

Address\*

Zip Code

Country\*

Site/Applicant Master File Number

Phone Number: \*

Fax Number:

Company Type \*

☐ API Manufacturer ☐ Finish Product Manufacturer ☐ Primary Packager ☐ Secondary Packager ☐ Finish Product Release Controller ☐ Finish Product Release Responsibility

Is GMP Inspection done? ☐

Add Cancel

Click “Add” when finished, and “Next” to advance to the next page.

**Manufacturing Activity Details**

Applicant Name \* AstraZeneca

Address\* 1800 Concord Place  
PO Box 15437

Zip Code 19850

Country\* United States of America

Site/Applicant Master File Number 12345

Phone Number: \* 3028863000

Fax Number: 123456789

Company Type \* ☒ API Manufacturer ☒ Finish Product Manufacturer ☒ Primary Packager ☒ Secondary Packager ☒ Finish Product Release Controller ☒ Finish Product Release Responsibility

Is GMP Inspection done? ☒

GMP Certificate Number 12345

GMP Inspection Date 8/14/14

**Add** **Cancel**

**Applicant Detail** **Medicine Detail** **Additional Info** **Manufacturing Activity** **Evidence of Payment** **Checklist**

**Summary**

**Manufacturing Activity**

**Company added successfully**

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

Applicant Name	Country	Applicant Type	Phone Number:	
AstraZeneca	United States of America	API Manufacturer	3028863000	<b>Delete</b>
AstraZeneca	United States of America	Finish Product Manufacturer	3028863000	<b>Delete</b>
AstraZeneca	United States of America	Primary Packager	3028863000	<b>Delete</b>
AstraZeneca	United States of America	Secondary Packager	3028863000	<b>Delete</b>
AstraZeneca	United States of America	Finish Product Release Controller	3028863000	<b>Delete</b>
AstraZeneca	United States of America	Finish Product Release Responsibility	3028863000	<b>Delete</b>

**Save** **Cancel** **Previous** **Next**

## Payment Info

On the “Evidence of Payment” page, enter in the receipt number and the dispatch method or waybill number. Hit “Next” when finished.

The first screenshot shows the 'Evidence of Payment' page with the following elements:

- Navigation tabs: Applicant Detail, Medicine Detail, Additional Info, Manufacturing Activity, Evidence of Payment (selected), Checklist.
- Summary tab: Evidence of Payment.
- Form fields: Receipt Number, Dispatch method or Waybill number.
- Buttons: Save, Cancel, Previous, Next (highlighted with a red circle).

The second screenshot shows the same page with the following elements:

- Navigation tabs: Applicant Detail, Medicine Detail, Additional Info, Manufacturing Activity, Evidence of Payment (selected), Checklist.
- Summary tab: Evidence of Payment.
- Form fields: Receipt Number (12345), Dispatch method or Waybill number (12345).
- Buttons: Save, Cancel, Previous, Next (highlighted with a red circle).

On the “Checklist” tab, ensure that all parts of the application are included and check the boxes as appropriate. Click “Next” when finished.



**Applicant Detail** **Medicine Detail** **Additional Info** **Manufacturing Activity** **Evidence of Payment** **Checklist**

**Summary**

Checklist

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

1	Letter of application	Module 1	<input type="checkbox"/>
1.1	Comprehensive table of content (module 1)	Module 1	<input type="checkbox"/>
1.2	Application	Module 1	<input type="checkbox"/>
1.3	Bangladesh labelling and packaging	Module 1	<input type="checkbox"/>
1.4	Information about the experts	Module 1	<input type="checkbox"/>
1.5	Specific requirements for different types of application	Module 1	<input type="checkbox"/>
1.6	Environmental risk assessment	Module 1	<input type="checkbox"/>
1.7	Good manufacturing practice	Module 1	<input type="checkbox"/>
1.8	Foreign regulatory status	Module 1	<input type="checkbox"/>
1.9	Pharmacovigilance plan	Module 1	<input type="checkbox"/>
1.1	Details of compliance with screening outcomes	Module 1	<input type="checkbox"/>
1.11	Bioequivalence trial information	Module 1	<input type="checkbox"/>
1.12	Information on price	Module 1	<input type="checkbox"/>
1.13	Paediatric development program	Module 1	<input type="checkbox"/>
1.14	Risk management plan	Module 1	<input type="checkbox"/>
2.1	CTD Table of contents (Modules 2 to 5)	Module 2	<input type="checkbox"/>
2.2	CTD introduction	Module 2	<input type="checkbox"/>
2.3	Quality overall summary	Module 2	<input type="checkbox"/>
2.4	Nonclinical overview	Module 2	<input type="checkbox"/>
2.5	Clinical overview	Module 2	<input type="checkbox"/>
2.6	Nonclinical written and tabulated summaries	Module 2	<input type="checkbox"/>
2.7	Clinical summary	Module 2	<input type="checkbox"/>

**Save** **Cancel** **Previous** **Next**

Applicant Detail
Medicine Detail
Additional Info
Manufacturing Activity
Evidence of Payment
Checklist

Summary

Checklist

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

1	Letter of application	Module 1	<input checked="" type="checkbox"/>
1.1	Comprehensive table of content (module 1)	Module 1	<input checked="" type="checkbox"/>
1.2	Application	Module 1	<input checked="" type="checkbox"/>
1.3	Bangladesh labelling and packaging	Module 1	<input checked="" type="checkbox"/>
1.4	Information about the experts	Module 1	<input checked="" type="checkbox"/>
1.5	Specific requirements for different types of application	Module 1	<input checked="" type="checkbox"/>
1.6	Environmental risk assessment	Module 1	<input checked="" type="checkbox"/>
1.7	Good manufacturing practice	Module 1	<input checked="" type="checkbox"/>
1.8	Foreign regulatory status	Module 1	<input checked="" type="checkbox"/>
1.9	Pharmacovigilance plan	Module 1	<input checked="" type="checkbox"/>
1.1	Details of compliance with screening outcomes	Module 1	<input checked="" type="checkbox"/>
1.11	Bioequivalence trial information	Module 1	<input checked="" type="checkbox"/>
1.12	Information on price	Module 1	<input checked="" type="checkbox"/>
1.13	Paediatric development program	Module 1	<input checked="" type="checkbox"/>
1.14	Risk management plan	Module 1	<input checked="" type="checkbox"/>
2.1	CTD Table of contents (Modules 2 to 5)	Module 2	<input checked="" type="checkbox"/>
2.2	CTD introduction	Module 2	<input checked="" type="checkbox"/>
2.3	Quality overall summary	Module 2	<input checked="" type="checkbox"/>
2.4	Nonclinical overview	Module 2	<input checked="" type="checkbox"/>
2.5	Clinical overview	Module 2	<input checked="" type="checkbox"/>
2.6	Nonclinical written and tabulated summaries	Module 2	<input checked="" type="checkbox"/>
2.7	Clinical summary	Module 2	<input checked="" type="checkbox"/>

Save
Cancel
Previous
Next

On the “Summary” tab, you can view all of the information you have provided. If you would like to change anything, click “Previous” to go back and make the appropriate changes. When done, go back to the “Summary” tab and hit “Submit.”

**Applicant Detail** **Medicine Detail** **Additional Info** **Manufacturing Activity** **Evidence of Payment** **Checklist**

**Summary**

Summary

▶ Applicant Detail

▶ Person Responsible/Authorized to communicate to the council.

▼ Medicine Detail

Proprietary Name (Brand Name):	Nexium	Product Type:	Allopathy
Generic/Approved Name:	esomeprazole	Application Type:	New Chemical Entity
Dosage Form:	CAPSULE, DELAYED RELEASE	Dosage Strength:	20
Dosage Unit:	mg	Product Category:	Human
Route of administration:	ORAL	Age Group:	Adult
Pharmacological Classification:	67 Proton Pump inhibitor	Product Description and Physical Appearance:	purple pill

▶ List the Active Substances

▶ Pharmacotherapeutic group

▶ Additional Info

▶ Manufacturing Activity

▶ Evidence of Payment

▶ Checklist

Save Cancel Previous **Submit**

You will be directed to a new page and receive a notification that your application has been submitted. To view the acknowledgement letter, you can go to the letters tab below and click on download button.

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

Logged in as MSN | Settings | Logout

Home Registration

**Product Registration Application**

Download

Your application for registration of Nexium is successfully submitted. Please click on the link below to download the acknowledgement letter.

Read  
Exit

Application saved successfully

Application submitted successfully.

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

## 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.

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

Home Registration

Welcome to the Medicine Regulatory Council

Quick Links

- Registered Products
- Registered Applicants
- Register Me
- Logged In User
- Application Status
- Applicant Login
- User Setting
- Links
- About Us
- Guidelines for Registration
- News and Events
- Contact Us

The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, Government of the People's Republic of Bangladesh, is the Drug Regulatory Authority of the country. This DGDA supervises and implements all prevailing Drug Regulations in the country and regulates all activities related to import, procurement of raw and packing materials, production and import of finished drugs, export, sales, pricing, etc. of all kinds of medicines including those of Ayurvedic, Unani, Herbal and Homeopathic systems drugs and medicines.

At present, there are 35 district offices under the DGDA in the country. All the officers of the DGDA function as "Drug Inspector" in pursuant to the Drug Laws and assist the Licensing Authority in discharging his responsibilities properly. Besides, a number of Committees, such as Drug Control Committee (DCC), Standing Committee for imports of raw materials and finished drugs, Pricing Committee and a number of other relevant Committees, which comprise of experts of different fields, are there to advise Licensing Authority and recommend him about the matters related to drugs and medicines.

Registration

- Registered Applicants
- Registered Products
- Registration Forms
- Product Registration Form
- Current Applications
- Submitted Applications
- Saved Applications

**Submitted Applications**

Product Name	Generic Name	Registration Status	Product Category	Date Submitted	Applicant Name
Muzum	esomeprazole	New Application	Human	Aug 13, 2014	SIAPS.Ry

## 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.

Registration

- Registered Applicants
- Registered Products
- Registration Forms
- Product Registration Form
- Current Applications
- Submitted Applications
- Saved Applications

**Saved Applications**

No products found

DRAFT