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# PRODUCT REGISTRATION ONLINE APPLICATION MANUAL

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The Marketing Authorization business process provides for application for product registration in Uganda. The following categories of Medicines are handled under the module:

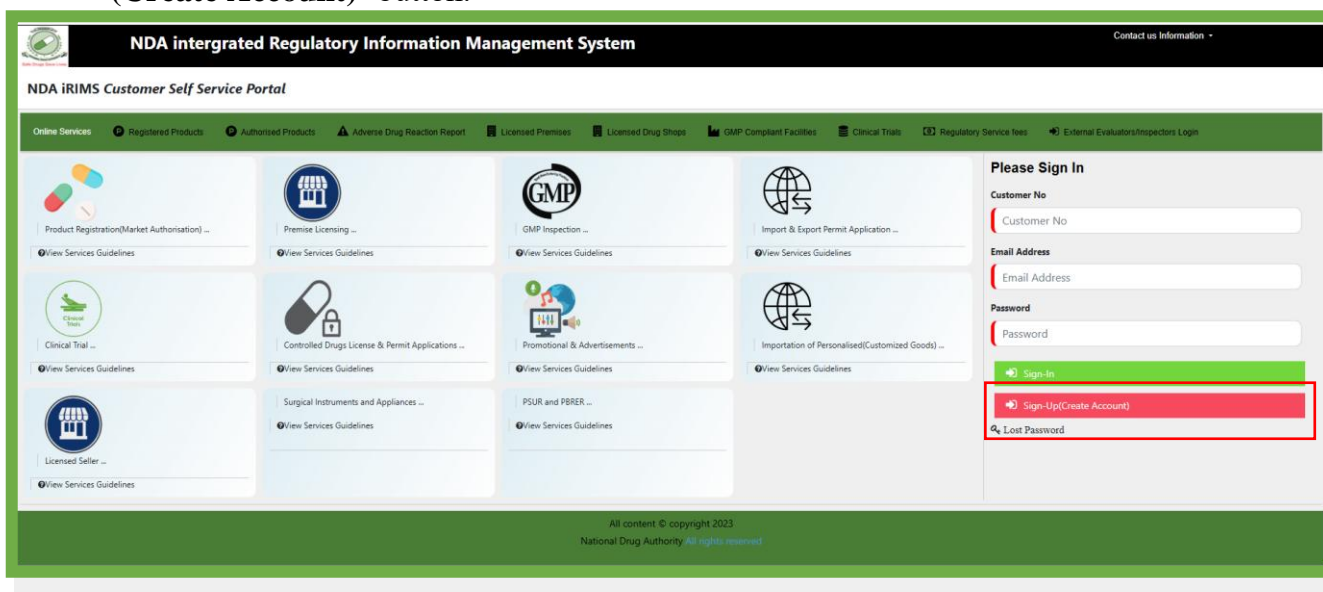
1. Human Medicines
2. Human Herbal Medicines
3. Veterinary Medicines
4. Veterinary Herbal Medicines

**Note:**

- The Required Product Information is distinct from one Product Type to the other and this guideline provides for a general overview of the required process which is uniform.
- Applications are submitted through the Applicant's, and not the LTR Account. An account should therefore be created for the Applicant (Proposed License Holder/Market Authorization Holder).

**A. CREATION OF AN ACCOUNT**

1. Click the link <https://irims.nda.or.ug/portal> to direct you to the NDA Client Portal. This automatically displays the home page. Click the 'Sign- Up (Create Account)' button.



2. A pop-up for entering the applicant details appears. Fill in the necessary information and click 'Create Account'. Please note that the account type should be **Market Authorization Holder**. The Name and Address details captured should be for the proposed MAH of the product.

The image displays two screenshots of a 'Create Account' form. The top screenshot shows the form with a loading spinner and the title 'Account Information'. The bottom screenshot shows the form with a 'Create Account' button highlighted in a red box.

**Create Account**

Account Information

**Account Type**  
Market Authorization Holder (MAH)

**Customer/Company Name**  
Customer Name

**Email Address**  
Email Address

**Choose Your Subscription Module**  
Select the Module

**Country**  
Select Country

**Create Account**

3. NDA customer self-service portal account details will be sent to the captured email address. This includes The Trader Account No, Account Email Address and Account User Password. Sign in to the portal using the account details and complete the Account creation process.

## B. PRODUCT MODULE

After logging in to the NDA Portal, the online services dashboard will be displayed.

1. Look for **PRODUCT REGISTRATION** module and click the **Proceed with Application Link**.

The screenshot shows the 'Explore our Online Services' section of the NDA Portal. The 'PRODUCT REGISTRATION' module is highlighted with a red box. Other modules include Drug Shops Application, Premises Registration, GMP Inspections, Import & Export, Controlled Drugs License(s), Clinical Trials Applications, Promotion & Advertisement, Disposal Application, Surgical Instruments Application, and Account Management. Each module has a 'Proceed with Application' link and a 'View Services Guidelines' link.

2. You will be directed to the **Product Registration Dashboard**.

The screenshot shows the 'Product Registration Dashboard' with the following statistics:

Category	Count
PENDING SUBMISSION	39
INVOICES PENDING PAYMENT	0
QUERIED APPLICATIONS	0
APPROVED APPLICATIONS	0
REJECTED APPLICATIONS	0

Below the statistics, there are filters for 'Application processing' and a table for application details. The table currently shows 'No data'.

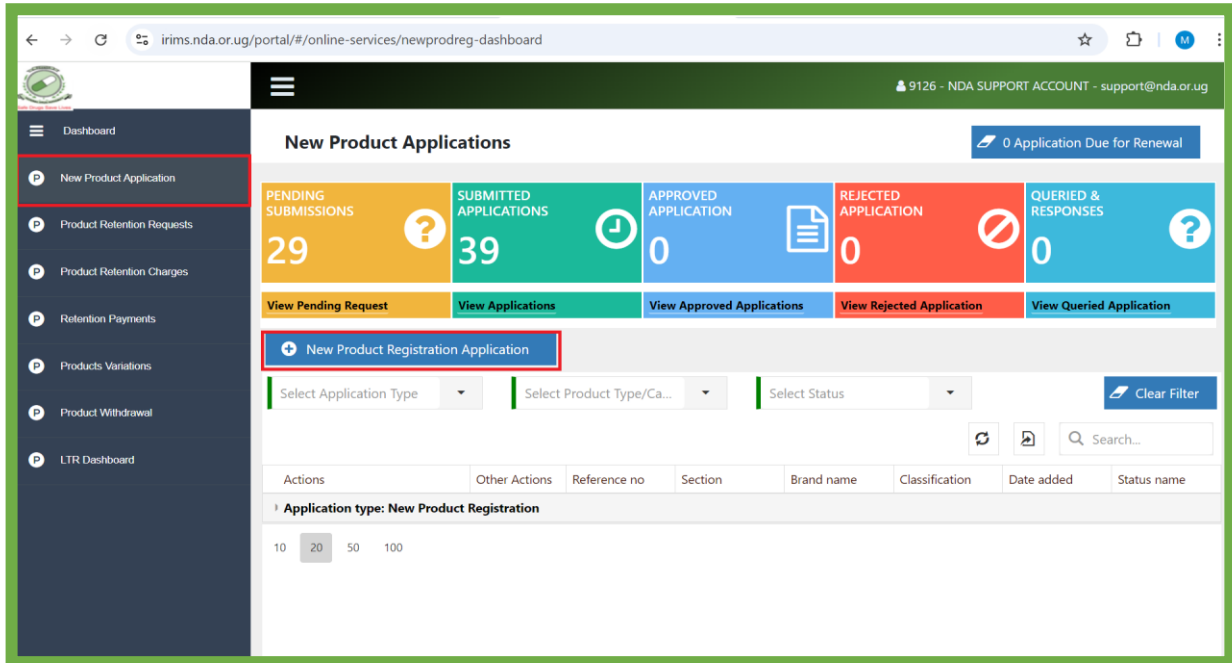
The dashboard provides for the following:

1. Provision to initiate the following applications on the left-hand side menu
  - a. New Product Registration Application for the listed product types
  - b. Submission of Retention Invoices for Products
  - c. Submission of Variation Applications for Products
  - d. Submission of Product Renewal Applications
  - e. Submission of withdrawal Applications for Products
  - f. LTR Dashboard
  
2. Analytics of applications under the different categories, with an option of viewing these applications (including statuses).
  - a. Pending submission
  - b. Invoices pending payment
  - c. Queried application
  - d. Approved applicaions
  - e. Rejected applications
  
3. Execution of actions on the initiated product application, including:
  - a. **Edit:** Provision to continue with already initiated product applications for submission under all the categories and processes
  - b. **Preview:** Preview already submitted product registration applications
  - c. **Query Responses:** Provision to respond to Request for Additional Information
  - d. **Preview Invoice and Payment Details:** Provision to preview and print Proforma invoices and payment confirmations (receipt)
  - e. **Print Options:** Print Product Registration Certificates, letters of rejection, requests for additional information, etc.

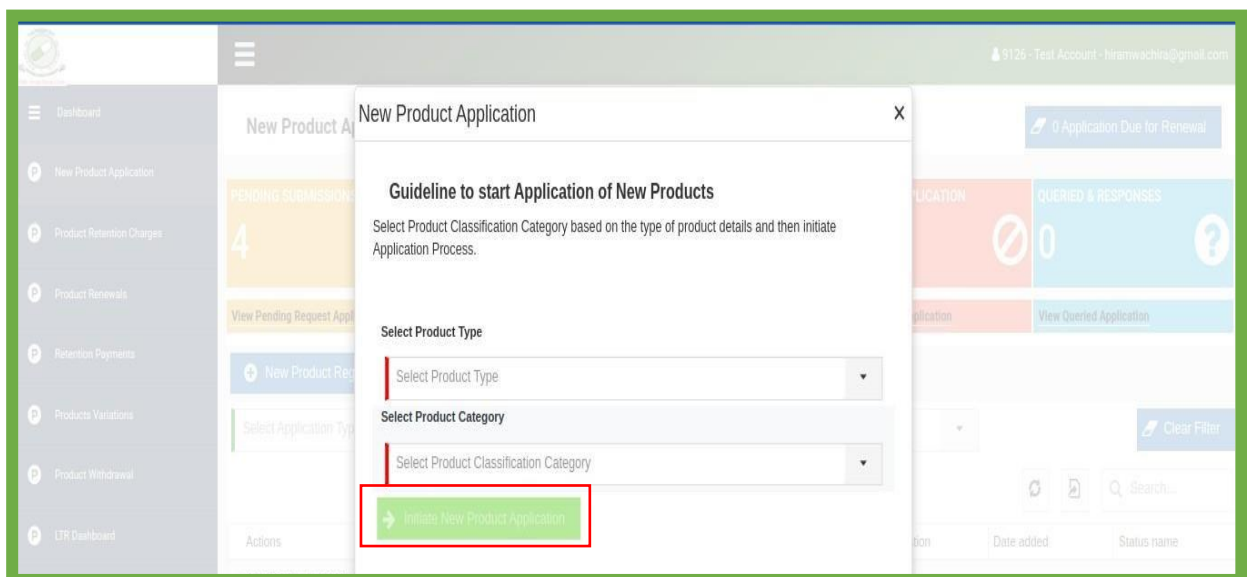
## C. THE PRODUCT REGISTRATION APPLICATION PROCESS.

### 1. Initialization of new product registration application

- a) To initiate an application, click on the ‘**New Product Application**’ on the left-hand side menu to display the New Product Applications dashboard shown below. Then Click the **New Product Registration Application** Button.



- b) This will take you to a pop-up to **select product type and category** and **initiate a new product registration application**.



## 2. The Application Process

This involves taking the application through steps 1 up to 6.

### Step 1: Product Application Details

Fill in the Product Application Details after which you **save** and proceed to the next step. Take note of the generated tracking number.

The screenshot displays a web-based application form for 'Product Application Details'. At the top, there is a progress bar with seven steps: Step 1 (Product Application Details), Step 2 (Product Composition), Step 3 (Quality Overall Summary Dossier), Step 4 (Bioequivalence Trial Information), Step 5 (Dossier Documents Submission), Step 6 (Product Mock-Ups/Labels/Art work), and Submission. The 'Application Status' is shown as 'New'. The form is divided into several sections: 'Medicine Type' (Human Medicines), 'Certification Status' (Select Certification Status), 'Product Type' (Select Product Type), 'Therapeutic Group' (Select Therapeutic Group), 'Distribution Category' (Strength Distribution Category), 'Proposed shelf life (in months)' (shelf\_life), 'Product Manufacturing Country' (Product Manufacturing Country), 'Indications' (Enter Indications), 'Product Physical Appearance e.g Color' (Physical description), and 'Local Technical Representative' (NDA SUPPORT ACCOUNT). The 'Classification' section includes 'Select Classification', 'Product Class Category', 'Product Category', 'ATC Code', 'Select ATC Code', 'Dosage Form', and 'Strength Dosage Form'. The 'Assessment Type' section includes 'Select Assessment Types', 'Proprietary Name', 'Enter Proprietary Name', 'ATC Description', 'Route Of Administration', 'Route of Administrations...', 'Proposed storage conditions after first opening(°C)', 'Proposed storage conditions after first opening(°C)', 'Proposed shelf life (after reconstitution or dilution months)', and 'shelf\_life'. A 'Dashboard' button is located at the bottom left, and a 'Save product Application & Next Step' button is highlighted with a red box at the bottom right.

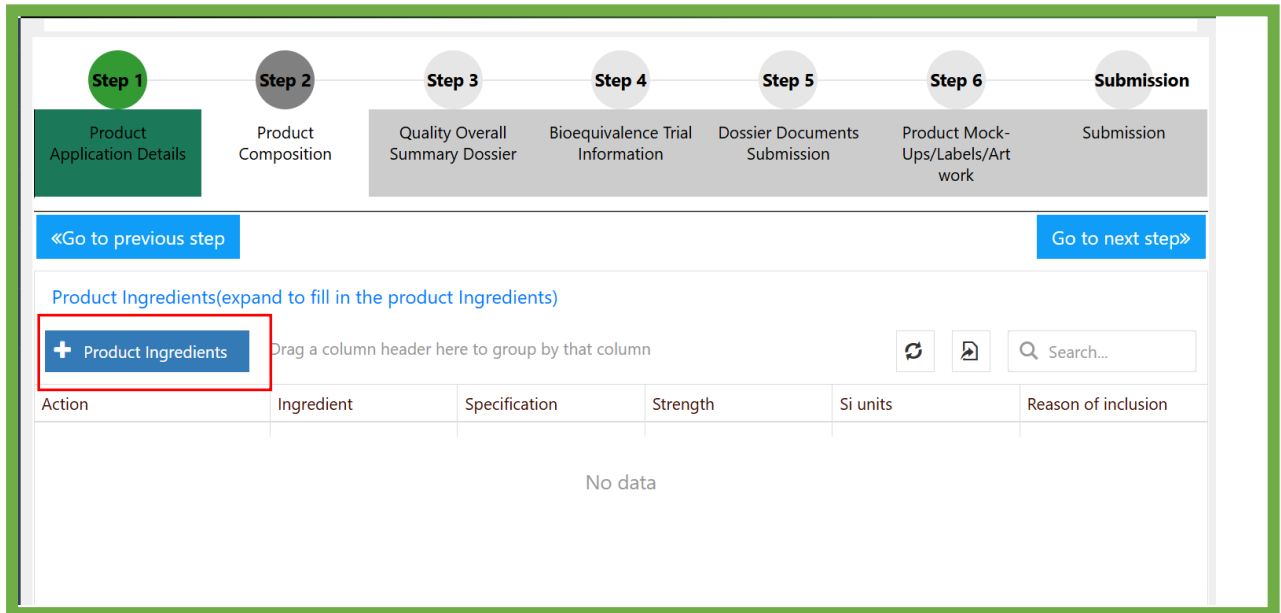
### Step 2: Product Composition Details

This includes the following information:

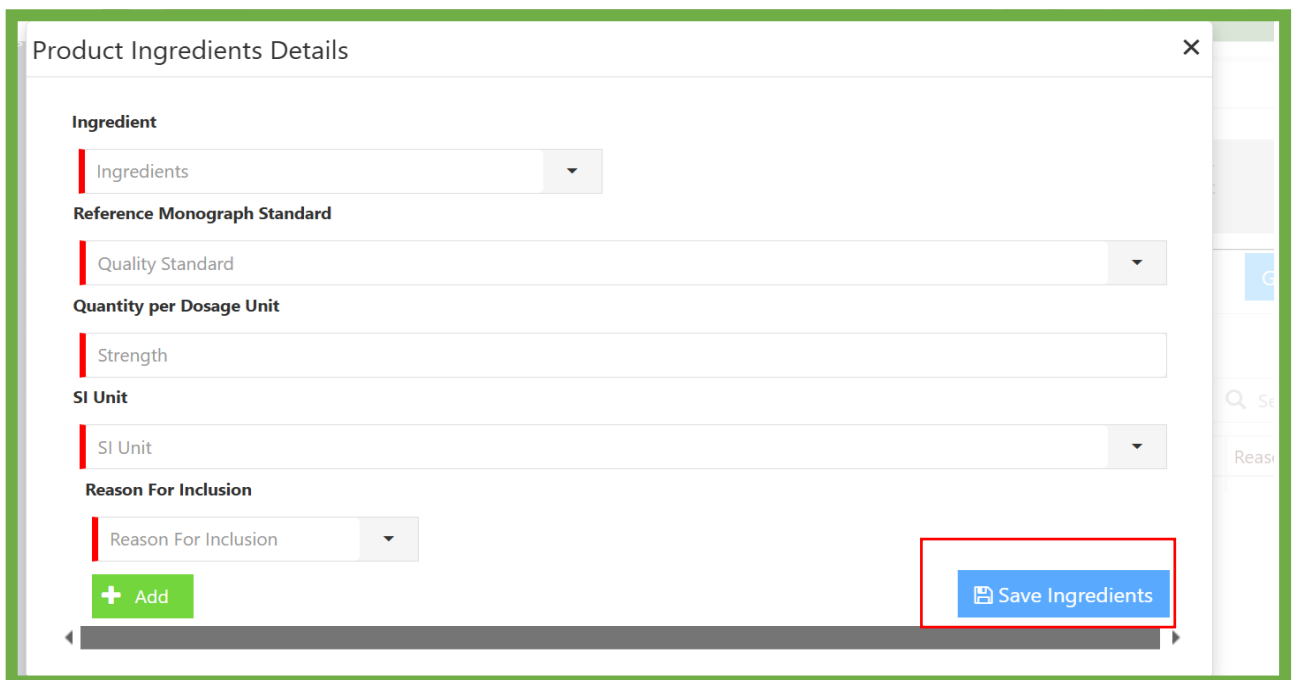
- Product Ingredients
- Finished Product Manufacturer
- Active Pharmaceutical Product Manufacturer
- Inspection status in other Countries/States (Optional)
- Product registration in other countries (Optional)
- Packaging information

**a) Product Ingredients**

i. To include product ingredients, click the + **Product Ingredients** Button.



ii. Upon clicking the Product Ingredients button, a pop-up for entering the product details appears. Fill in the required information and **Save** the information. To add another ingredient, click the **Product Ingredients** Button and repeat the procedure.

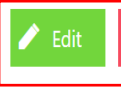
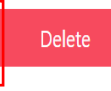

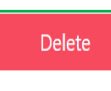


iii. After entering all ingredients, a table that contains all ingredients is displayed. Confirm if the captured information is correct. To change details of a particular ingredient, click the **Edit** button. Click the **Delete** button if an ingredient was erroneously entered.

Product Ingredients(expand to fill in the product Ingredients)

+ Product Ingredients Drag a column header here to group by that column

Refresh Print Search...

Action	Ingredient	Specification	Strength	Si units	Reason of inclusion
 Edit  Delete	Amoxicillin	In-house monograph	500	MG	Active
 Edit  Delete	Magnesium stearate	National Formulary	2000	MG	Lubricant

***b) Finished Product Manufacturer(s).***

i. To include Finished Product Manufacturer(s), click the + **Product Manufacturers** Button.

Finished Product Manufacturers(expand to fill in the finished manufacturers)

+ Product Manufacturers Drag a column header here to group by that column

Refresh Print Search...

Action	Manufacturing site Number	GMP Certificate number	Manufacturing Site Name	Physical address	Country	Manufacturing role	Product line	Product line category	Gmp status
No data									

ii. Upon clicking the **Product Manufacturers** button, a pop-up for entering the Manufacturing Site details appears. Click the **search** button.

Product Manufacturing Sites

Manufacturing Site Name

Physical Address

Search

iii. Another pop-up appears that contains sites already inspected by NDA and those for which applications for GMP inspection have been submitted. If the Manufacturing Site falls within the above listed categories, **search** and **select** the required site. For new Sites, click the + **Manufacturers** button.

Manufacturer(s) Information

Drag a column header here to group by that column

+ Manufacturers

Search...

Action	Gmp certificate no	Manufactu... name	Country name	Region name	Physical address	Postal address	Email address	Product linedetails	Registration status
Select Manufact...			UGANDA						Approved
Select Manufact...	NDA/GMP/...		UGANDA						Approved
Select Manufact...	NDA/GMP /...		INDIA						Approved
Select Manufact...	NDA/GMP/...		INDIA						Approved
Select Manufact...	NDA/GMP /...		SOUTH AFRI...						Approved

Page #1. Total: 32 (1555 items) 1 2 3 4 5 ... 32

iv. After clicking the + **Manufacturers** button, a pop-up for entering the New manufacturing site details appears. Fill in the required information and click **save Manufacturer**.

New Manufacturer

Manufacturer Name

Country

Region/City

+ Add Region

District(Optional)

+ Add

Email Address

Postal Address

Physical Address

Telephone No

Mobile No

+ Save Manufacturer

v. Upon Selecting the required site or Saving Manufacturer, the manufacturing site name and physical address auto populate. You will then fill the remaining information and click **save Product Manufacturer**.

Product Manufacturing Sites

Manufacturing Site Name Q Search

Physical Address

Manufacturing Scope

Other Manufacturing Activities

Has the Manufacturing Site been Inspected/Submitted Request for Inspection to the NDA

Select...

**Save Product Manufacturer**

vi. To add another Manufacturing site, click the + **Product Manufacturers** Button and repeat the procedure. After entering all Product manufacturers, a table that contains all captured manufacturers is displayed. Confirm if the captured information is correct. Click the **Delete** button if a manufacturer was erroneously entered.

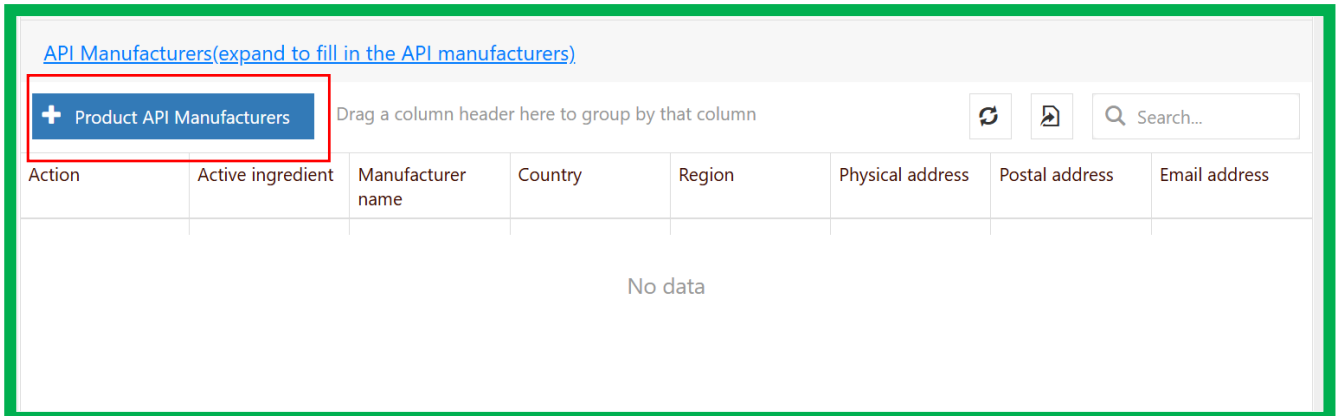
Drag a column header here to group by that column

Refresh Print Search...

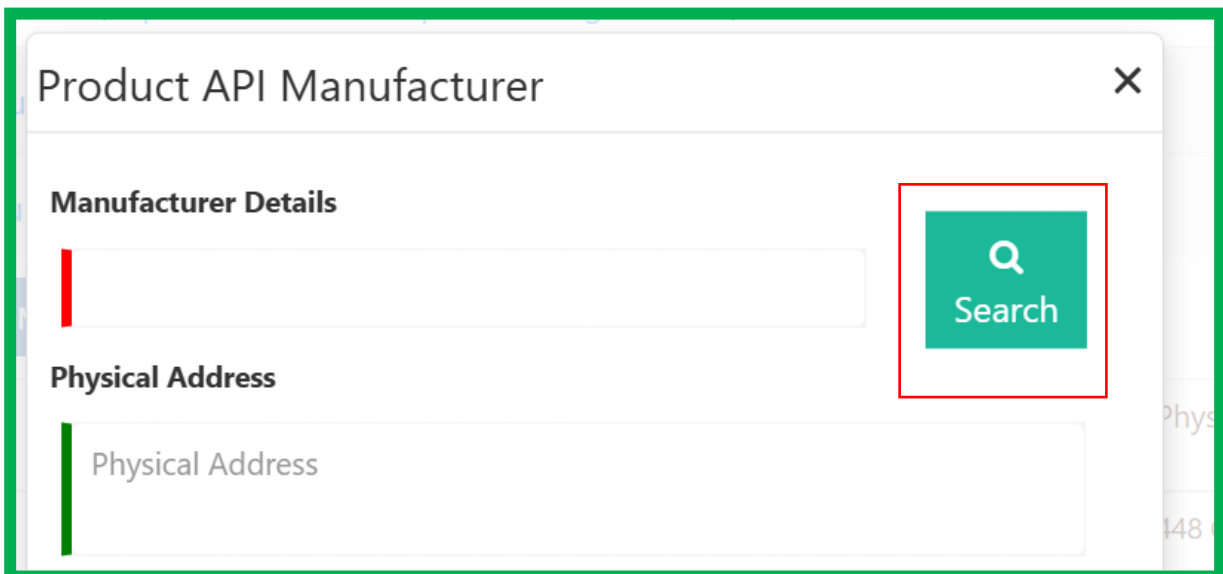
Action	Manufacturing site Number	GMP Certificate number	Manufacturing Site Name	Physical address	Country	Manufacturing role	Product line	Product line category	Gmp status
<b>Delete</b>		MGR-24/Ne...	BDR Pharma...	R.S. No. 578,...	INDIA	Complete M...	Tablets	Cytotoxic	Approved

c) **API Manufacturers**

i. To include API Manufacturer(s), click the + **Product API Manufacturers** Button.



ii. Upon clicking the + **Product API Manufacturers** button, a pop-up for entering the Manufacturing Site details appears. Click the **search** button.



iii. Another pop-up appears that contains sites already in the Database. **Search** and **select** the required site. For Sites not in the system, click the + **Manufacturing Site** button.

Manufacturing Information

+ Manufacturing Site

Drag a column header here to group by that column

Search...

Action	Manufacturer name	Country name	Region name	Physical address	Postal address	Email address
Select Manufac		UGANDA				
Select Manufac		UGANDA				
Select Manufac		INDIA				
Select Manufac		INDIA				
Select Manufac		SOUTH AFRICA				
Select Manufac		SOUTH AFRICA				

Page #1. Total: 32 (1554 items)

1 2 3 4 5 ... 32

iv. After clicking the + **Manufacturing Site** button, a pop-up for entering the New manufacturing site details appears. Fill in the required information and click **save Manufacturing Site**.

New Manufacturing Sites

Manufacturing Site

Country

Region/City

+ Add Region

District(Optional)

+ Add

Email Address

Postal Address

Telephone No

Mobile No

Physical Address

TIN No

Contact Person

Save Manufacturing Site

v. Upon Selecting the required site or Saving Manufacturing Site, the manufacturing site name and physical address auto populate. You will then select the Active Ingredient from the drop-down and click **save API Manufacturer**.

### Product API Manufacturer ✕

**Manufacturer Details**

🔍
Search

**Physical Address**

Physical Address

**Active Pharmaceutical Ingredients**

Select Active Pharmaceutical Ingredients
▼

👤 Save API Manufacturer

ions In other States/Countries(Optional)

vi. To add another API Manufacturing site, click the + **Product API Manufacturers** Button and repeat the procedure. After entering all Product manufacturers, a table that contains all captured manufacturers is displayed. Confirm if the captured information is correct. Click the **Delete** button if a manufacturer was erroneously entered.

API Manufacturers(expand to fill in the API manufacturers)

+ Product API Manufacturers

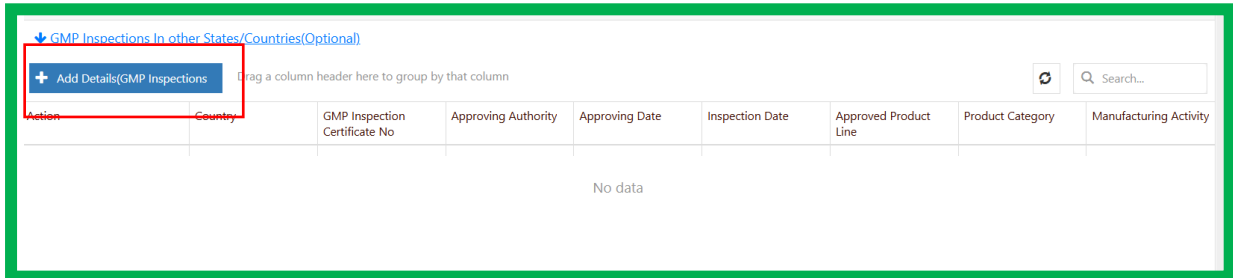
Drag a column header here to group by that column

↻
📄
🔍 Search...

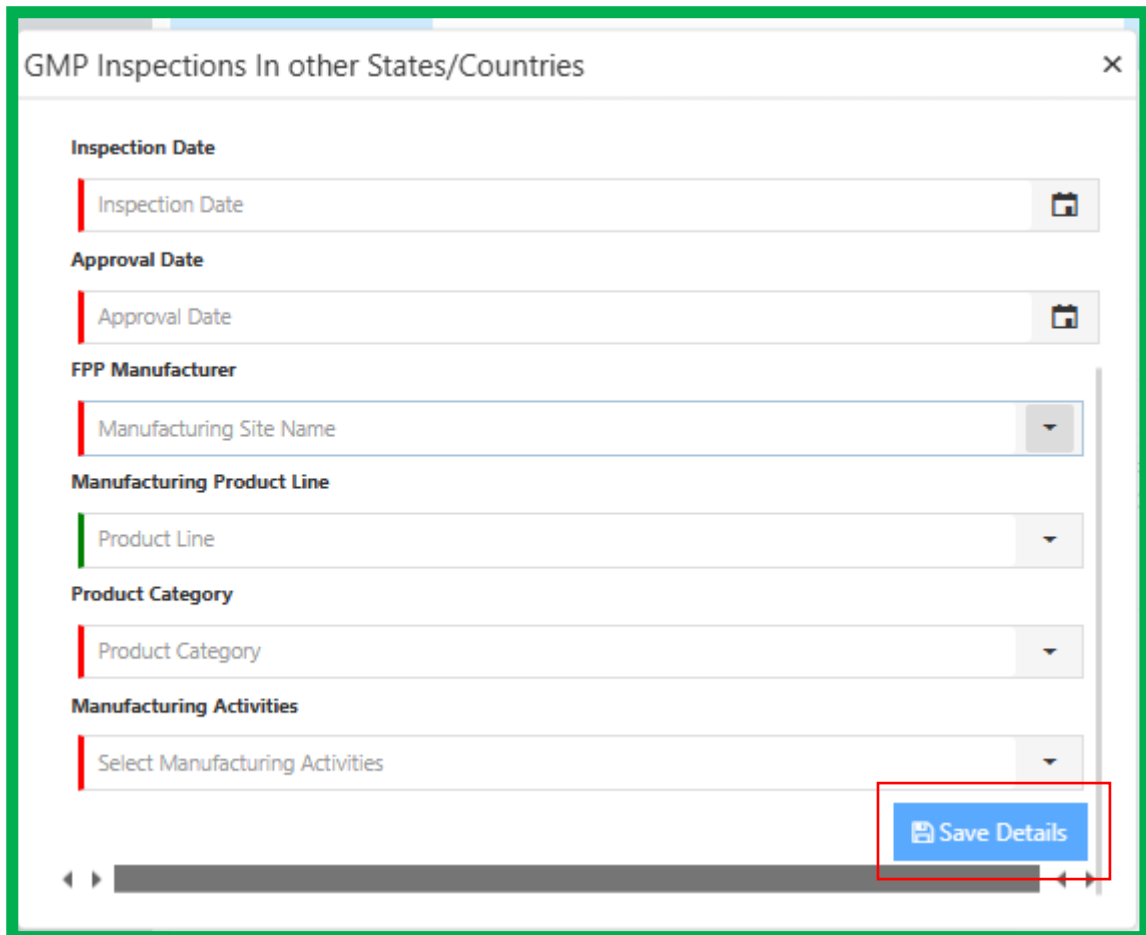
Action	Active ingredient	Manufacturer name	Country	Region	Physical address	Postal address	Email address
<div style="border: 2px solid red; padding: 2px; background-color: #dc3545; color: white; padding: 5px 10px; border-radius: 5px; display: inline-block;">Delete</div>	Amoxicillin	S [redacted] ...	C [redacted]		[redacted]	S [redacted]	

***d) GMP Inspections in other states/Countries (Optional)***

**i.** Click the ‘+ Add Details (GMP Inspections)’ Button.



**ii.** After capturing all required information, **save** details. Click **Add Details (GMP Inspections)**’ Button to add more countries where the FPP Manufacturer has been inspected.



e) **Product Registration (Market Authorization) status in other states/Countries(optional)**

i. Click the '+ **Product Registration**' Button.

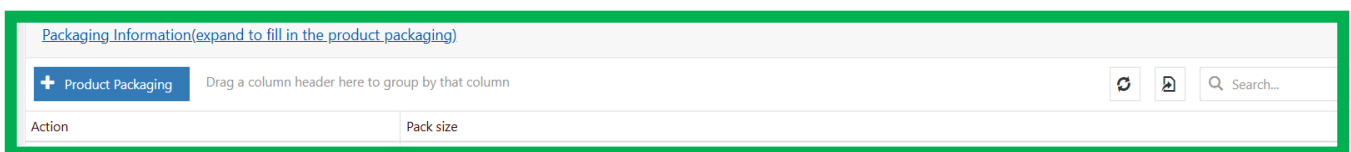


ii. After capturing all required information, **save details**. Click **Product Registration**' Button to add more countries where the product has been registered.



f) **Packing information**

i. To capture packaging information, click the + **Product Packaging** Button.



ii. A pop-up reading 'Packaging details' appears. Fill in the required information and **save** details at every step, starting from step 1 (Primary packaging). Please take note of the following;

- *Not all steps must be filled; Only fill steps applicable for the intended pack*
- *For combination products (including those with diluents), the section of Diluents must be filled. This section is also applicable to applicators or any medical devices packed separately from the formulation.*

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(ii) (Optional) Diluents (Optional)

Pack Type  
Pack Type

Pack Material  
Container Materials

Description of the packaging

>Next Save Packaging Details

*A product pack that has 3 blisters each containing 10 capsules (1x3x10 capsule blister) is written as below;*

Primary Packaging

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(ii) (Optional) Diluents (Optional)

Pack Type  
Blister

Pack Material  
Alu/pvc

Quantity/Volume Per  
10

Unit of Quantity/Volume  
CAPSULE

Description of the packaging  
Alu/PVC Blister contains 10 capsules

>Next Save Packaging Details

## Secondary Packaging

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(i) (Optional) Diluents (Optional)

Pack Type  
Carton

Pack Material  
Paper

No of Units in Pack  
3

Description of the packaging  
A carton contains 3 blisters

<previous >Next

Save Packaging Details

## Tertiary Packaging

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(i) (Optional) Diluents (Optional)

Pack Type  
Pack

Pack Material  
Paper

No of Units in Pack  
1

Description of the packaging  
Describing contents of one pack

<previous >Next

Save Packaging Details

A Product pack that has 10 trays, each containing 10 ampoules of 2ml (1X10X10X2ml Ampoule) is captured as below;

### Primary Packaging

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(ii) (Optional) Diluents (Optional)

Pack Type  
Ampoule

Pack Material  
Type I Amber Glass

Quantity/Volume Per  
2

Unit of Quantity/Volume  
ML

Description of the packaging  
An Ampoule of 2ml

»Next

Save Packaging Details

### Secondary Packaging

Packaging Details

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6

Primary Packaging Secondary Packaging Tertiary Packaging (Optional) Others(i) (Optional) Others(ii) (Optional) Diluents (Optional)

Pack Type  
Tray

Pack Material  
Plastic

No of Units in Pack  
10

Description of the packaging  
10 Ampoules are in a Tray

«previous »Next

Save Packaging Details

## Tertiary Packaging

The image displays two screenshots of the 'Packaging Details' form, illustrating the progression through the steps.

**Top Screenshot (Step 3 Selected):**

- Progress bar: Step 1 (Primary Packaging), Step 2 (Secondary Packaging), Step 3 (Tertiary Packaging (Optional)), Step 4 (Others(i) (Optional)), Step 5 (Others(ii) (Optional)), Step 6 (Diluents (Optional)).
- Form fields:
  - Pack Type: Carton
  - Pack Material: Paper
  - No of Units in Pack: 10
  - Description of the packaging: A carton contains 10 Trays
- Buttons: «previous, »Next, Save Packaging Details (highlighted in red).

**Bottom Screenshot (Step 4 Selected):**

- Progress bar: Step 1 (Primary Packaging), Step 2 (Secondary Packaging), Step 3 (Tertiary Packaging (Optional)), Step 4 (Others(i) (Optional)), Step 5 (Others(ii) (Optional)), Step 6 (Diluents (Optional)).
- Form fields:
  - Pack Type: Pack
  - Pack Material: Paper
  - No of Units in Pack: 1
  - Description of the packaging: Describing contents of one pack
- Buttons: «previous, »Next, Save Packaging Details (highlighted in red).

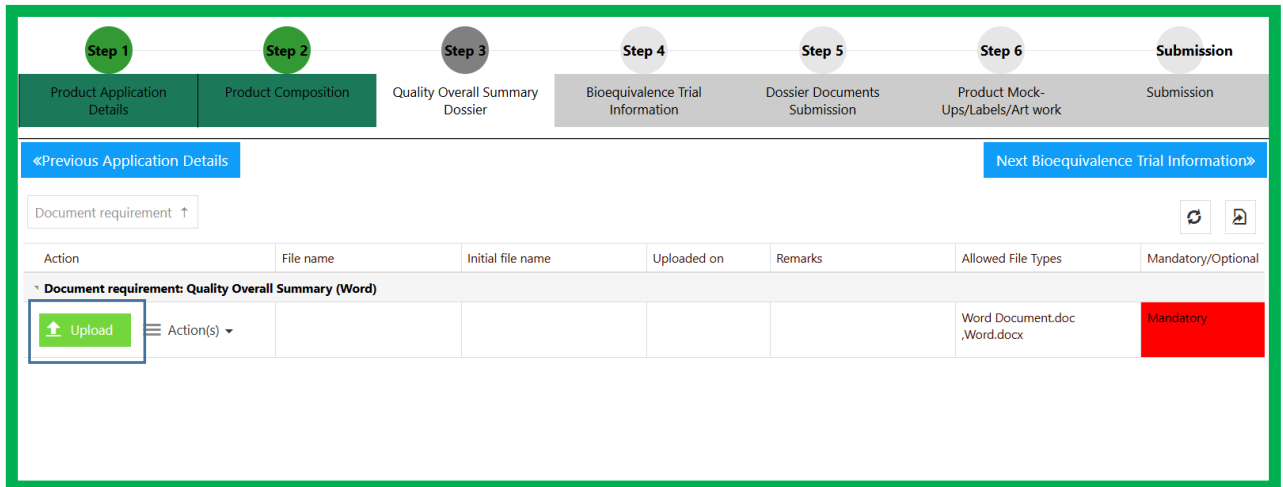
- iii. After entering all pack sizes, a table that contains the captured pack sizes is displayed. Confirm if the captured information is correct. Click the **Delete** or **Edit** buttons to update information captured. Click the **‘Go to next step’** button to proceed

Action	Pack size
<a href="#">Edit</a> <a href="#">Delete</a> <a href="#">View Details</a>	1x10x10x2ML Ampoule

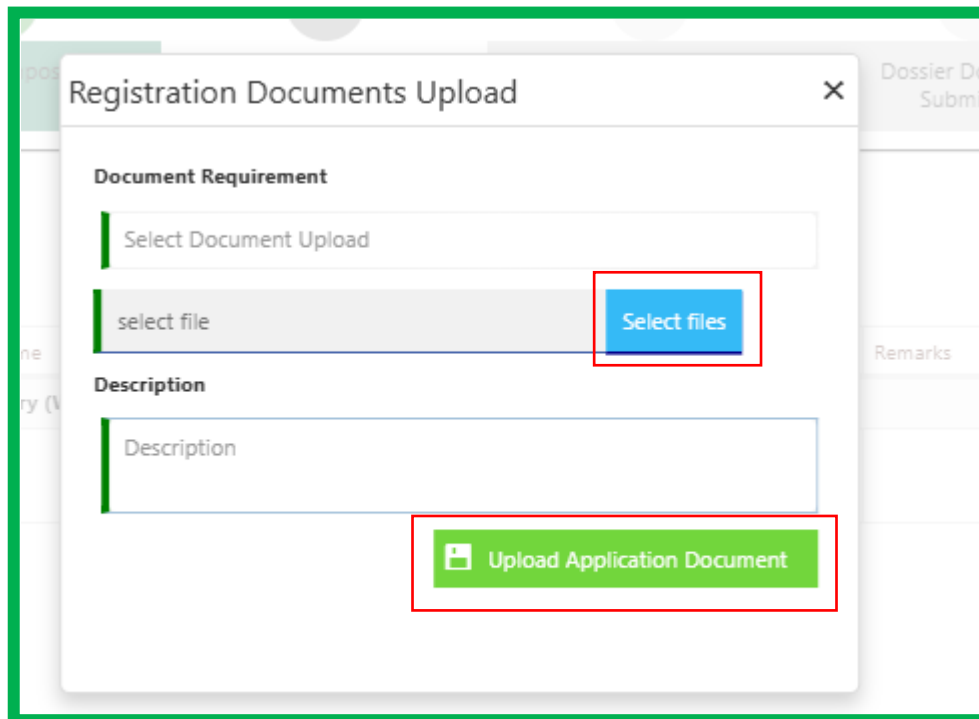
Buttons: «Go to previous step, Go to next step» (highlighted in red)

### Step 3: Quality Overall Summary Dossier.

a) To Upload the Quality Overall Summary(word), Click the ‘**Upload**’ button (green)



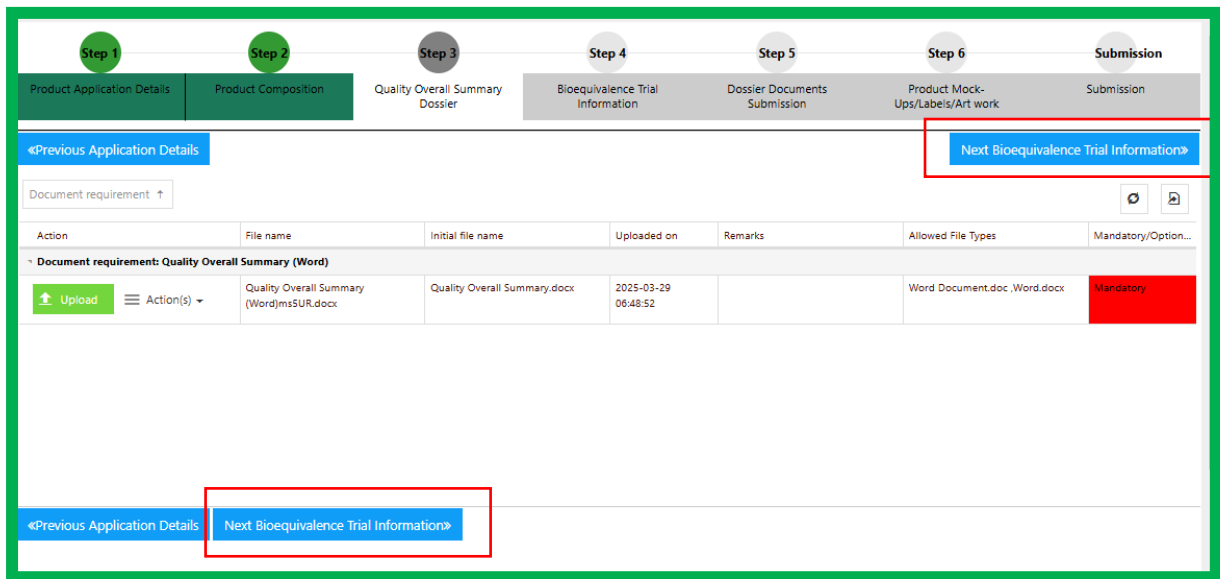
b) select the file you would like to upload then click ‘**Upload Application Document**’



c) To preview or delete the uploaded document, click the **Action(s)** button then the **Preview or Delete** options (respectively).

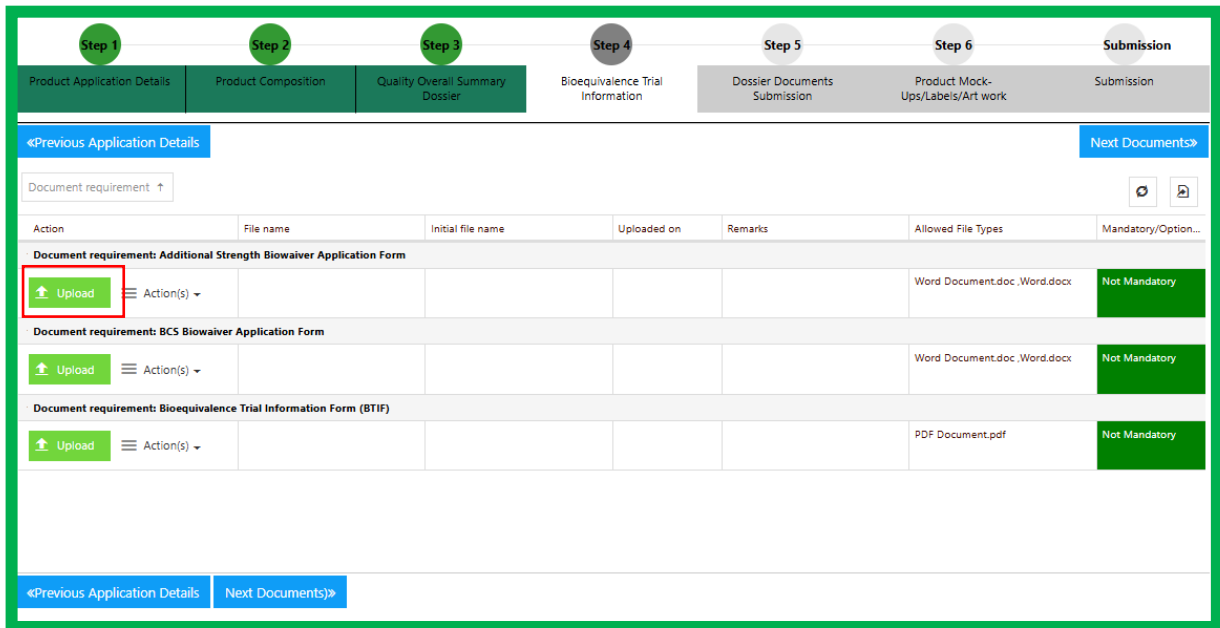


d) Click the ‘Next Bioequivalence Trial Information’ button to proceed.

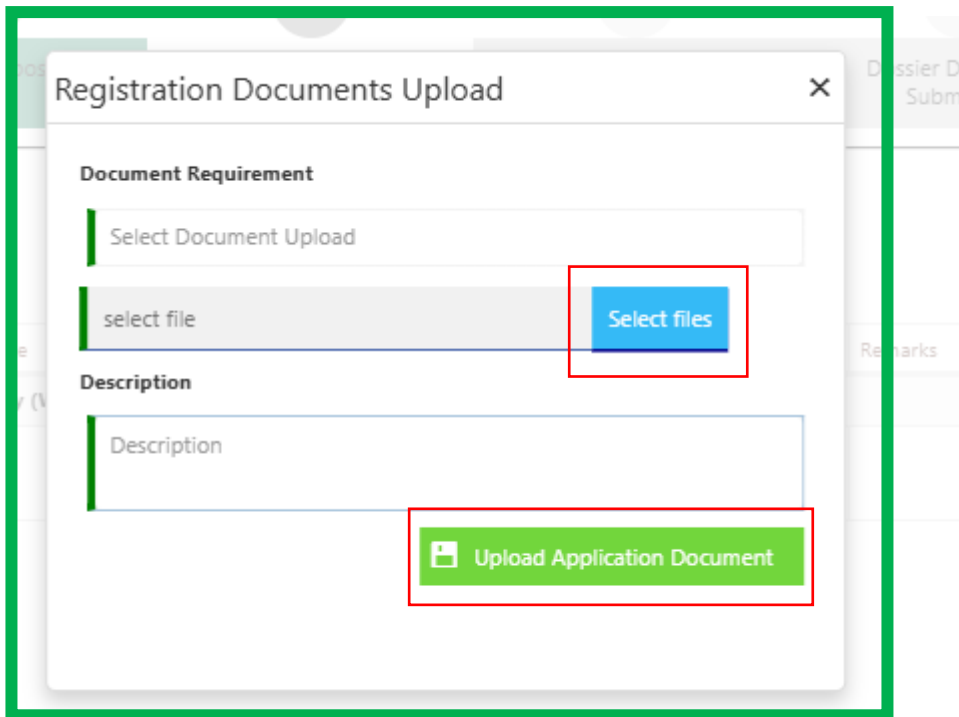


#### Step 4: Bioequivalence Trial Information (Safety and Efficacy)

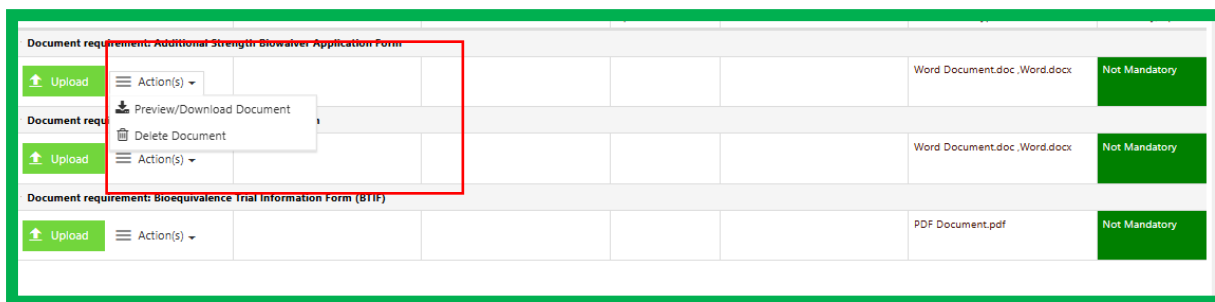
a) To upload documents, click the ‘upload’ button beneath the required document type (depending on the type of product for which the application is being submitted). If this section is not applicable to the type of application, click the ‘Next Documents’ button.



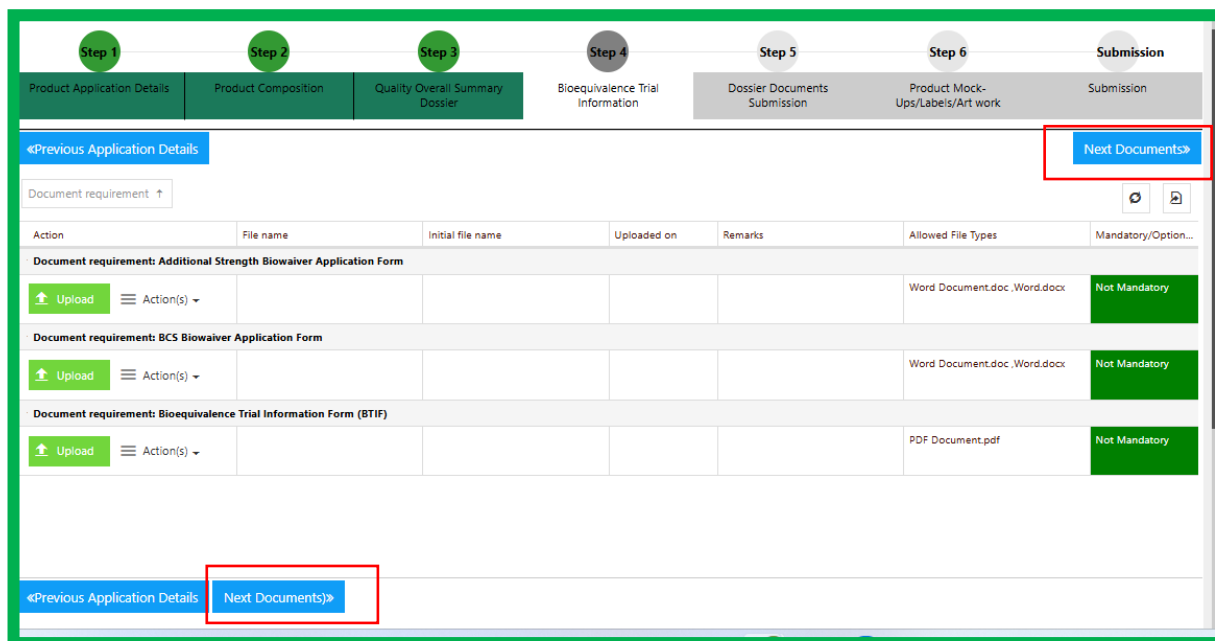
b) **Select** the file you would like to upload then click **'Upload Application Document'**



c) To preview or delete the uploaded document, click the **Action(s)** button then the **Preview or Delete** options (respectively).



d) Click the 'Next Documents' button to proceed.



### Step 5: Dossier Documents Submission.

In this section, you are required to upload documents as per sections in the Dossier (in CTD format). The names of the documents, allowed file types and Necessity (Mandatory or optional) have been specified. Please note that the requirement to submit a particular document is highly dependent on the type of product being applied for. For example, whereas it is mandatory for Oral Solid formulations to upload information related to excipients, this requirement is optional for some formulations of Dry powders for Injection. This particular section has been optional (to cater for the Dry Powders for Injections) much as it is a mandatory requirement for the Oral Solid formulations.

Step 1 Step 2 Step 3 Step 4 Step 5 Step 6 Submission

Product Application Details Product Composition Quality Overall Summary Dossier Bioequivalence Trial Information Dossier Documents Submission Product Mock-Ups/Labels/Art work Submission

«Previous Application Details Next Product Label(S)»

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option.
Document requirement: Document 1. Application Form					PDF Document.pdf	Mandatory
Document requirement: Document 2. A Notarized Power of Attorney					PDF Document.pdf	Not Mandatory
Document requirement: MODULE 1 Section 1.2 Cover letter					PDF Document.pdf	Mandatory
Document requirement: MODULE 1 Section 1.4 Quality Information Summary (QIS-PD)					PDF Document.pdf	Mandatory
Document requirement: MODULE 1 Section 1.4 Quality Information Summary (QIS-WORD)					Word Document.doc, .Word.docx	Mandatory

a) To upload a particular document, click the **‘Upload’** button beneath the desired document name

Document requirement: Document 1. Application Form

Upload Action(s) ↓ PDF Document.pdf Mandatory

b) **Select** the file to be uploaded then click **‘Upload Application Document’**.

Registration Documents Upload

Document Requirement

Select Document Upload

select file Select files

Description

Description

Upload Application Document

- c) To preview or delete the uploaded document, click the ‘**Action(s)**’ button **then** the ‘**Preview**’ or ‘**Delete**’ options (respectively).

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option...
<b>Document requirement: Document 1. Application Form</b>						
Upload <b>Action(s)</b> ▾ Preview/Download Document Delete Document					PDF Document.pdf	Mandatory
<b>Document requirement: Document 2. A Notarized Power of Attorney</b>						
Upload					PDF Document.pdf	Not Mandatory

- d) After uploading the required documents, Click the ‘**Next product Label(s)**’ to proceed. This is located at the upper right corner or lower left corner of this page.

Tracking No: 24/HM/007      Application Status: Draft Application(New Application Pending Submission)

Step 1: Product Application Details    Step 2: Product Composition    Step 3: Quality Overall Summary Dossier    Step 4: Bioequivalence Trial Information    Step 5: Dossier Documents Submission    Step 6: Product Mock-Ups/Labels/Art work    Submission

Document requirement: Document 1. Application Form

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option...
Upload <b>Action(s)</b> ▾					PDF Document.pdf	Mandatory

Document requirement: Document 2. A Notarized Power of Attorney

Document requirement: Module 5 Section 5.3.6 Reports of Postmarketing Experience

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option...
Upload <b>Action(s)</b> ▾					PDF Document.pdf	Not Mandatory

Document requirement: Module 5 Section 5.3.7 Case Report Forms and Individual Patient Listings

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option...
Upload <b>Action(s)</b> ▾					PDF Document.pdf	Not Mandatory

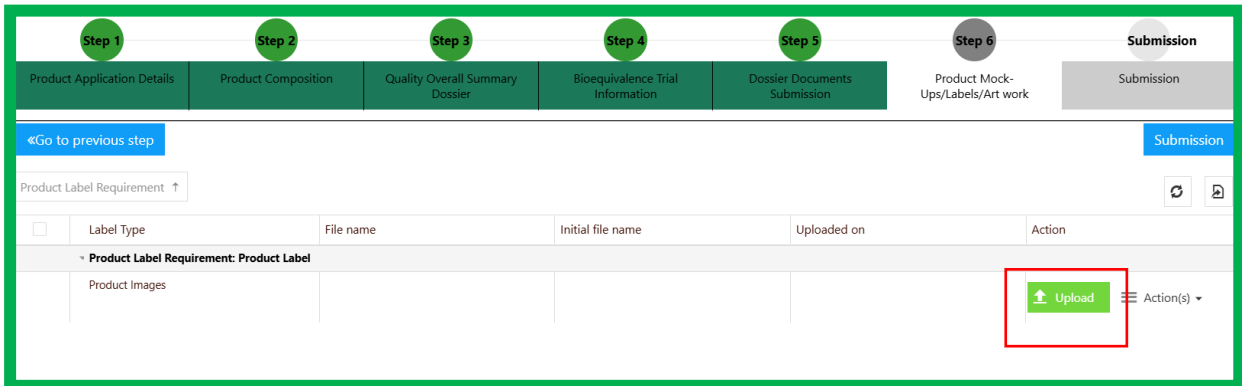
Document requirement: Module 5 Section 5.4 Literature References

Action	File name	Initial file name	Uploaded on	Remarks	Allowed File Types	Mandatory/Option...
Upload <b>Action(s)</b> ▾					PDF Document.pdf	Not Mandatory

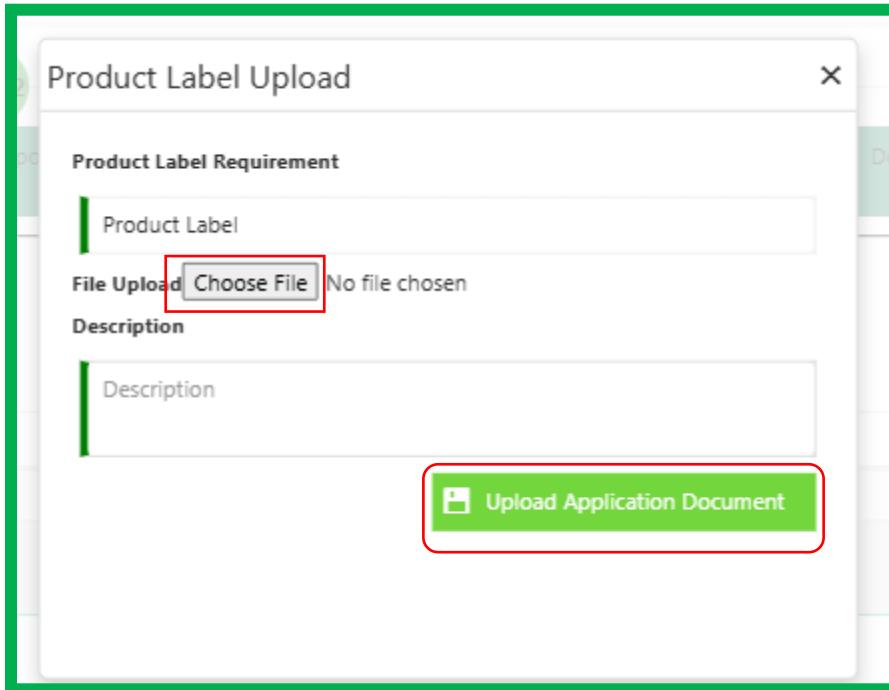
Navigation: <<Previous Application Details    **Next Product Label(S)>>**

## Step 6: Product Mockups/labels/Artwork

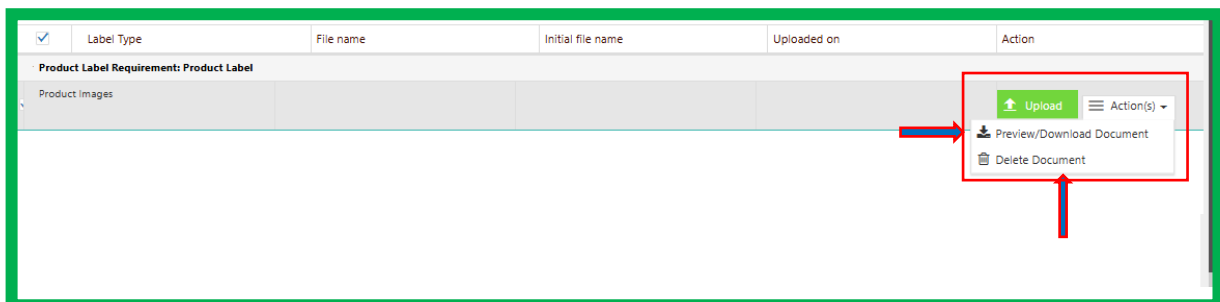
a) To upload pictures of the sample, click the 'Upload' button



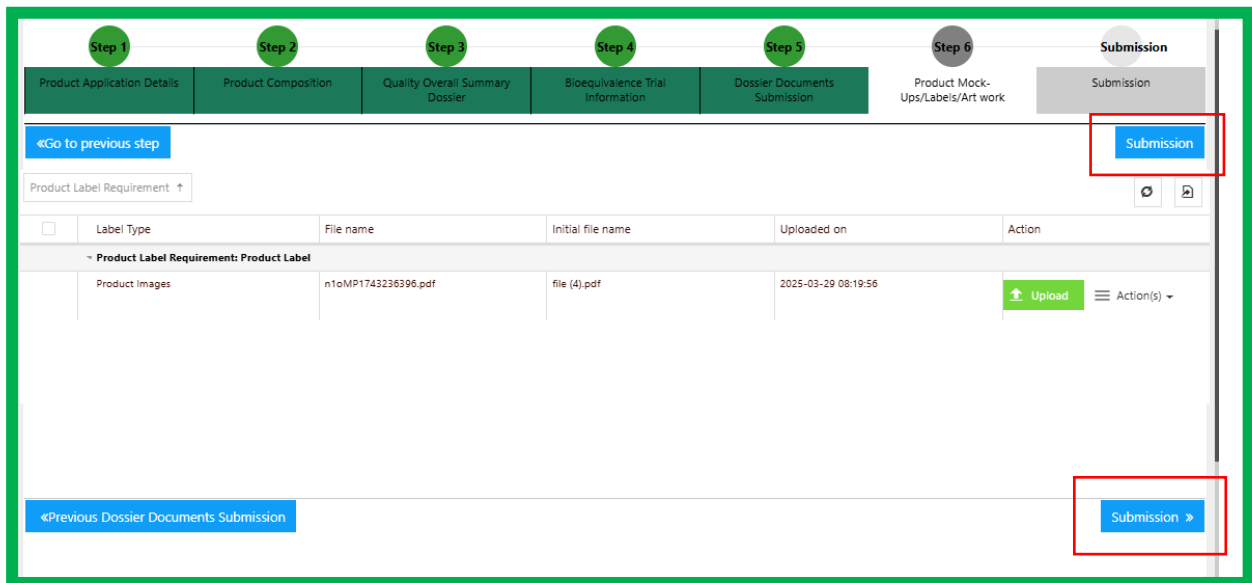
b) choose the file to be uploaded then click 'Upload Application Document'.



c) To preview or delete the uploaded document, click the 'Action(s)' button then the 'Preview' or 'Delete' options (respectively).



d) After uploading the required documents, Click the ‘**submission**’ button to proceed. This is located at the upper or lower right corner of this page.

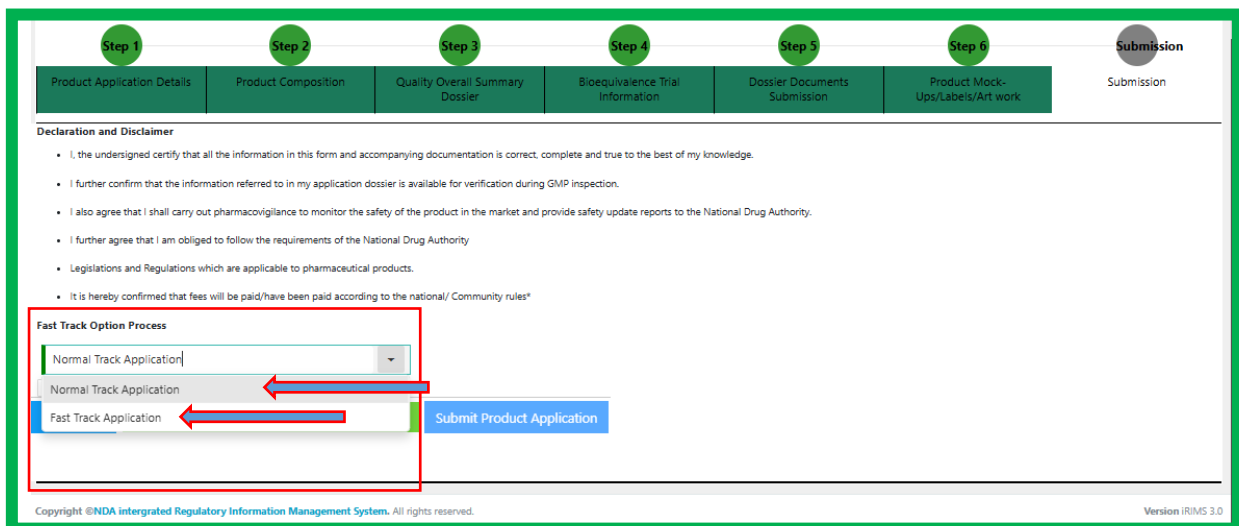


### 3. Submission

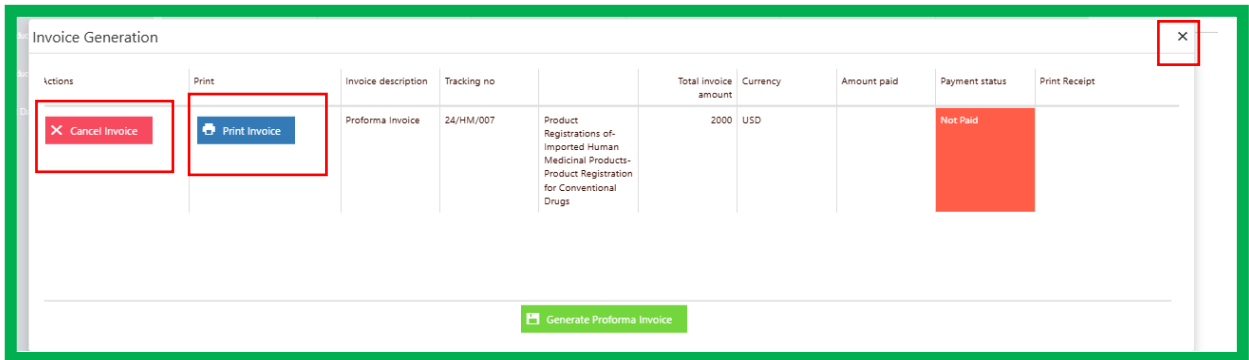
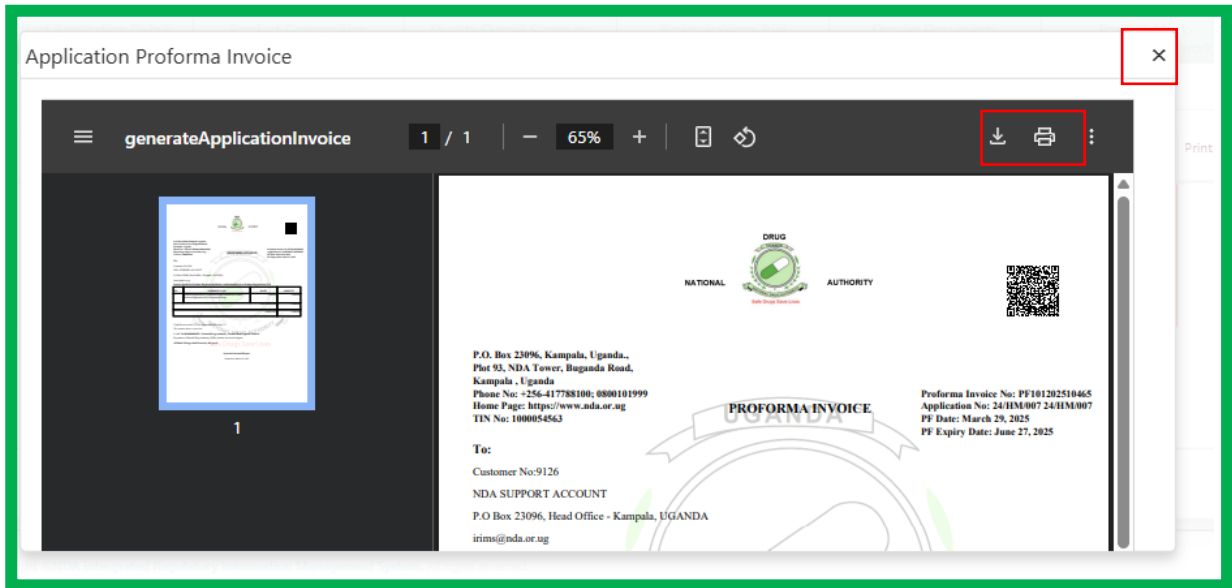
This involves Generation of the Proforma Invoice and Submission of the Application for processing

#### a) Generation of a proforma invoice

i. Select urgency of the application by clicking Normal Track Application or Fast Track Application.

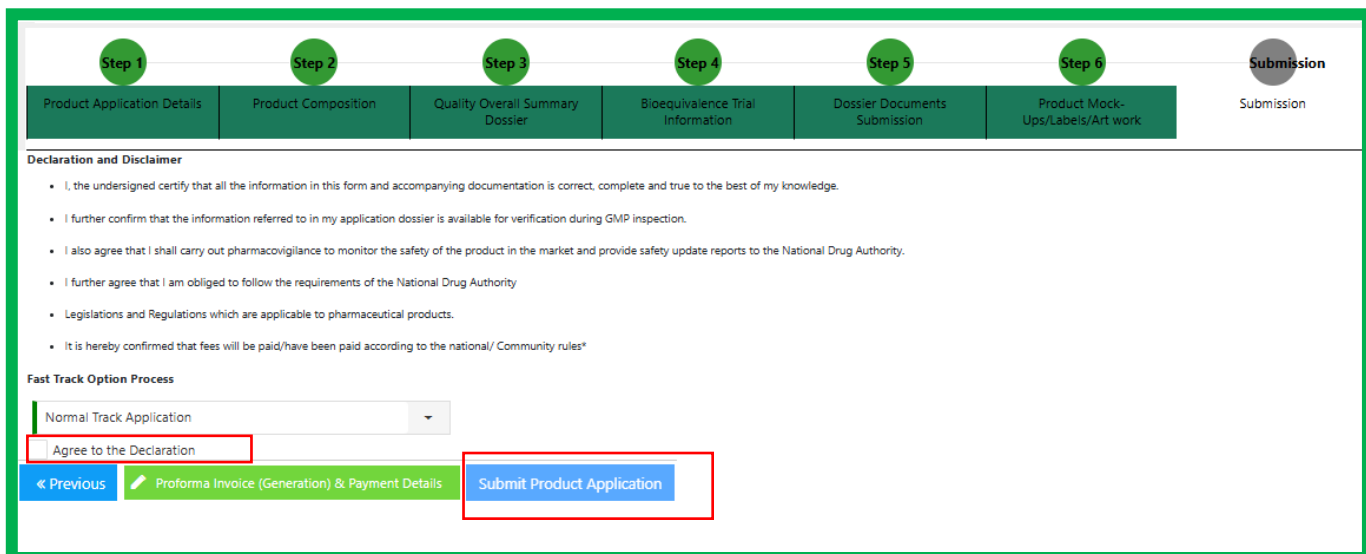






## b) Submission

To submit the application, click 'Agree to the Declaration' and then 'Submit Product Application'.



**D. PAYMENT OF REGISTRATION FEES**

Present the downloaded invoice to any Stanbic bank for payment.

**E. SAMPLE SUBMISSION**

After payment of registration fees, you will be required to sample the commercial samples to NDA for commencement of the assessment process.