

Government of India

Online National Drugs Licensing System (ONDLS)

USER MANUAL

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1. Manufacturer: -



Diagram 1: - Site Dashboard

1.1 Product Management: -

- From your Dashboard you can choose any suitable option and proceed.
- If you click on Product Management there you can click on product type as per your choice as shown in figure 1.



Figure 1: Site Dashboard

1.1.1 Allopathic Product: -



- If you will click on Allopathic product as shown in figure 2, you will be directed to the page where you have to give all details about the products details as shown in figure 3 and 4.

Figure 2: Product Type

Allopathic Product Draft Page

Drug Basic Details

Manufacturing Purpose*
Select Purpose

Product Type*
Select

Dosage Form*
Select Dosage

Pharmacological classification of Drug*
Select classification

Drug Use For*
Select

Pharmacopoeial Monograph*
Select

Strength*
Enter Strength

Unit*
Select Unit

Brand Name (Optional)
Enter Brand Name

Shelf Life*
Enter Shelf Life

Shelf Life Unit*
Select Unit

Each unit dosage form contains*
each tablet contains ... or each 5 ml contains ...

Packaging Presentation*
Packaging Presentation

Product Description
Product Description

Upload Supporting Documents

Analytical Document*
Choose File No file chosen

Leaflet/Other Document
Choose File No file chosen

Ingredients Detail

Ingredient Type*
Select

Ingredient Name*
Ingredient Name

Pharmacopoeial Monograph*
Select

Equivalent To (Optional)
Equivalent To

Strength*
Enter Strength

Unit*
Select Unit

Add Ingredients Click here

Show 10 entries Search:

ID	Ingredient Type	Ingredient Name	Pharmacopoeial Monograph	Strength	Equivalent To	Action
No data available in table						

Showing 0 to 0 of 0 entries Previous Next

Indication Details

Indication for which proposed to be used (Optional)
Enter Indication

Add Indication Click here

Figure 3: Allopathic Product Details

- After filling up all the details like ingredients and its indication, you need to click on to add ingredients and add indication as shown in Figure 3.

Show 10 entries Search:

Indication Name	Action
No data available in table	

Showing 0 to 0 of 0 entries Previous Next

Save & Proceed Click here

Figure 4: Product Details of Allopathic

- After add ingredients and add indication, click on Save & Proceed as shown on Figure 4.

1.1.2 Product Listing: -

- Now from the Product Management page click on Draft product and there you can see the product that you have added as shown in figure 5 and 6.



Figure 5: Product Management (Draft Product List)

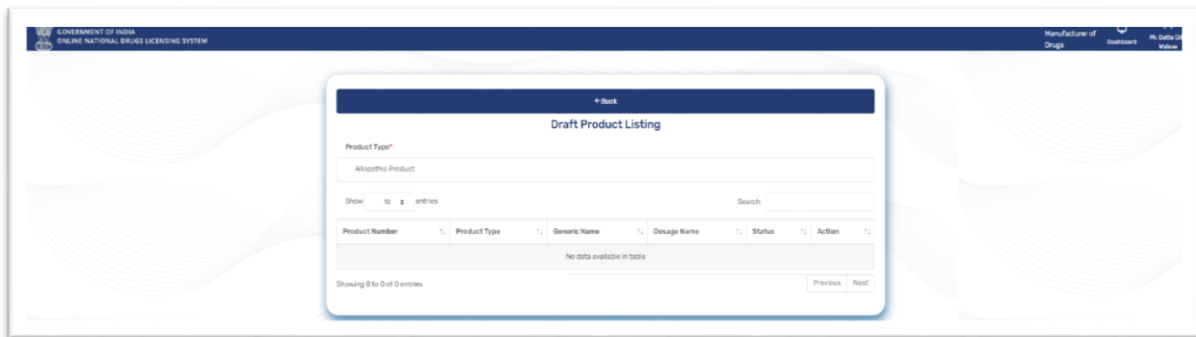


Figure 6: Product Listing

1.1.3 Vaccine Product: -

- If you want to add a vaccine product then click on vaccine product from product management and fill the required form as shown in figure 7.

The screenshot shows the 'Vaccine Product Details' form. It contains the following fields: Product Category (Select), Brand Name (Enter Brand Name), Product Type (Select), Storage Condition (Select), Product Description (Enter Product Details), Name of Product (Enter Product Name), Product Class (Enter Product Class), Pharmacological Monograph (Select), and Container Type (Select). There are also two file upload sections: 'Upload Analytical Document' and 'Upload PI Document', each with a 'Choose File' button and a note '(No file chosen)'. A 'Save' button is located at the bottom center of the form.

Figure 7: Vaccine Product

1.1.4 Blood Product: -

- And if you want to add blood product then click on blood product from product management as shown in figure 8.

The screenshot shows the 'Blood Product Details' form. It has a header with a 'Back' button. The form is divided into two columns. The left column contains: 'Name of Product*' (text input), 'Therapeutic Class*' (text input), 'Storage Condition*' (select dropdown), 'Pharmacopoeial Monograph*' (select dropdown), and 'Analytical Document' (file upload). The right column contains: 'Brand Name' (text input), 'Product Type*' (select dropdown), 'Container Type*' (select dropdown), 'Product Description' (text area), and 'Leaflet/Other Document' (file upload). A 'Save' button is located at the bottom center of the form.

Figure 8: Blood product

1.1.5 Approved Product :-

- If you want to see approved product list then click on Approved Product from product management and fill the required form as shown in figure 9.



Figure 9: Approved product

- In Approved Product Listing there is add Action as shown in figure 10.
Add action:-
 - Add Batch
 - Add Brand

1.1.5.1 Add Batch: -

- In Approved Product Listing, Add action there is Add Batch as shown in figure 10 .

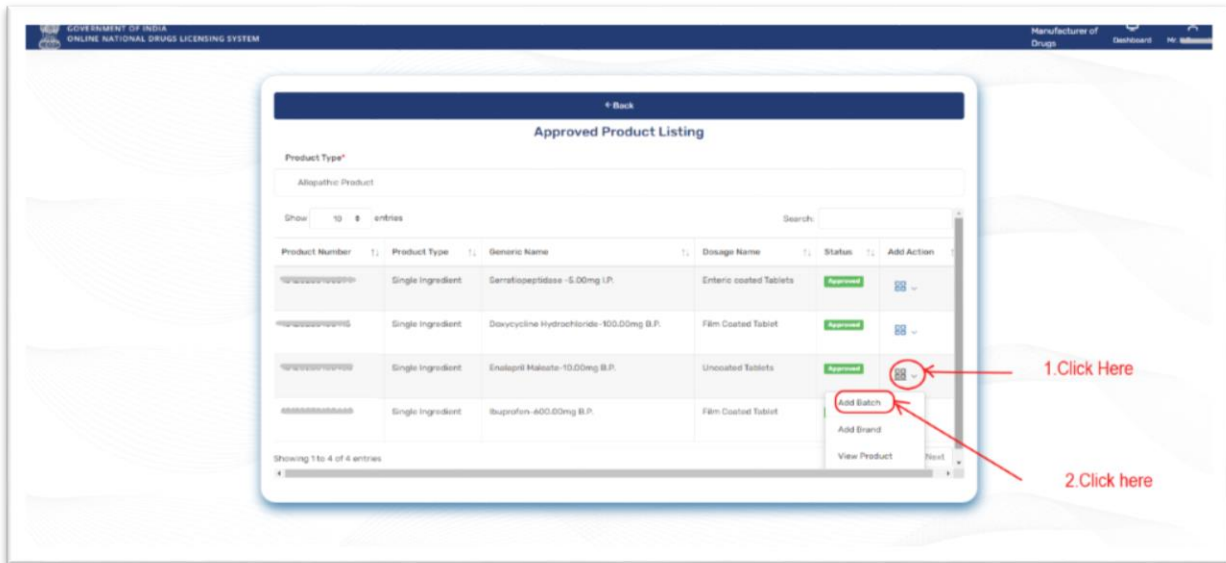


Figure 10: Approved product Listing (Add Batch Action)

1.1.5.1 Add Batch Page:-

- After fill all detail, we can click on Save Batch Detail as shown in figure 11.
- All detail view in following table as shown in figure 11.

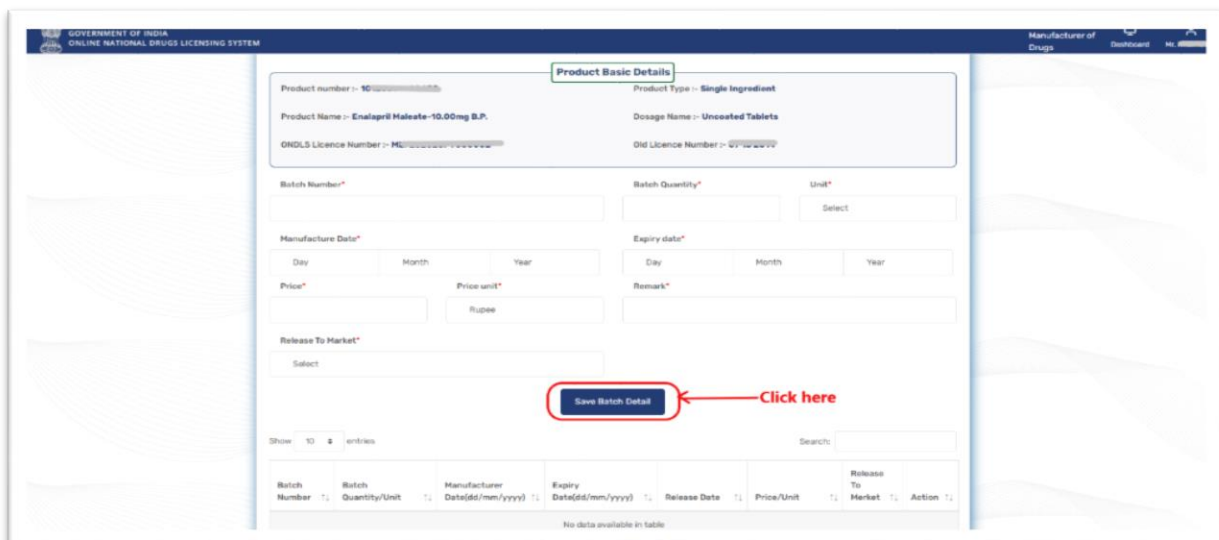


Figure 11: Add Batch detail

1.1.5.2 Add Brand:-

- In Approved Product Listing, Add action there is Add Brand as shown in figure 12.

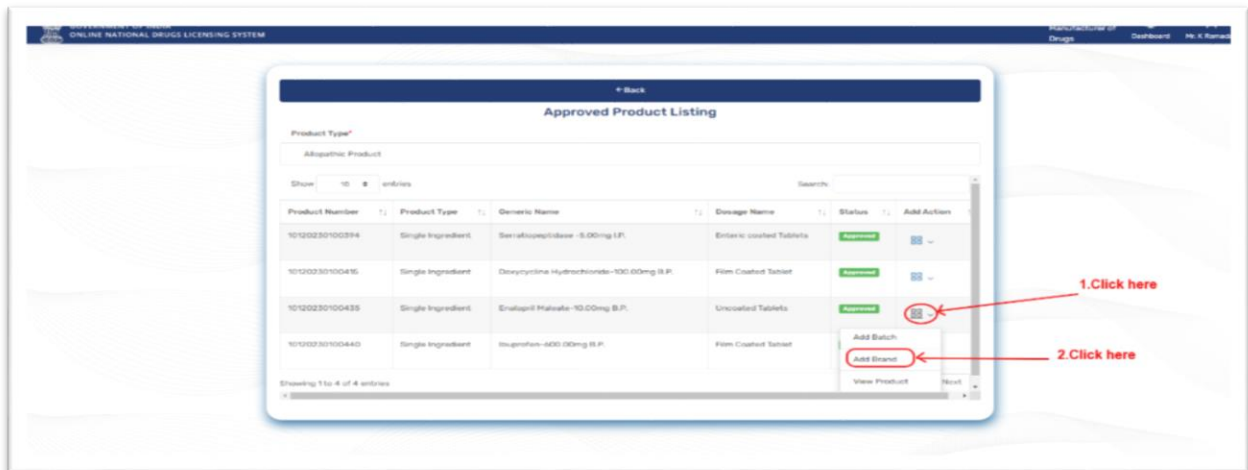


Figure 12: Approved product Listing (Add Brand Action)

1.1.5.2 Add Brand Page:-

- After fill all detail, we can click on Save Brand Detail, if want to generate Form51 then click on Generate Form51 button by selecting Brand name, can download Form 51 by click Download Form51 and upload that form by clicking Upload Form as shown in figure 13.

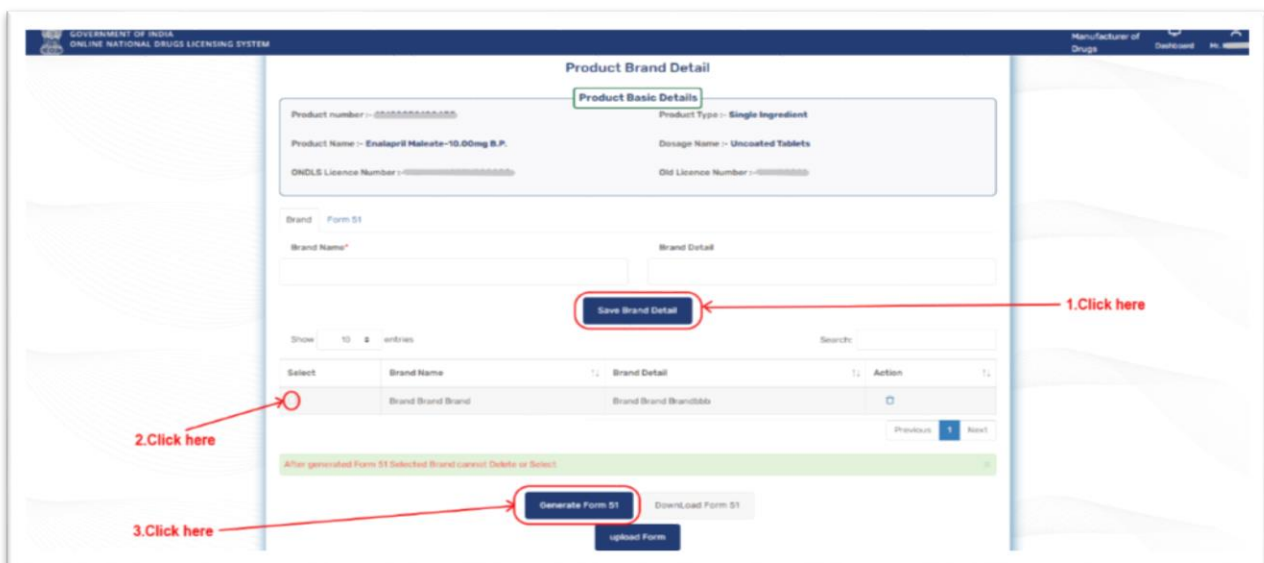
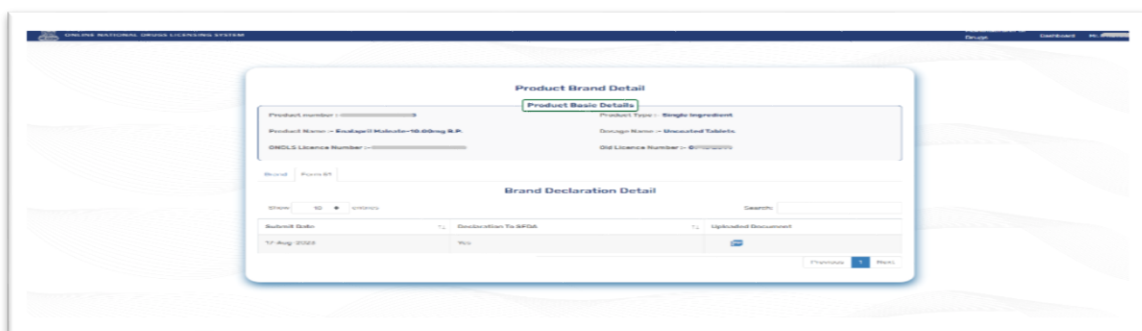


Figure 13: Add Brand Detail



- Click On tab Form51 for see detail of Form 51 as shown in following figure 14.

Figure 14:Form 51 Detail

1.2 Application Processing: -

- After adding product, we can click on Application processing as shown in figure 15.

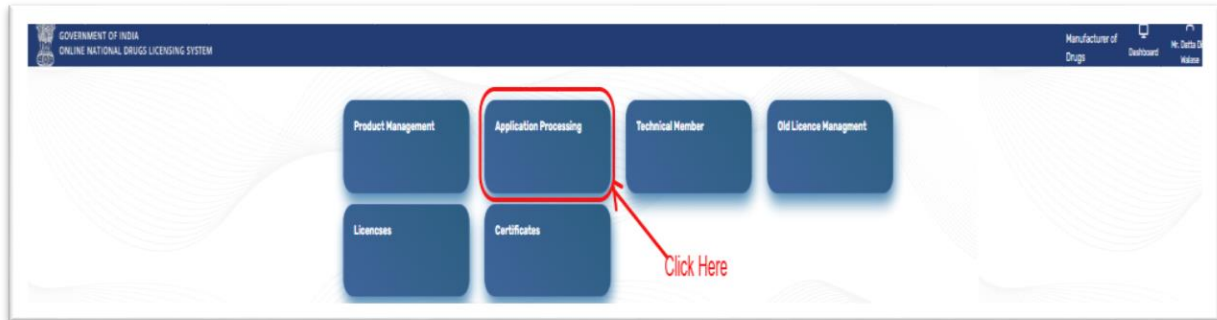


Figure 15: Firm Dashboard (Application Processing)

1.2.1 Fresh Application Submission:-

- After click on Application Processing we can see Fresh Application Submission as shown in figure 16.

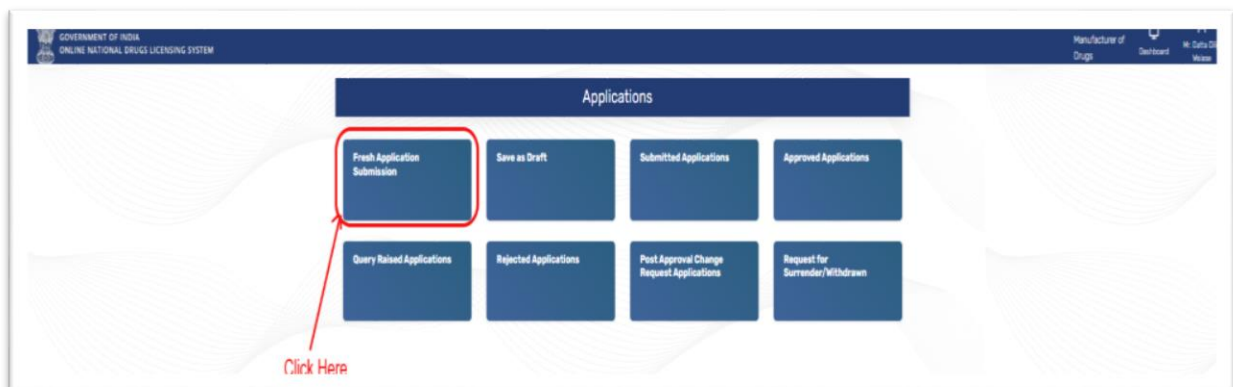


Figure 16: application processing tiles (Fresh Application Submission)

1.2.2 Manufacturing License: -

- After clicking on fresh application submission, the page where you have to mention the application type and form name then click on submit as shown in figure 17.

Figure 17: Application Initial Page

- After submitting the application initial page, you will get directed to the Firm Details Confirmation page as shown in figure 17.
- Now check all the details that you have mentioned are correct and then click on save details as shown in figure 18.

Figure 18: Firm Details Confirmation

- After clicking on save details you will get directed to the application product mapping page as shown in figure 19.
- Now click on the product which you have added and then click on save as shown in figure 19.

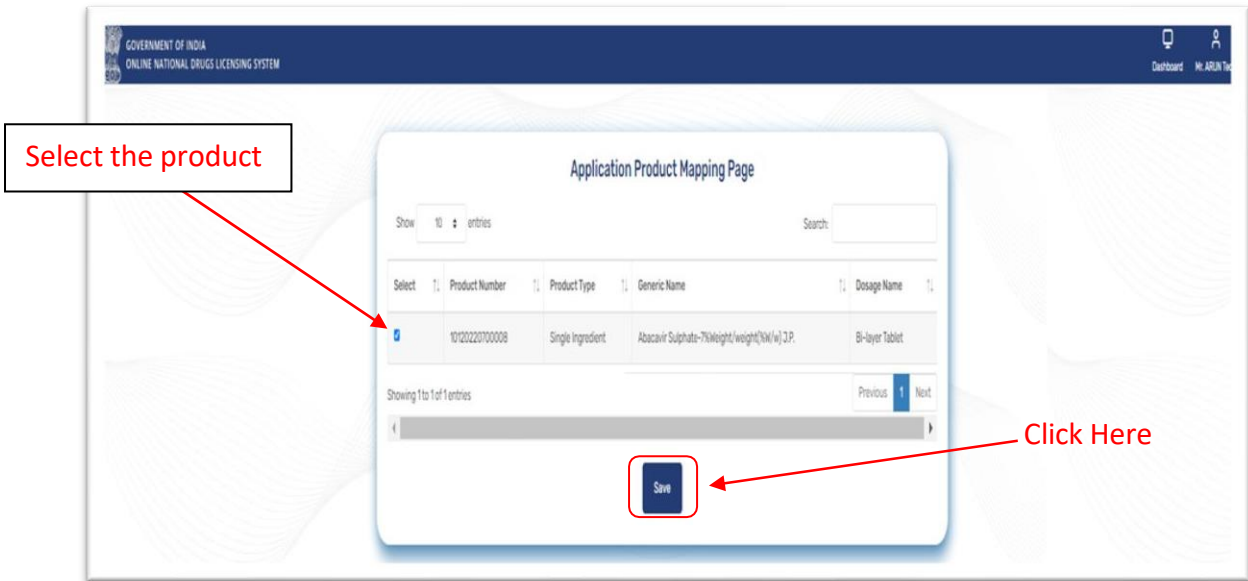


Figure 19: Product Mapping

- Now after selecting the product, you have to select the technical person and then click on next as shown in figure 20.

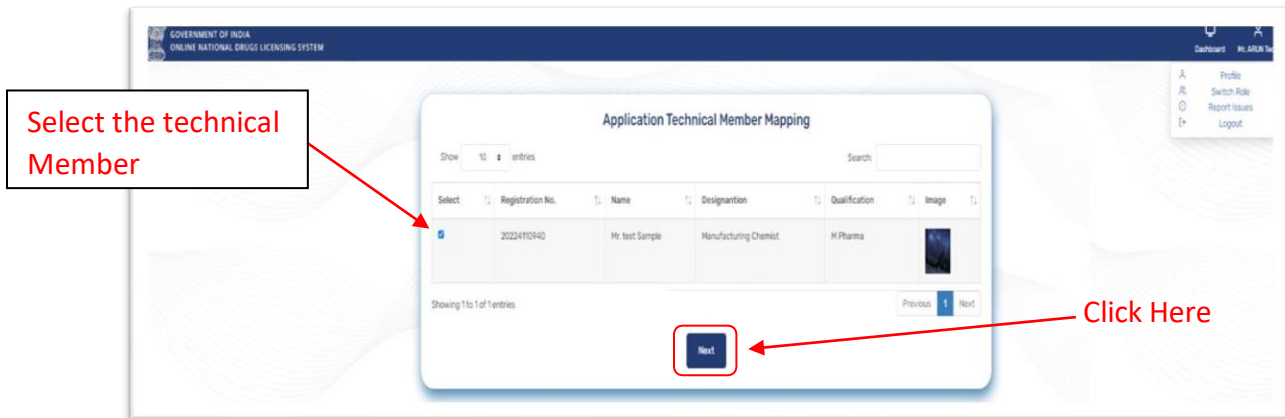


Figure 20: Technical Member Mapping

- After selecting the technical member, you will get to preview your application form, in this you can either edit the application form or you can proceed as shown in figure 21.

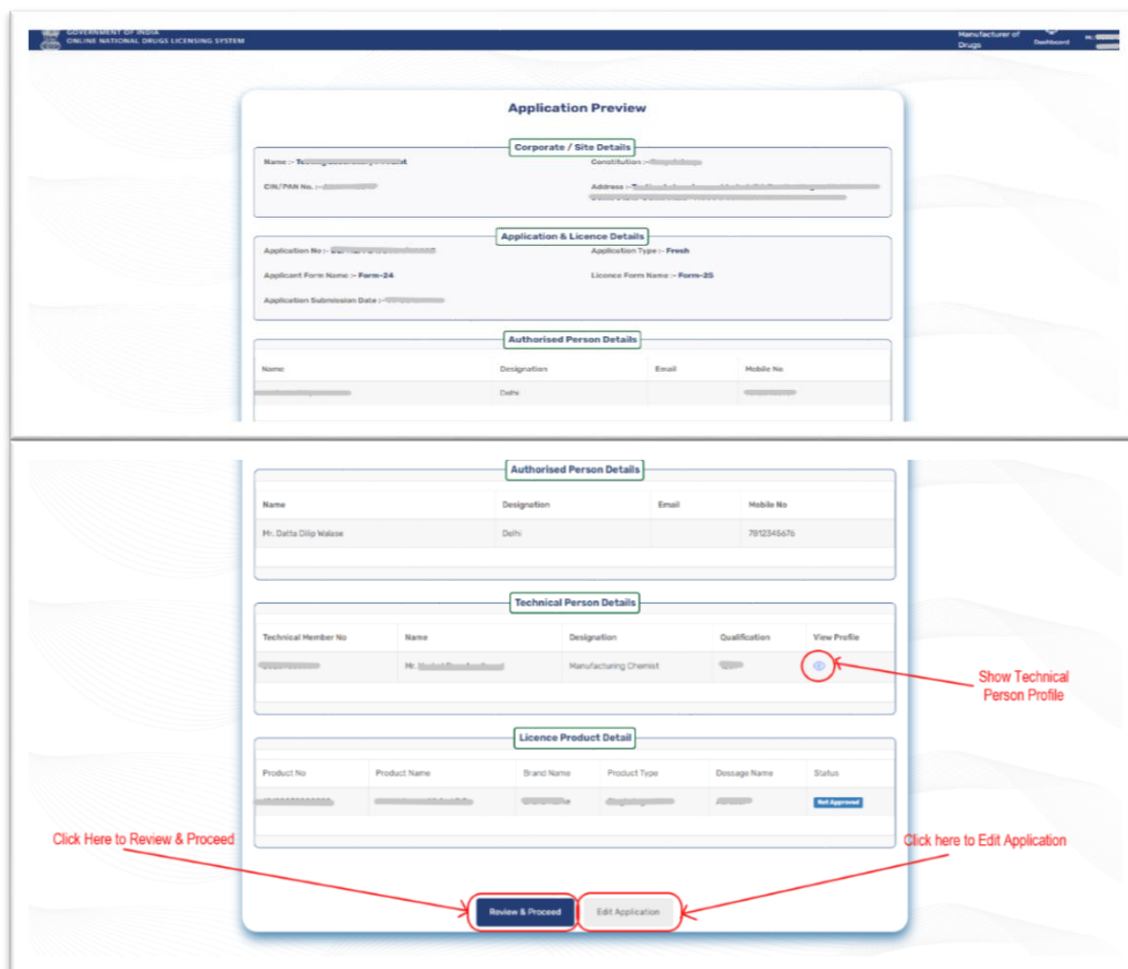


Figure 21: Application Preview

- Now after application preview you have to Verify and upload all the required documents then click on Proceed as shown in figure 22.

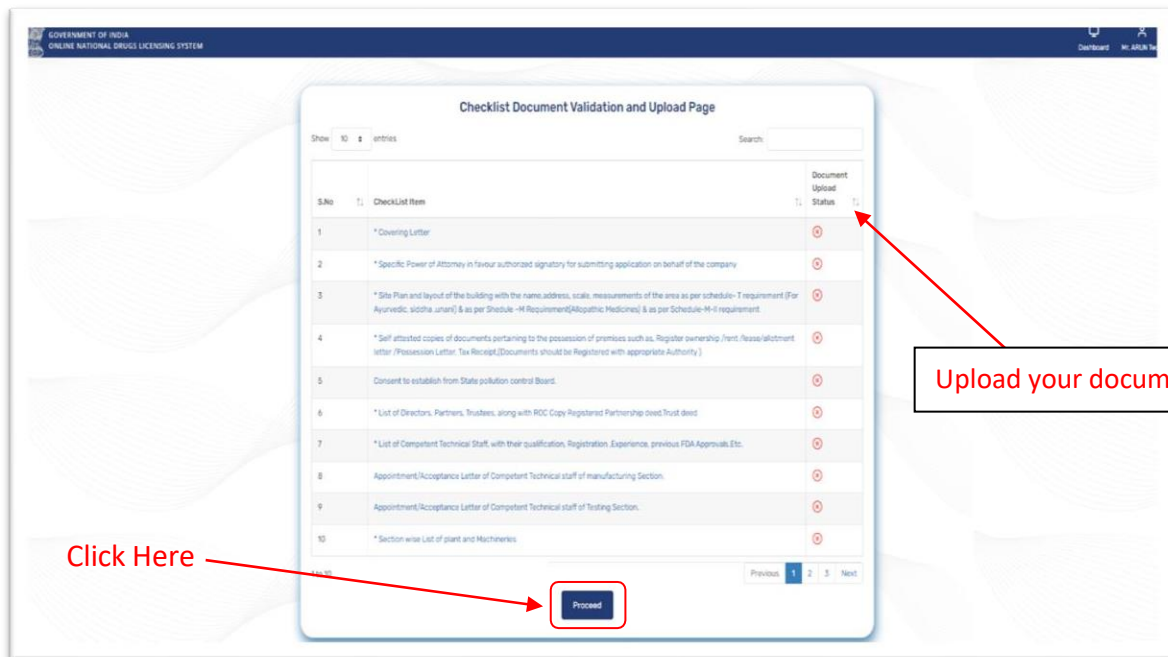


Figure 22: Document Validation and Upload Page

- Now you have to make payment, first fill the required details then click on save and proceed as shown in figure 23.

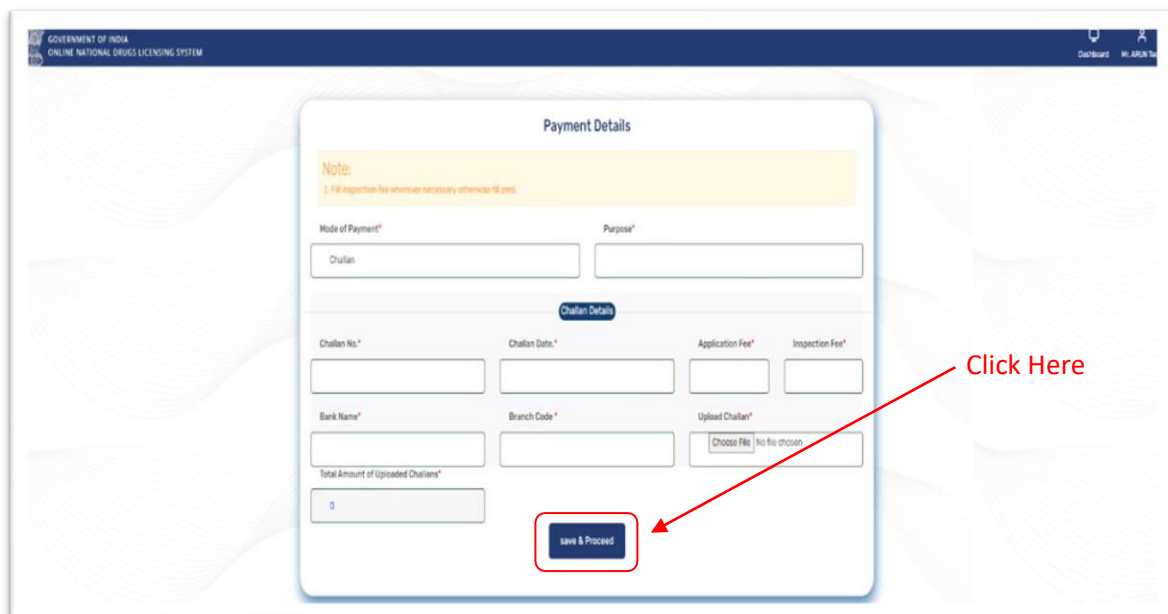


Figure 23: Payment Details

- After payment details you will get to review your form again, after checking all the details click on proceed as shown in figure 24 and 25.

Application Preview

Corporate Details
 Name - Cdac Noida Constitution - Co-Operative
 CIN/PAN No. - AC08D4448K Address - cdac noida, b 30, noida, District-East Delhi, State-Delhi, India -110095, Contact Number-8796574567

Site Details
 Name - Cdac Noida Constitution - Co-Operative
 CIN/PAN No. - AC08D4448K Address - B 30, Tonk, District-Central Delhi, State-Delhi, India -110069

Application & Licence Details
 Application No - DL/ML/F24/2022/00003 Application Type - Fresh
 Applicant Form Name - Form-24 Licence Form Name - Form-25

Authorised Person Details

Name	Designation
Mr. ARUN Toch	HEAD

Technical Person Details

Technical Member No	Name	Designation	Qualification	View Profile
20224702940	Mr. test Sample	Manufacturing Chemist	M Pharma	View Profile

Figure 24: Preview Application

Authorised Person Details

Name	Designation
Mr. ARUN Toch	HEAD

Technical Person Details

Technical Member No	Name	Designation	Qualification	View Profile
20224702940	Mr. test Sample	Manufacturing Chemist	M Pharma	View Profile

Licence Product Detail

Product No	Product Name	Brand Name	Product Type	Dosage Name	Status
10/20220700008	Atacavir Sulphate-750mg/weight(200/14) Z.P.	test	Single Ingredient	B-layer Tablet	Not Approved

Payment Details
 BarB Name - icddr Amount - 1120
 Challen Date - 2022-07-05 00:00:00.0

Legal Form Download Section
 Form-24

[Review & Proceed](#) Click Here

Figure 25: Review Application

- Now after reviewing your page, you have to upload the final form and the click on submit as shown in figure 26.

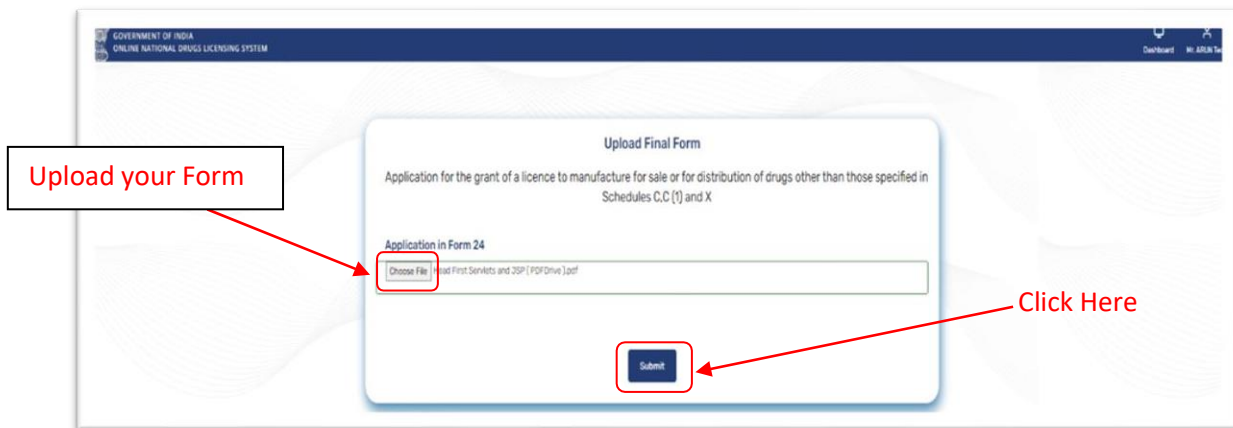


Figure 26: Upload Final Form

- After uploading the form your application form will get submitted and File number will get generated as shown in figure 27.

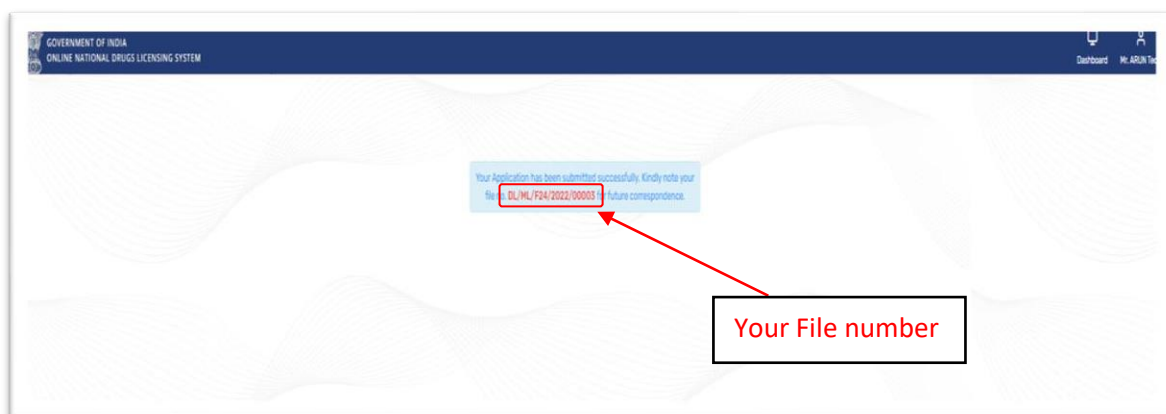


Figure 27: File Number

1.2.3 Test License: -

- If you want to apply for test License then go to application processing as shown in figure 28.



Figure 28: Fresh Application Submission

- Select the required details from application initial page as shown in figure 29 and click on submit.

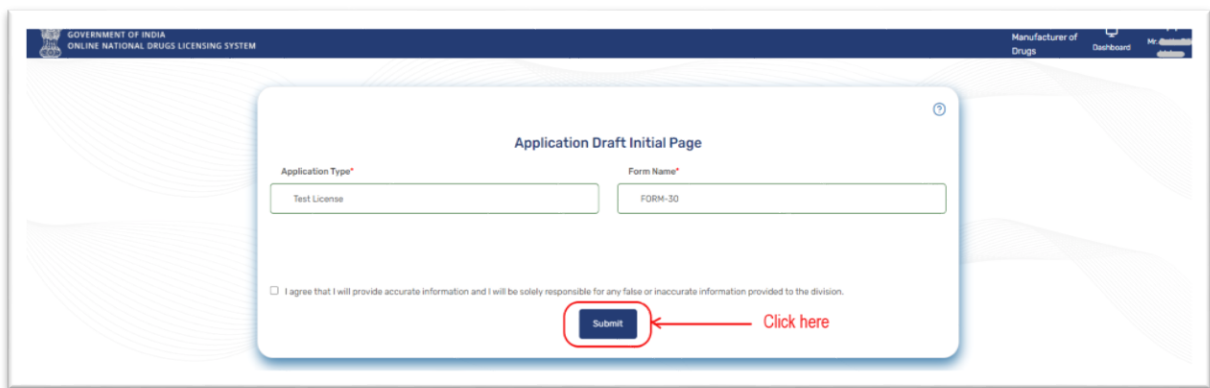


Figure 29: Initial Page

- Now you have to give the firm details confirmation by selecting the authorized person as shown in figure 30 & click on save Details.

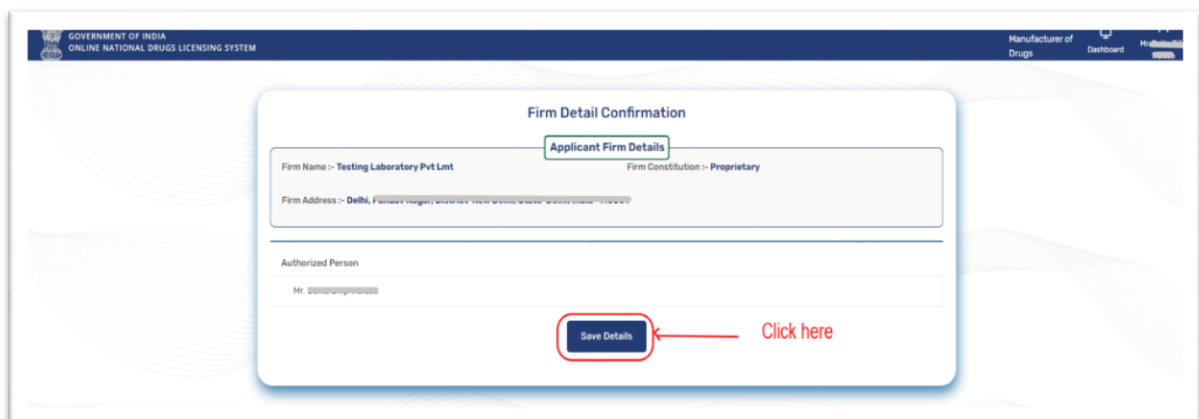


Figure 30: Firm Details Confirmation

- Now you have to select the product for which you are applying for the license as shown in figure 31.

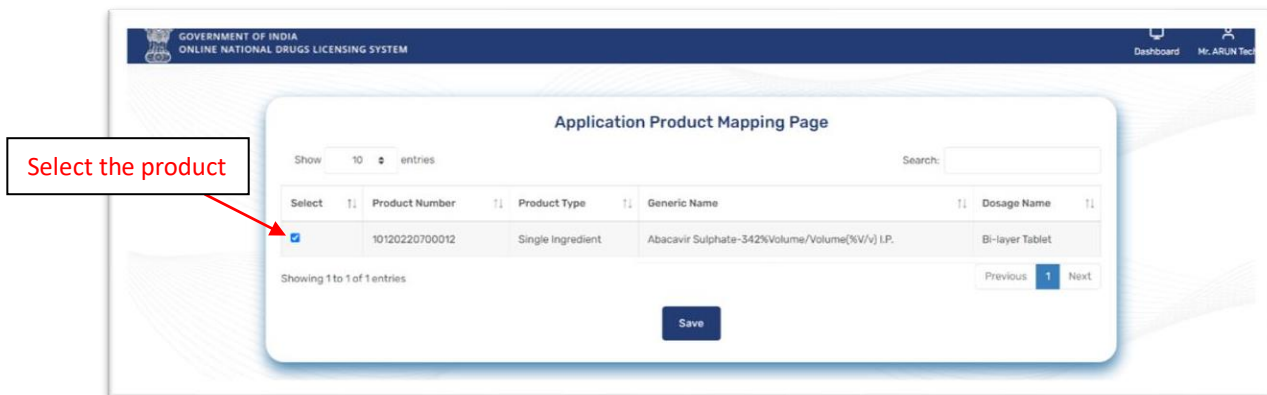


Figure 31: Product Mapping

- Now you have to select the technical person as shown in figure 32.

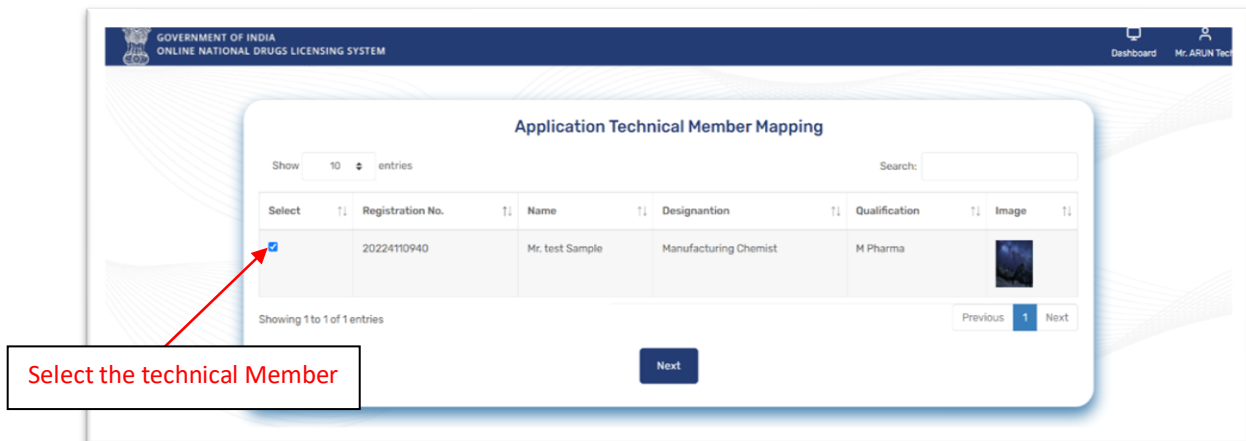


Figure 32: Technical Member Mapping

- After selecting the technical member, you will get to preview your application form, in this you can either edit the application form or you can proceed as shown in figure 33.

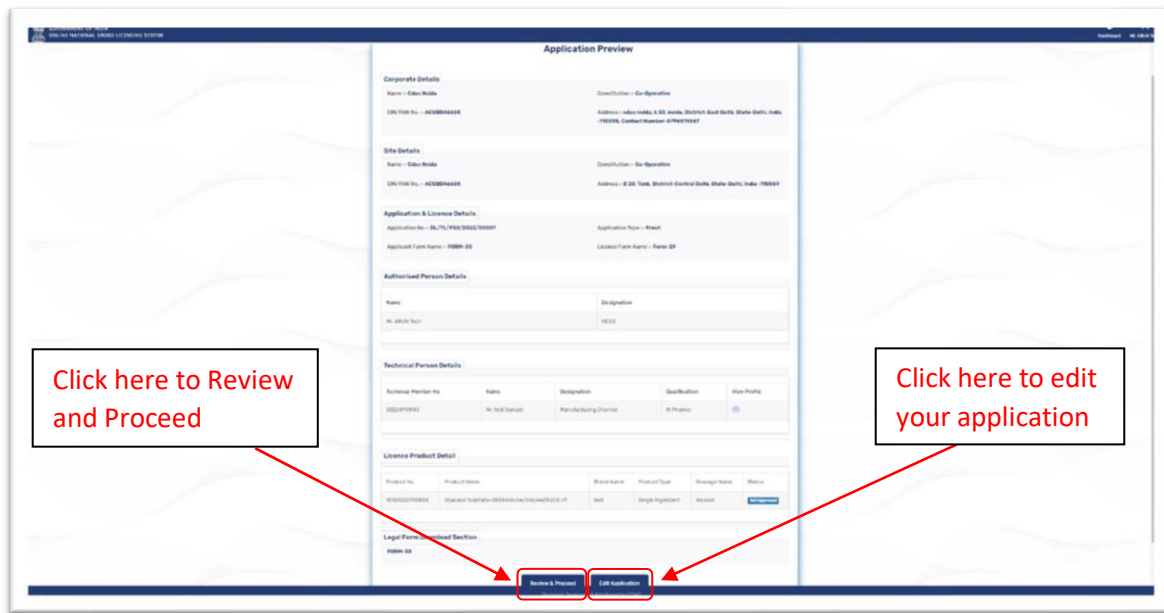


Figure 33: Preview Application

- Now upload the documents which are required and the click on proceed as shown in figure 34.

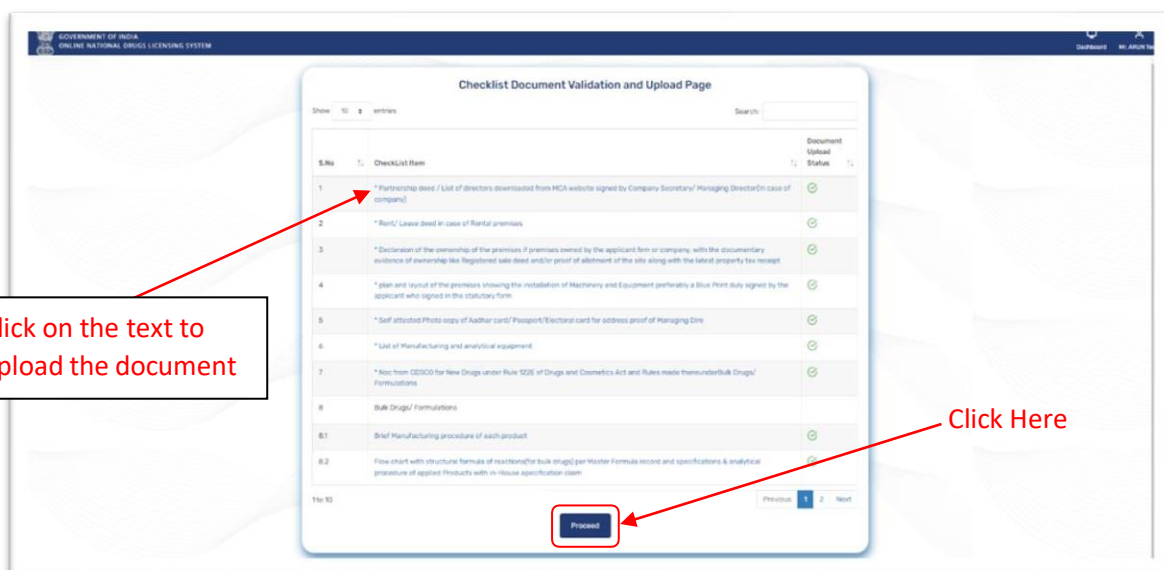


Figure 34: Upload Document

- Give all the payment details as asked then click on save and proceed as shown in figure 35.

Payment Details

Note:
1. Fill inspection fee wherever necessary otherwise fill zero.

Mode of Payment*
Challan

Purpose*
test

Challan Details

Challan No.*
123321

Challan Date.*
06/07/2022

Application Fee*
1000

Inspection Fee*
120

Bank Name*
icici

Branch Code*
rttyt

Upload Challan*
Choose File | Head First Ser_DFDrive).pdf

Total Amount of Uploaded Challans*
1120

save & Proceed

Click Here

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Figure 35: Payment Details

- After payment details you will get to review your form again, after checking all the details click on proceed as shown in figure 36.

Application Preview

Company / Site Details

Name: M/s. ...
Company No.: ...

Director Details

Name: ...
Designation: ...
Email: ...

Application & License Details

Application No.: ...
Application Type: ...

Authorized Person Details

Name: ...
Designation: ...

License Product Detail

Product No.	Product Name	Brand Name	Product Type	Manufacture	Status
...

Payment Details

Amount: ...

Legal Form Download Section

...

save & Proceed

Click Here

Figure 36: Application Preview

- Now after reviewing your page, you have to upload the final form and the click on submit as shown in figure 37.

Figure 37: Upload Final Form

- After uploading the form your application form will get submitted and application number will get generated as shown in figure 38.

Figure 38: File Number

1.3 Save as Draft: -

- Now if by chance you have left the application form in between you can go to save as draft from the dashboard page and complete the rest of the application form as shown in figure 39.

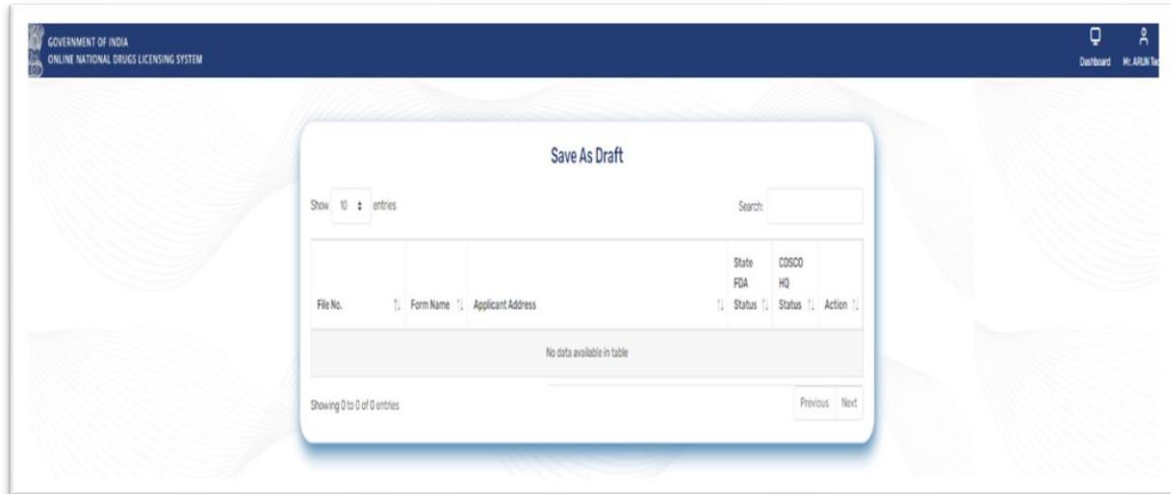


Figure 39: Save as Draft

1.4 Submitted Application: -

- If you want to view whether your application is submitted or not, then click on submitted from the dashboard page then you can view your application as shown in figure 40.

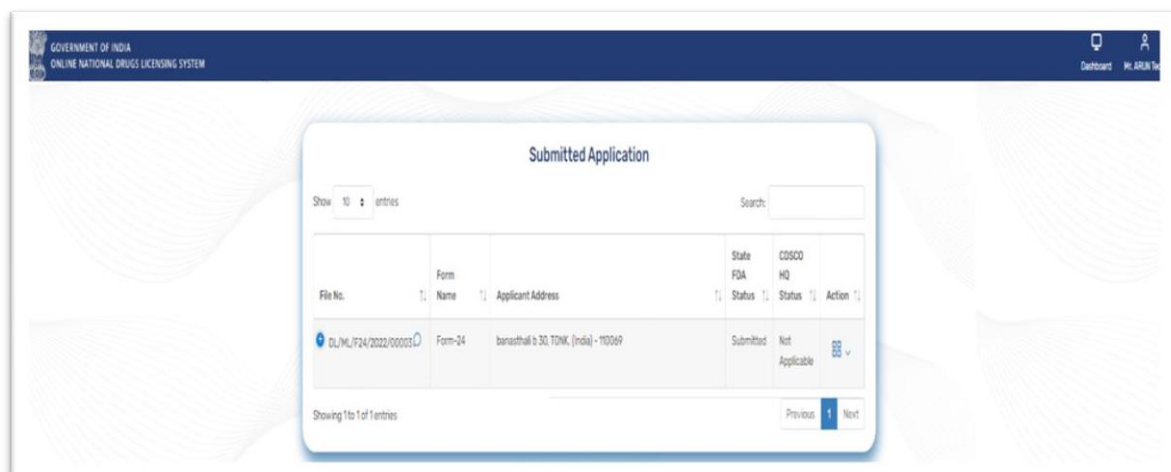


Figure 40: Submitted Application

1.5 Approved Application: -

- Now if you want to see whether your application form is approved or not, then click on approved from the dashboard then you can view your application status as shown in figure 41.

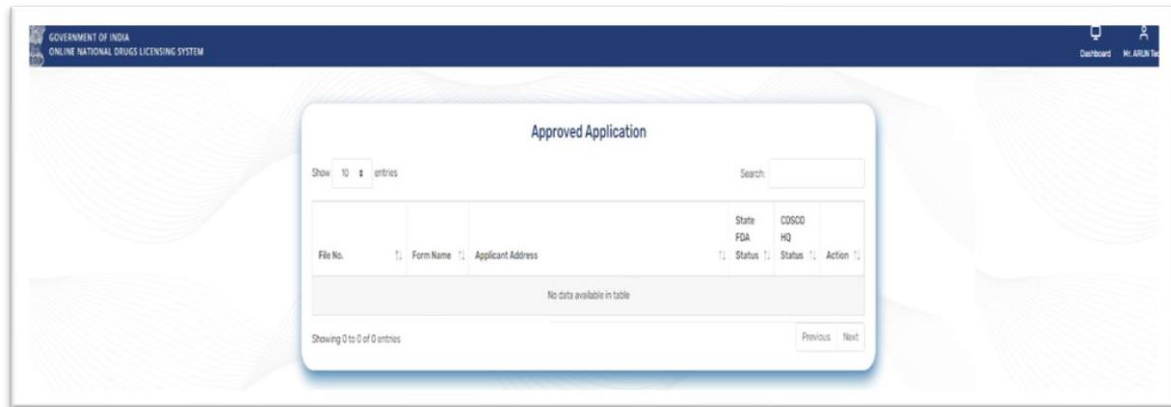


Figure 41: Approved Application

1.6 Query Raised Application: -

- If any query is raised on your application you can click on query raised from the dashboard and can see whether there is any query or not as shown in figure 42.

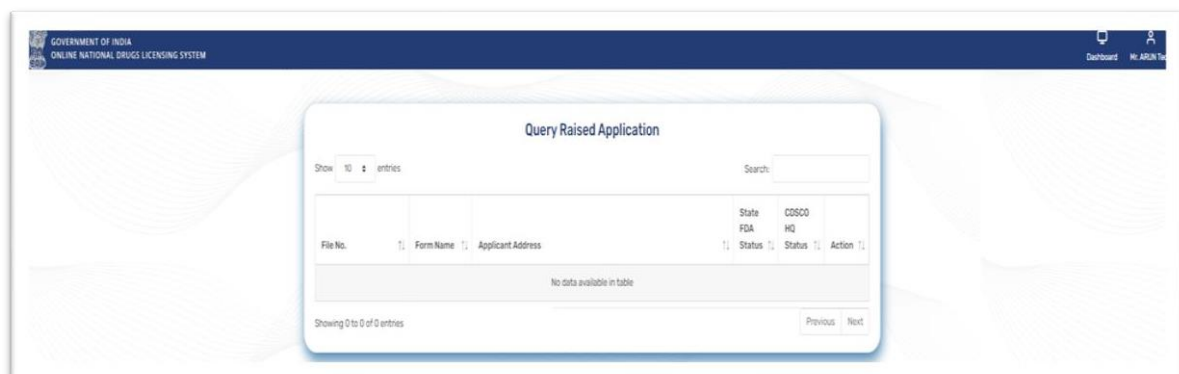


Figure 42: Query Raised

1.7 Request for Surrender / Withdrawn: -

- If you want to withdraw your application then you can click on request for surrender/withdrawn from the dashboard as shown in figure 43.

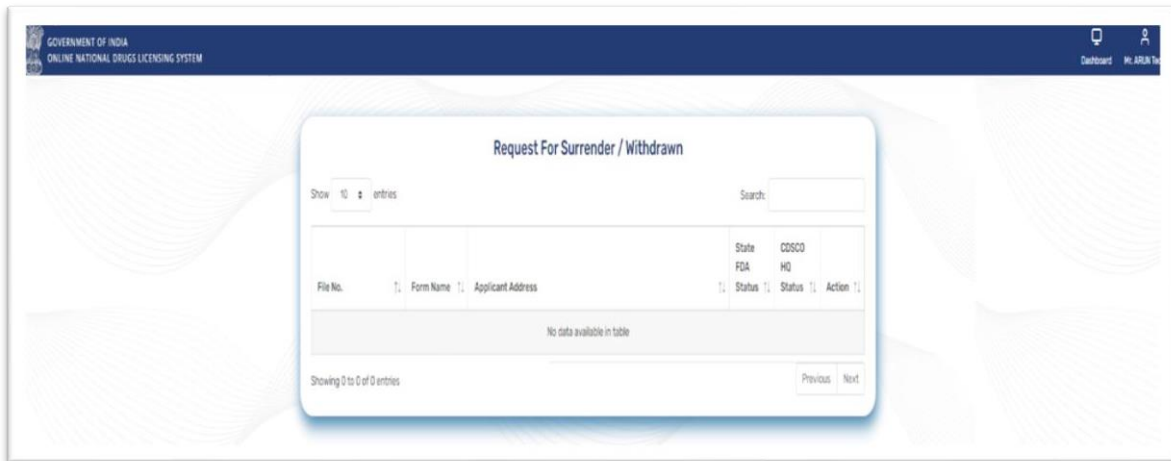


Figure 43: Request for Surrender / Withdrawn

1.8 Cancelled Application: -

- If you want to see your cancelled application then click on cancelled application from the dashboard as shown in figure 44.

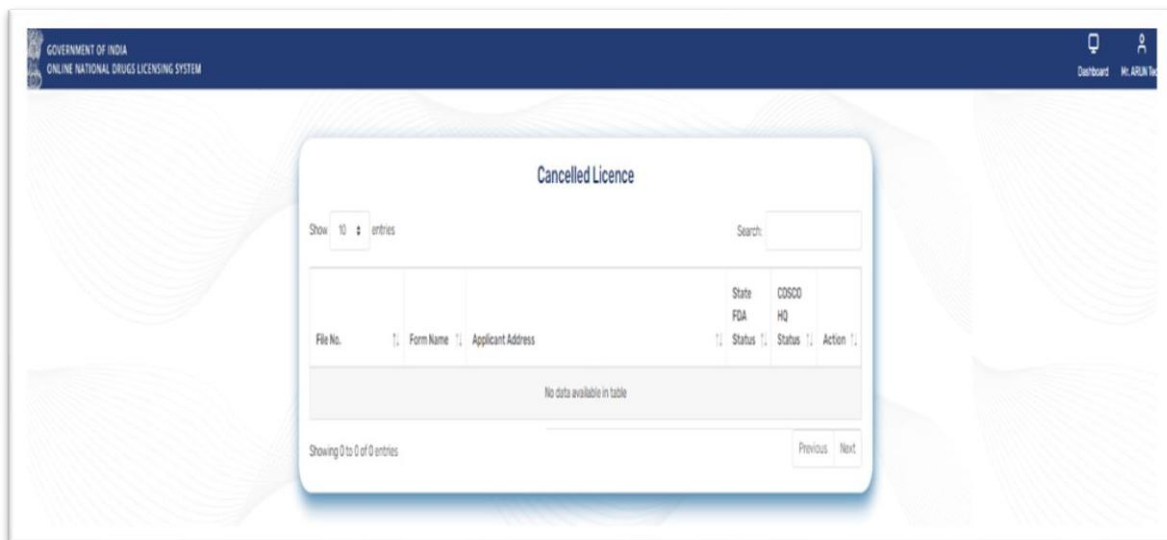


Figure 44: Cancelled Application

1.9 Add Technical Member: -

- Now if you haven't added any technical member then you can click on add Technical member from the dashboard as shown in figure 45 .

Figure 45: Add Technical Member

- After entering the registration number click on fetch data as shown in figure 38 and after going through the technical persons profile add it.

1.10 Hired Technical Person Pool: -

- If you want to see the technical persons list the click on hired technical person pool from the dashboard as shown in figure 46.



Registration No.	Member Name	Gender	Assigned Role / Designation	Joining Date	Action
2022410940	Mr. test Sample	Male	Manufacturing Chemist	07-JUL-2022	 

Figure 46: Hired Technical Pool

1.11 License Management: -

- Now if you want to Renew your license the click on License management from the dashboard and you will get directed to the License management dashboard as shown in figure 47.



Figure 47: License Management

- Same process as it is shown in 1.1 Product Management.

1.12 Loner Firm Approval: -

- In this you can approve the firm(s) request.

1.13 Old Licence Management: -

- From your Dashboard you can choose any suitable option and proceed.
- If you click on Old Licence Management as per your choice as shown in figure 48.

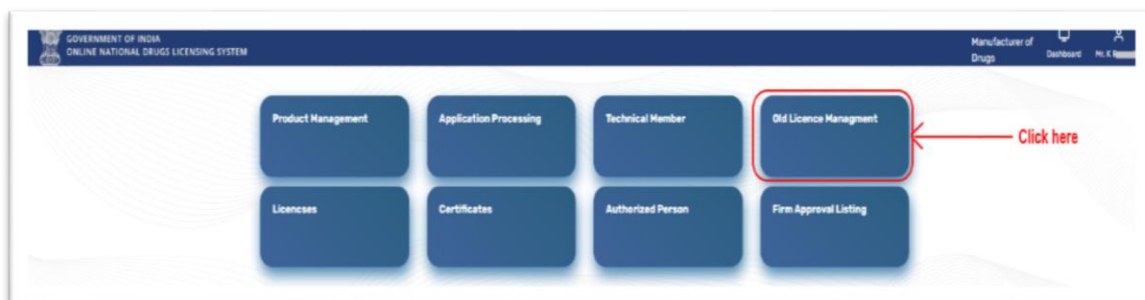


Figure 48: Old Licence Management

1.14.1 Old Draft Licence :-

- If you click on Old Draft Licence as per your choice as shown in figure 49.
- Give all the Licence basic details and click on Record and Proceed button as shown in figure 50.



Figure 49: Licence Management

The screenshot shows the 'Licence Basic Detail' form. The 'Record and Proceed' button at the bottom is highlighted with a red box and a red arrow pointing to it from the text 'Click here' to its right. The form contains fields for Licence Type, Licence Form Number, Application Form Number, Licence Number, Licence First Issue Date, Licence Current Validity Date, and Licence Document.

Figure 50: Old Draft Licence

1.14.1.1 Old Licence Retention Detail: -

- If Licence Current Validity Date (as shown in figure 50) is after today date that must next ask Licence Retention details.
- Give all Licence retention details and click on Record and Proceed as shown in figure 51.

Figure 51: Old Licence Retention Details

1.14.1.2 Licence Member Details:-

- Select technical Person and click on Record and Proceed as shown in figure 52.

Select	Registration No.	Name	Designation	Qualification	View Profile
<input type="checkbox"/>	2000000000	Mr. J. J. J.	Manufacturing Chemist	B Pharma	View Profile
<input type="checkbox"/>	0000000000	Mr. J. J. J.	Analytical Chemist	PG Biochemistry	View Profile

Figure 52: Licence Member Details

1.14.1.3 Licence Product Mapping:-

- Select Product Number and click on Save as shown in figure 53.

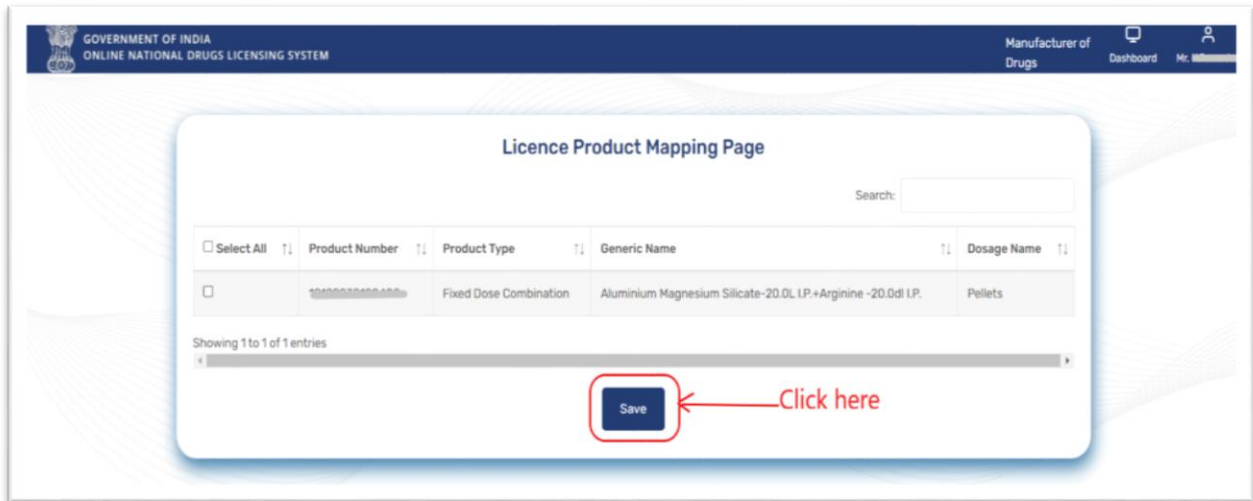


Figure 53: Licence Product Mapping

1.14.1.4 Draft Licence Preview:-

- All entered and selected details are shown in Licence Basic Detail, Licence Retention/Renewal detail, Licence Technical Person details and Licence Product details as shown in figure 54 and figure 55.

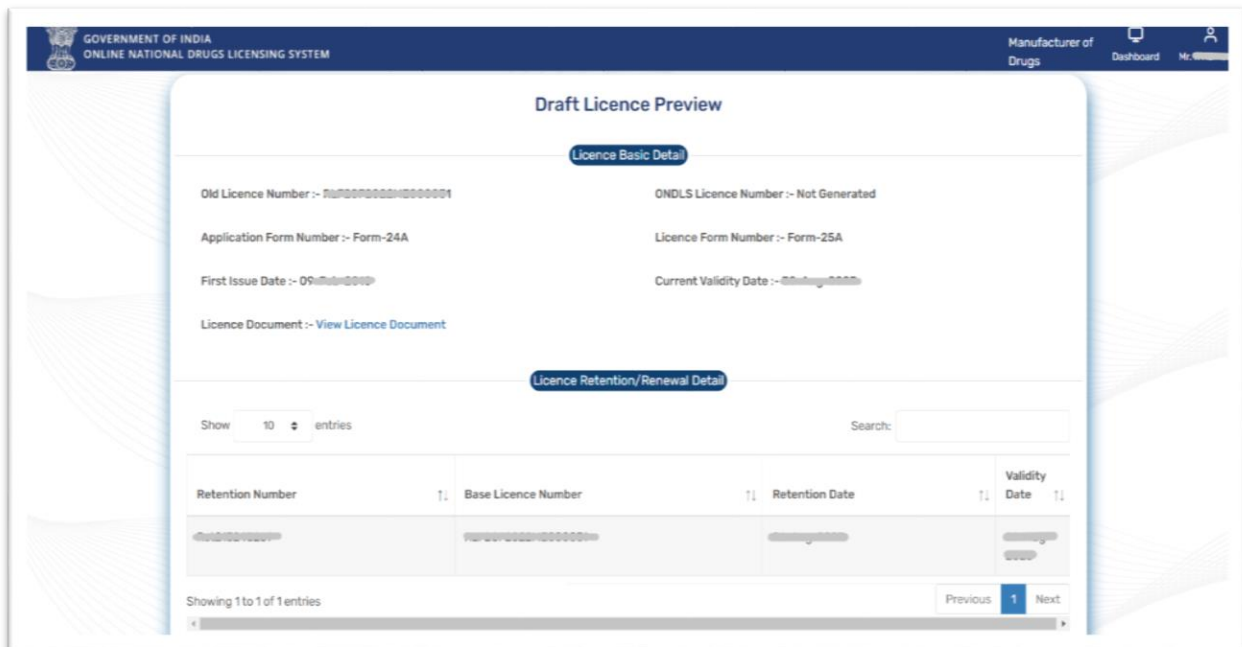


Figure 54: Draft Licence Preview

- Ensure all the details are correct and click on Submit for Review as shown in figure 55.

Licence Technical Person Detail

Show 10 entries Search:

Registration Number	Name	Designation	Qualification	View Profile
[Redacted]	Mr. [Redacted]	Manufacturing Chemist	B Pharma	[View Profile]
[Redacted]	Mr. [Redacted]	Analytical Chemist	PG Biochemistry	[View Profile]

Showing 1 to 2 of 2 entries Previous 1 Next

Licence Product Detail

Product No	Product Name	Brand Name	Product Type	Dosage Name	Status
[Redacted]	[Redacted]	Packaging Presentation	Fixed Dose Combination	Pellets	Not Approved

Submit for Review Click here

Figure 55: Draft Licence Preview Details

1.14.1.5 Licence Submitted Review:-

- After Save Licence Submitted Preview detail it redirect to Licence Submitted Review page as shown in figure 56.

Licence Submitted Review

Show 10 entries Search:

Old Licence Number	Licence Form	Application Form	Issue Date	Validity Date	Submission Date	Current Status
[Redacted]	Form-25	Form-24	[Redacted]	[Redacted]	[Redacted]	Licence Approved
[Redacted]	Form-28	Form-27	[Redacted]	[Redacted]	[Redacted]	Licence Approved
[Redacted]	Form-25A	Form-24A	[Redacted]	[Redacted]	[Redacted]	Licence Submitted For Approval

Showing 1 to 3 of 3 entries Previous 1 Next

Figure 56: Licence Submitted Review

1.15 Old Licence Under Rectification: -

- If want to see old Licence under retention click on Old Licence Under Rectification as shown in figure 57.

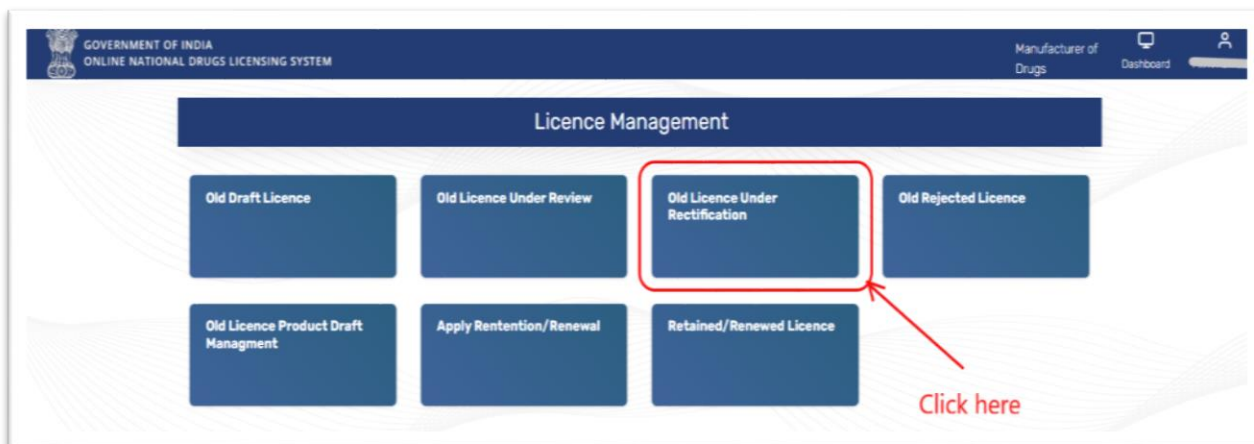


Figure 57: Old Licence under Rectification

- Here show the list of Old Licence under Retention or Renewal as shown in figure 58.

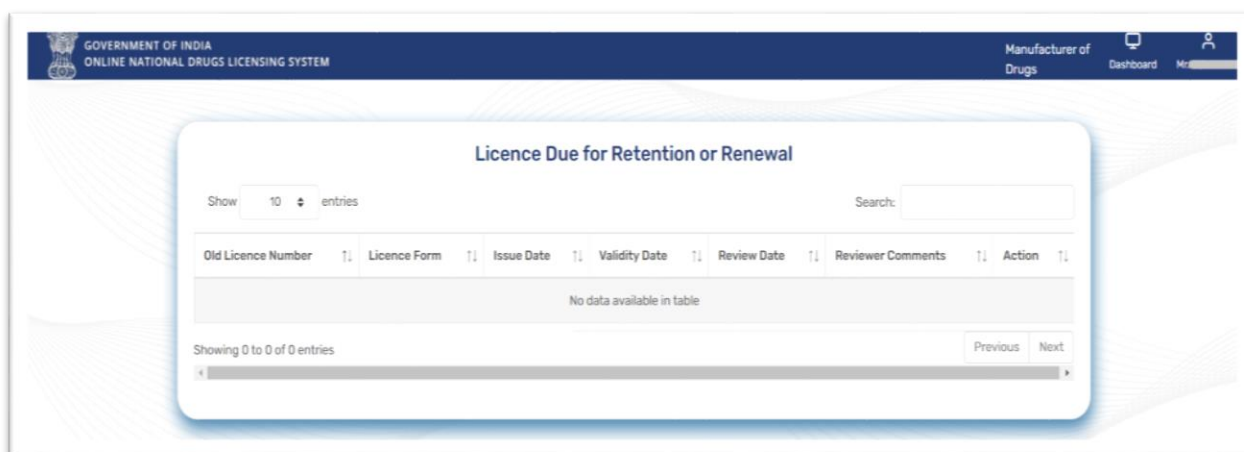


Figure 58: Old Licence under Retention or Renewal list

1.15 Old Rejected Licence: -

- In Dashboard select Old Rejected Licence as shown in figure 59.



Figure 59: Old Rejected Licence

➤ Here show the list of Old Rejected Licence List as shown in figure 60.

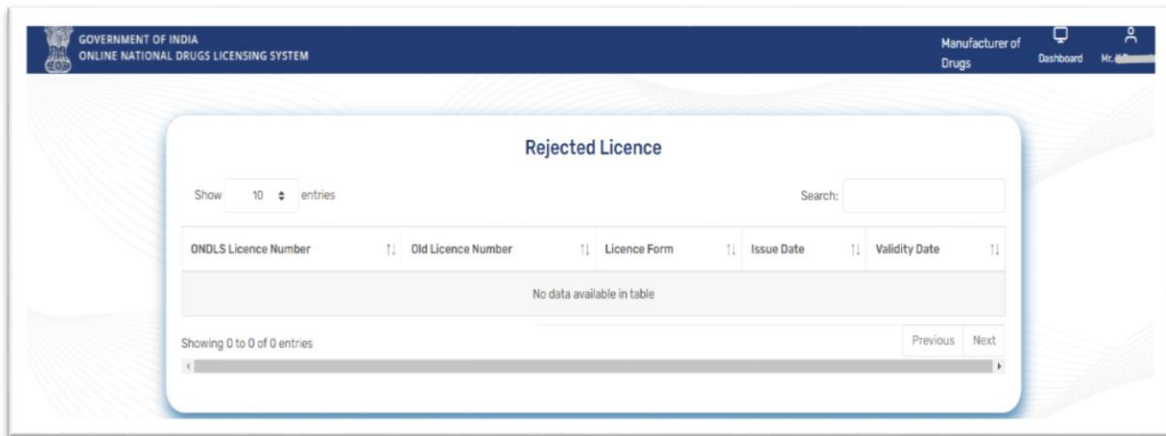


Figure 60: Old Rejected Licence

1.16 Licences: -

➤ In Dashboard select Licences as shown in figure 61.d

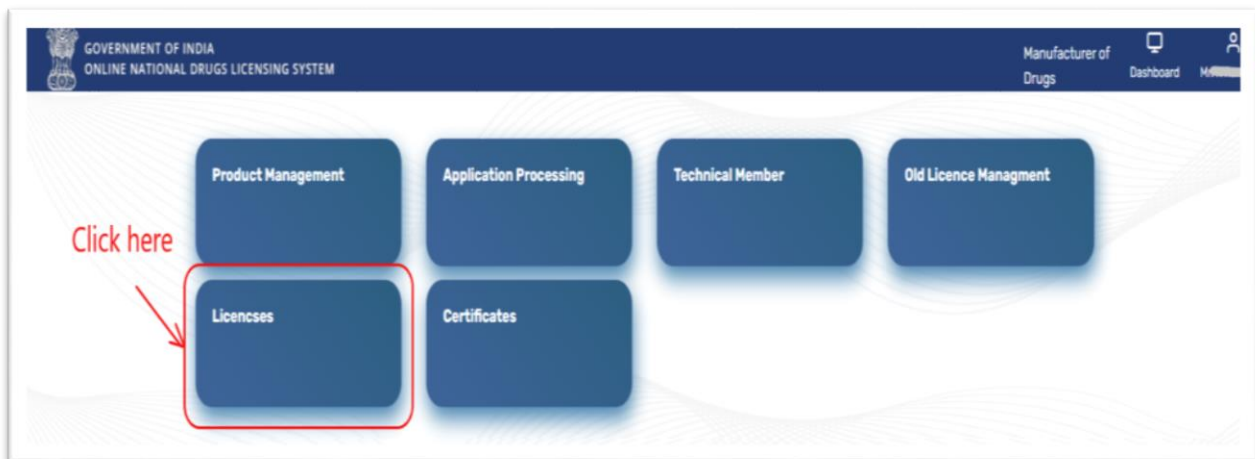


Figure 61: Licences

➤ Here show the list of Approved Licences List and Licence Number behave like a Link which give us to the Licence complete history as shown in figure 62.

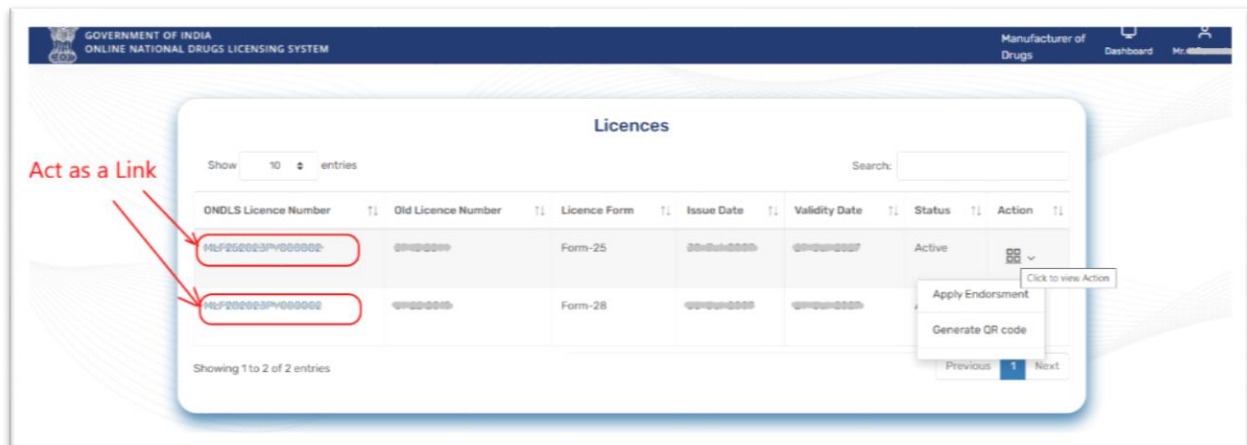


Figure 62: Approved Licences List

1.16.1 Licence Endorsement: -

- In list of Licences in action Click Apply Endorsement as shown in figure 63.
- The Endorsement is used to apply fresh application all the steps are same As the fresh application.

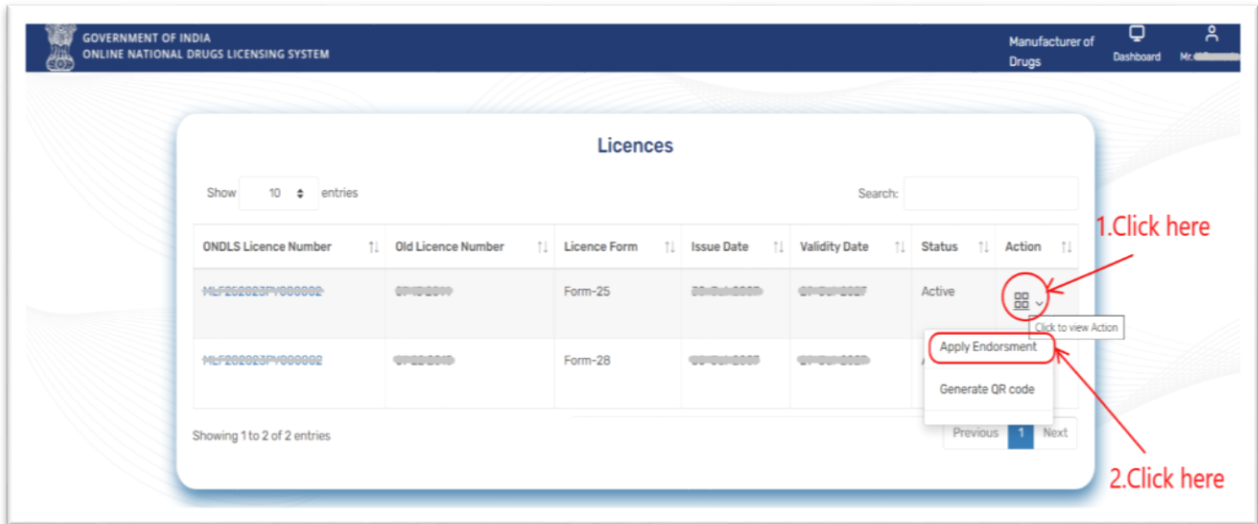


Figure 63: Endorsement

1.16.2 Generate QR Code: -

- In list of Licences in action Click Generate QR Code as shown in figure 63.

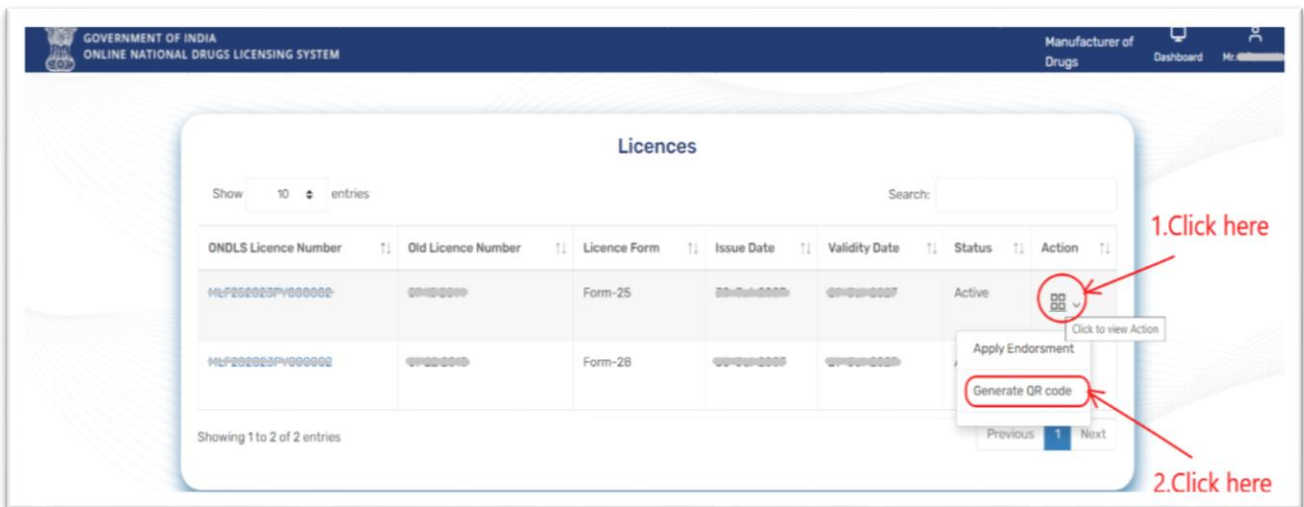


Figure 64: Generate QR Code

1.17 Certificate: -

- In Dashboard click on Certificates as shown in figure 65.

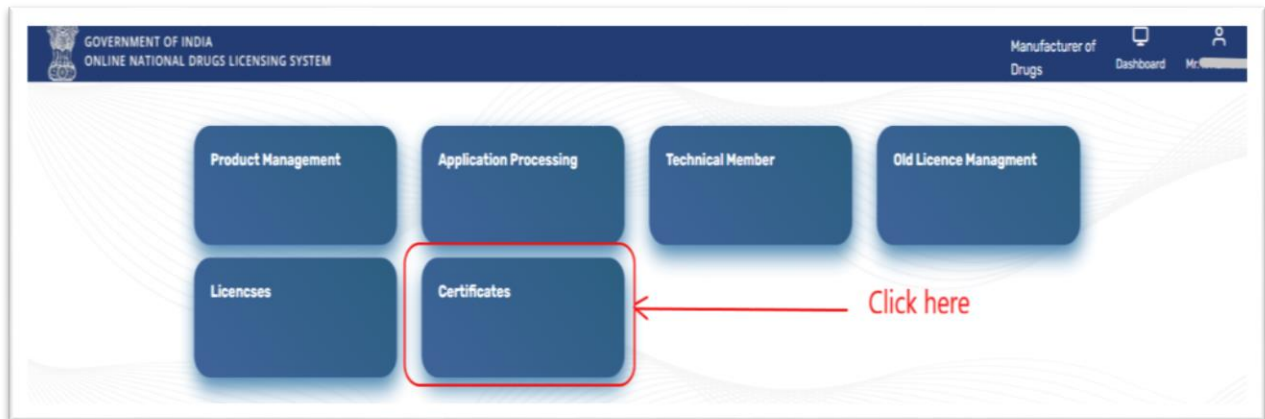


Figure 65: Certificates

- In Certificates show list of certificates as shown in figure 66.

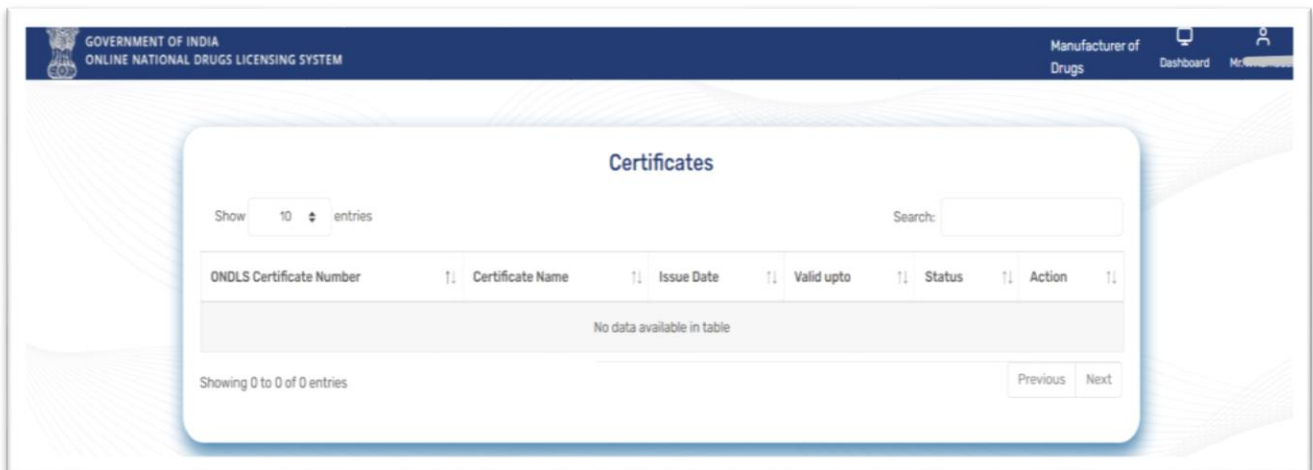


Figure 66: Endorsement

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