

Online National Drugs Licensing System (ONDLS)

USER MANUAL For WHO-GMP / COPP

CENTRE FOR DEVELOPMENT OF ADVANCED COMPUTING

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WHO-GMP Login

1. Homepage

- Open the link for online Licensing “www.statedrugs.gov.in” after that click on “Login/ Register” as shown in figure 1.



Figure 1: Home Page

1.1 Login (User Name and Password)

- Login using username, password and Captcha then click on Validate and proceed as show in figure 2.

➤ Figure 2: Sign in (Username and Password)

1.2 Login (OTP)

- Enter registered mobile number and then Press “Get OTP” Button as shown in figure 3.

REGISTER OR SIGN IN
An OTP will be sent to your mobile number for verification

Enter your mobile number

GET OTP

By Sign In/Registration, I agree to the Terms of Service and Privacy Policy

OR

SIGNIN WITH USER NAME AND PASSWORD

Figure 3: Sign In (Mobile number)

- You will get OTP on your Mobile number. Enter your OTP Then Press “Validate Proceed” Button as shown in figure 4.

OTP VERIFICATION
An OTP will be sent to your mobile number for verification
XXX XXX 8888

One Time Password

An OTP has been sent to your registered Email Id and Mobile Number
OTP SENT 54

VALIDATE & PROCEED

By Sign In/Registration, I agree to the Terms of Service and Privacy Policy

OR

SIGNIN WITH USER NAME AND PASSWORD

➤ Figure 4: OTP verification through registered mobile number

WHO-GMP Dashboard

2. Homepage

- After login on ONDLS portal you will be redirected to this page. Click on Application processing as shown in Figure 5.

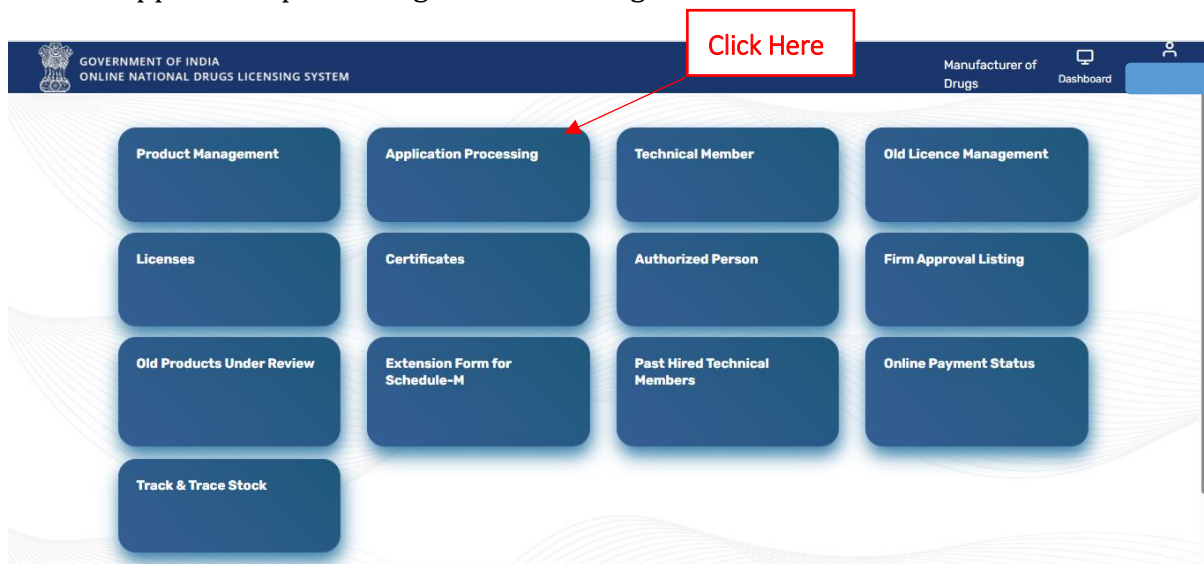


Figure 5: Dashboard

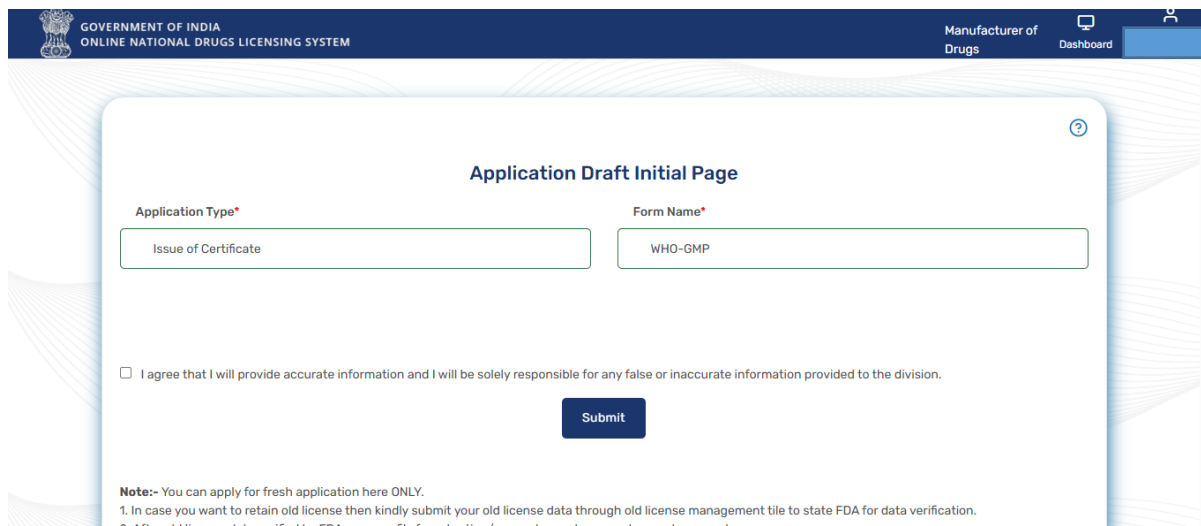
2.1 Application Processing

- After clicking on Application processing page open like this. From here you can see your application Draft, Submitted, Approved & the below tiles Application for your reference. Click on Fresh Application Submission as shown in figure 6.



Figure 6: Application Page

- After clicking on Fresh application tiles, a page open like this as shown in figure 7(a). You have to fill all details and submit.

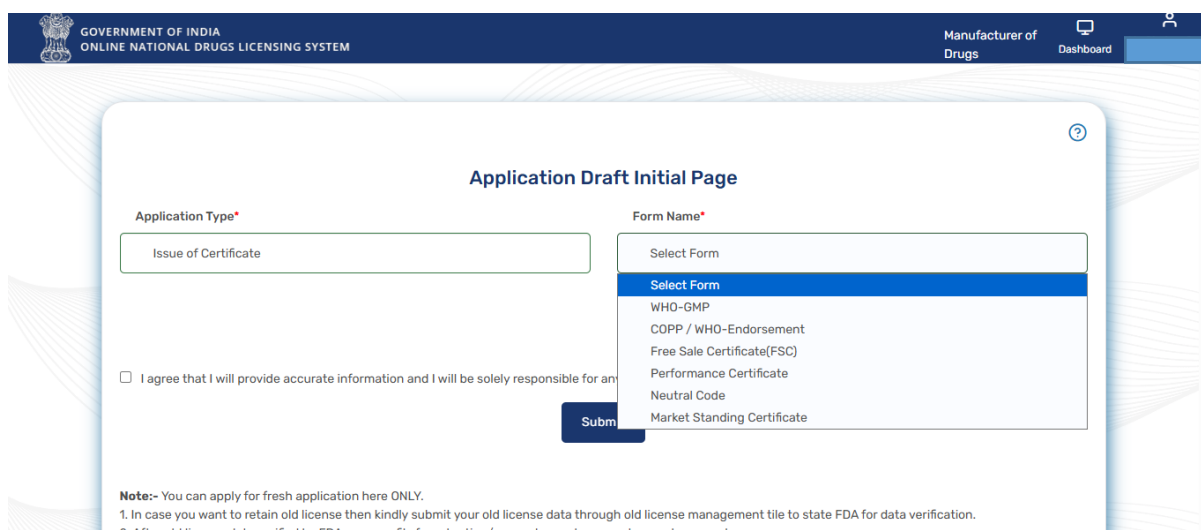


The screenshot shows the 'Application Draft Initial Page' with the following details:

- Application Type*:** Issue of Certificate
- Form Name*:** WHO-GMP
- I agree that I will provide accurate information and I will be solely responsible for any false or inaccurate information provided to the division.
- Submit** button
- Note:-** You can apply for fresh application here ONLY.
1. In case you want to retain old license then kindly submit your old license data through old license management tile to state FDA for data verification.
2. After old license data verified by FDA you may file for retention/renewal or endorsement or post approval.

Figure 7(a): Initial Page

- This page allows users to create a new application by selecting the application type and choosing the required form (e.g., WHO-GMP, FSC, COPP). Users must accept the declaration and click **Submit** to proceed. Applicable only for fresh applications. From here you can apply for the below listed certificates as shown in Figure 7(b).
- **WHO-GMP-** If you are applying for fresh application you only select WHO-GMP.
- **COPP/WHO- Endorsement-** If you are adding new product on the same Lab then you have to apply for copp/who-endorsement.



The screenshot shows the 'Application Draft Initial Page' with a dropdown menu open for 'Form Name*':

- Application Type*:** Issue of Certificate
- Form Name*:** Select Form (dropdown menu)
- I agree that I will provide accurate information and I will be solely responsible for any...
- Submit** button
- Note:-** You can apply for fresh application here ONLY.
1. In case you want to retain old license then kindly submit your old license data through old license management tile to state FDA for data verification.
2. After old license data verified by FDA you may file for retention/renewal or endorsement or post approval.

The dropdown menu for 'Form Name*' contains the following options:

- Select Form
- Select Form
- WHO-GMP
- COPP / WHO-Endorsement
- Free Sale Certificate(FSC)
- Performance Certificate
- Neutral Code
- Market Standing Certificate

Figure 7(b): Certification page

- This page allows users to select the licence, product, and brand for approval under WHO-GMP. If applying for COPP, users must also select the target country from the dropdown list. After entering the required details, users can proceed to save and confirm the application as shown in Figure 7(c).

(Select Product For Approval with WHO-GMP. Select Country only if COPP is Required.)

Select Licence*

Select Product*

Clarithromycin (Film Coated Tablet) [Export Product] [10120241201006]

*** Product could be selected from selected Dosage

Select Brand

Add Brand

Brand Will Reflect After Successfully Uploading of Form-51

Select Country

Select

Afghanistan

Albania

Algeria

American Samoa

Andorra

Save

Confirm and

Figure 7(c): Add Country name from COPP

- Review and confirm your firm's registered details, including name, address, site type, and license information. Select an authorized person and save the details to proceed with the application process as shown in figure 8.

GOVERNMENT OF INDIA
ONLINE NATIONAL DRUGS LICENSING SYSTEM

Manufacturer of Drugs

Dashboard

Firm Detail Confirmation

Applicant Firm Details

Firm Name :- Emc...

Firm Constitution :- Public LTD.

Firm Address :- ...

Site Type :- Own Site

Site Id :- ...

Authorized Person

Select

Save Details

Figure 8: Registered Detail

- Select product for approval with WHO-GMP with valid Licence. Add brand name & select country only if COPP is required as shown in figure 9.

GOVERNMENT OF INDIA
ONLINE NATIONAL DRUGS LICENSING SYSTEM

Manufacturer of Drugs | Dashboard | Jan Rather

Application for WHO-GMP

(Select Product For Approval with WHO-GMP. Select Country only if COPP is Required.)

Select Licence*
select

Select Product*
select
*** Product could be selected from selected Dosage

Select Brand
[] Add Brand
Brand Will Reflect After Successfully Uploading of Form-51

Select Country
[]
*** If country is selected, corresponding COPP certificate will be issued.

Save

Confirm and Proceed

Figure 9: Product approval

2.2 Add Brand Name

- Choose the appropriate brand linked to the selected license from the dropdown list. Only approved brands will be displayed. If the required brand is not available, use the “**Add Brand**” option to create a new one.as shown in Figure 10.

GOVERNMENT OF INDIA
ONLINE NATIONAL DRUGS LICENSING SYSTEM

Manufacturer of Drugs | Dashboard | Mr. Ghulam Qadir Jan Rather

Application for WHO-GMP

(Select Product For Approval with WHO-GMP. Select Country only if COPP is Required.)

Select Licence*
MLF282024JK000001 [Approved]

Select Product*
Clarithromycin (Film Coated Tablet) [Export Product] [10120241201102]
*** Product could be selected from selected Dosage

Select Brand
[Select] Add Brand

Select Country
[]
*** If country is selected, corresponding COPP certificate will be issued.

Save

Confirm and Proceed

Figure 10: Brand Name

- Clicking on Add Brand you will be redirected to this page. After that you have to fill all the detail like Brand Name & Brand detail as shown in figure 11.

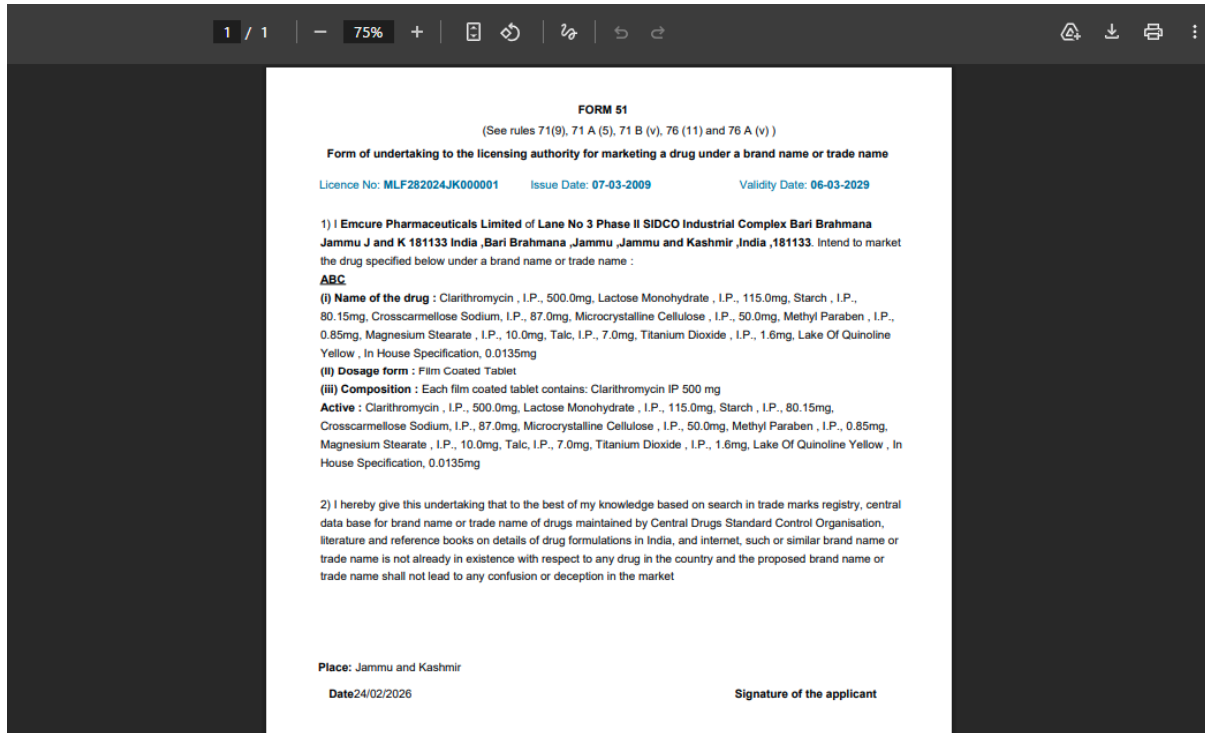
Figure 11: Brand Detail

- After filling all detail, you will be redirected to this page. You have to generate the Form 51 and upload it as shown in Figure 12(a)

Select	Brand Name	Brand Detail	Action
<input type="checkbox"/>	Acem - 500	NA	
<input checked="" type="checkbox"/>	ABC	XYZ	

Figure 12(a): Generate Form 51

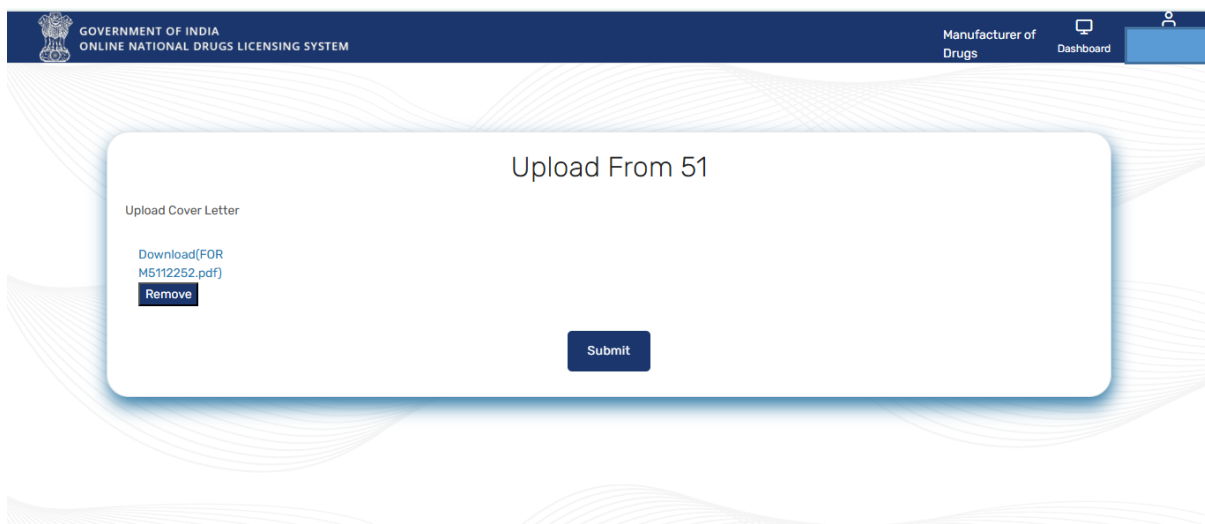
- Generate Form 51 after that you have to download it and sign it and upload it as shown in Figure 12(b).



The image shows a digital document titled "FORM 51" with the subtitle "(See rules 71(9), 71 A (5), 71 B (v), 76 (11) and 76 A (v))". The main heading is "Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name". It includes fields for "Licence No: MLF282024JK000001", "Issue Date: 07-03-2009", and "Validity Date: 06-03-2029". The text describes the applicant as "Emcure Pharmaceuticals Limited of Lane No 3 Phase II SIDCO Industrial Complex Bari Brahmana Jammu J and K 181133 India, Bari Brahmana, Jammu, Jammu and Kashmir, India, 181133" and states their intention to market a drug under the brand name "ABC". It provides detailed information about the drug's composition, including "Clarithromycin, I.P., 500.0mg, Lactose Monohydrate, I.P., 115.0mg, Starch, I.P., 80.15mg, Crosscarmellose Sodium, I.P., 87.0mg, Microcrystalline Cellulose, I.P., 50.0mg, Methyl Paraben, I.P., 0.85mg, Magnesium Stearate, I.P., 10.0mg, Talc, I.P., 7.0mg, Titanium Dioxide, I.P., 1.6mg, Lake Of Quinoline Yellow, In House Specification, 0.0135mg". It also specifies the dosage form as "Film Coated Tablet" and the composition of each tablet. A declaration follows, stating that the applicant has searched trade marks, central data base, literature, and reference books to ensure no confusion or deception in the market. The form is signed by the applicant on "24/02/2026" in "Jammu and Kashmir".

Figure 12(b): Form 51

- Upload form 51 and submit it as shown in Figure 12(c).



The image shows a web interface for uploading a document. At the top, it says "Upload From 51". Below this, there is a section for "Upload Cover Letter". A file named "Download(FOR M5112252.pdf)" is listed with a "Remove" button next to it. At the bottom of the upload area, there is a "Submit" button. The interface is part of the "GOVERNMENT OF INDIA ONLINE NATIONAL DRUGS LICENSING SYSTEM" and includes a user profile icon and "Manufacturer of Drugs" and "Dashboard" links in the top right corner.

Figure 12(c): Upload Form 51

- This page displays the selected license and product details for verification. Users can view brand, country, or product information, and perform actions like delete if required. After reviewing all details, click **Confirm and Proceed** to move forward with the application as shown in Figure 13(c).
- **View Brand:** Displays the selected brand details after successful upload, allowing users to verify the brand information.
- **View Country:** Shows the country associated with the selected brand/product and related certification details.
- **View Product:** Provides complete information about the selected product, including composition and specifications.
- **Delete Product:** Allows users to remove the selected product from the list permanently.

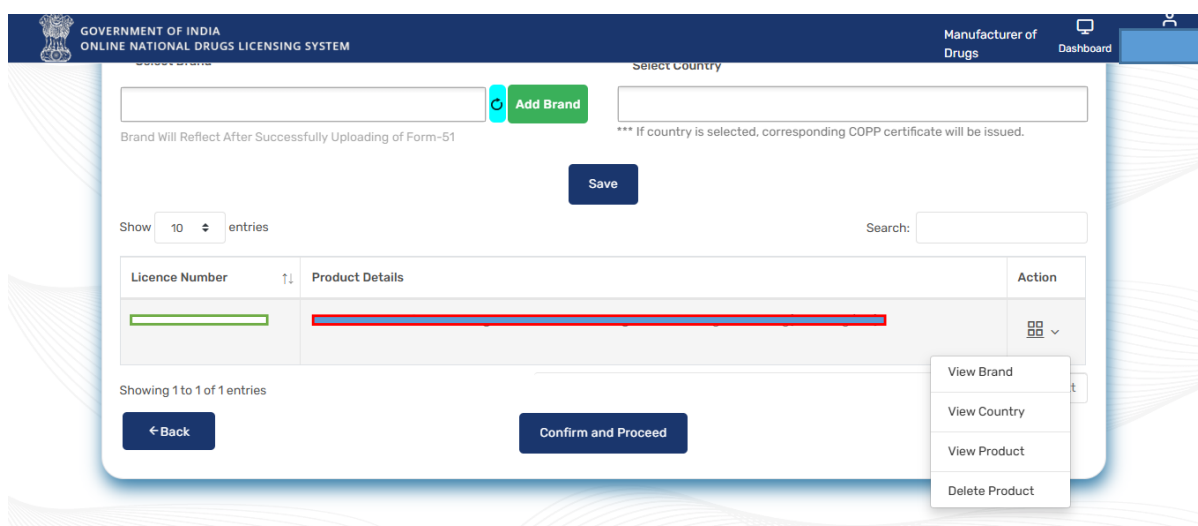


Figure 13(c): Product Information

2.3 Document to Upload

- After filling all details, you will be redirected to Documents checklist which you have to upload as shown in Figure 14(a).

The screenshot shows the 'Checklist Document Validation and Upload Page' for a manufacturer of drugs. The page title is 'Checklist Document Validation and Upload Page'. It features a search bar and a 'Show 10 entries' dropdown. The main content is a table with three columns: 'S.No', 'CheckList Item', and 'Document Upload Status'. The table lists 10 items, each with a red circle icon in the status column, indicating that documents are not yet uploaded. At the bottom, there is a 'Proceed' button and a pagination control showing '1 to 10' and 'Previous 1 2 3 Next'.

S.No	CheckList Item	Document Upload Status
1	* Application with covering letter on company's letter head duly signed and stamped by Authorized signatory indicating the name and designation of the authorized signatory along with the name and address of the firm	⊘
2	* Site Master file (as specified under WHO TRS 961) including Manufacturing layout Schematic diagram of water system specifying circulation loop and MOC Schematic diagram of HVAC system specifying terminal filter configuration List of equipment and Instrument. List of major changes after last inspection	⊘
3	* List of major changes after last inspection	⊘
4	* Section applied for COPP as per WHO Certification Scheme	⊘
5	* List of Products applied for issuance of Certificate of Pharmaceutical Product	⊘
6	* Copy of Product permission for product(s) applied for COPP	⊘
7	* List of Not of Standard Quality (NSQ) sample declared by State or Central Drugs Testing Laboratory	⊘
8	* Export Data of last 3 years in case of revalidation	⊘
9	* Application Form For Certificate of Pharmaceutical Product	⊘
10	Products Wise Checklist	

Figure 14(a): Checklist Documents.

- Upload all documents and proceed as shown in Figure 14(b).

The screenshot shows the 'Checklist Document Validation and Upload Page' for a manufacturer of drugs. The page title is 'Checklist Document Validation and Upload Page'. It features a search bar and a 'Show 10 entries' dropdown. The main content is a table with three columns: 'S.No', 'CheckList Item', and 'Status'. The table lists 7 items, each with a green checkmark icon in the status column, indicating that documents have been successfully uploaded. At the bottom, there is a 'Proceed' button and a pagination control showing '21 to 27' and 'Previous 1 2 3 Next'.

S.No	CheckList Item	Status
10.1.10	* Analytical Method Validation / Verification Protocol of the each applied product	✓
10.1.11	* Analytical Method Validation / Verification Report of the each applied product	✓
10.1.12	* List of Reference/ working/ primary standards or materials	✓
10.1.13	* Stability study data report as per requirements mentioning batch size. (should be presented in tabular form with details of Batch No, Batch size, Date of Manufacturing, Date of initiation, Packaging details) Accelerated (6 months, Real Time (12 months), Forced degradation/stress studies (if applicable), Post approval Stability Protocol and Stability Commitment as per WHO TRS 1010 Annex 10	✓
10.1.14	* List of the major changes after last inspection conducted	✓
10.1.15	* Proposed storage statement and shelf-life	✓
10.1.16	* Product summary Sheet	✓

Figure 14(b): Upload Documents.

2.4 Payment Details

- After uploading all checklist documents you will be redirected to the payment page. You have to fill all the offline payment details and tap on Save & Proceed Button as shown in Figure 15.

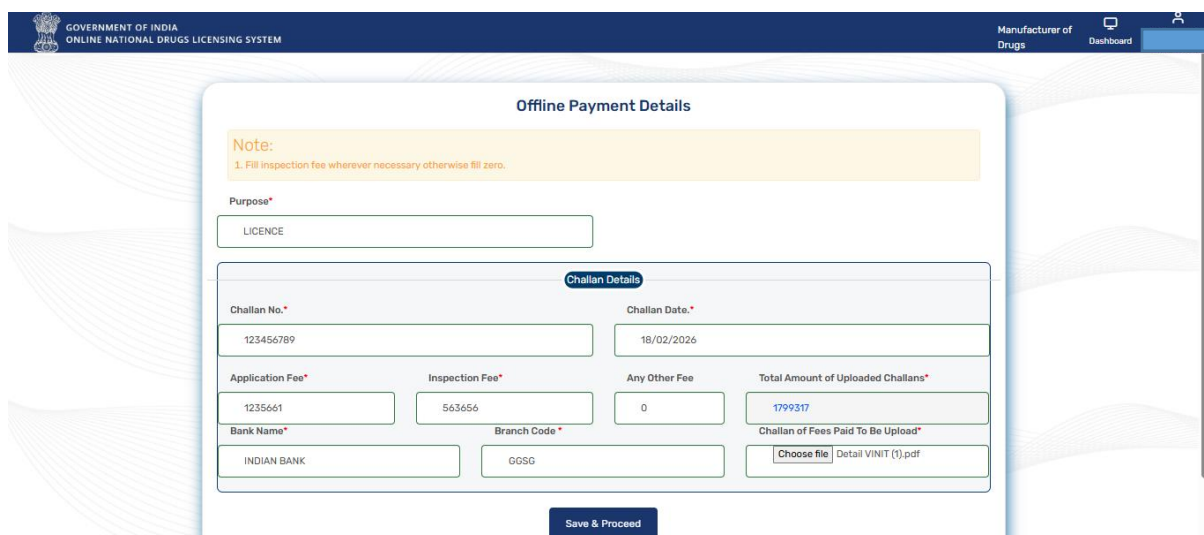


Figure 15: Offline Payment Detail.

- This page provides a preview of the firm's site information, including firm name, address, contact details, and identification numbers. Users can review uploaded documents and verify all details before proceeding further with the application Preview as shown in Figure 16.

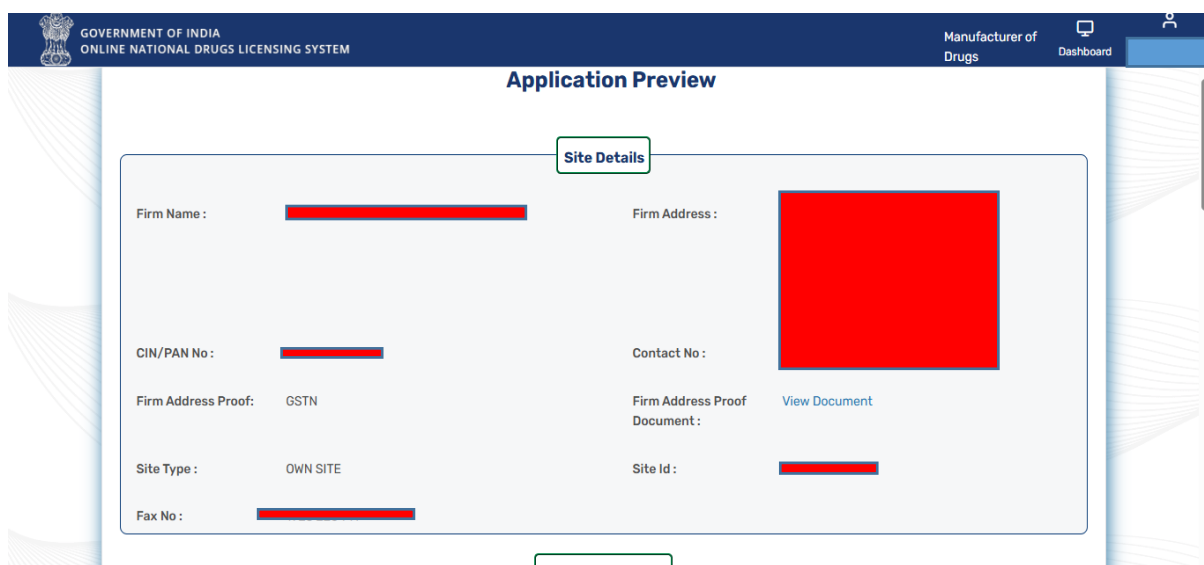


Figure 16: Application Preview

2.5 WHO- Associated Product Details

- Your product detail appears here for which you have applied for tap on Final Submit as shown in figure 17.

The screenshot displays the 'WHO-Associated Product Details' section of the ONLINE NATIONAL DRUGS LICENSING SYSTEM. The interface shows a table with one entry. The table has columns for 'Licence Number', 'Product Details', and 'Action'. The entry details are as follows:

Licence Number	Product Details	Action
MLF282024JK000001	Clarithromycin Tablets IP 500 mg-LP. 500.0mg(Bulk Drug/API) [10120241201102]	[Grid Icon] [Dropdown Arrow]

Below the table, there is a 'Final Submit' button. The interface also shows pagination controls: 'Showing 1 to 1 of 1 entries' and 'Previous 1 Next'.

Figure 17: Product Details

2.6 Final Submit

- After Final submit your application has been submitted. And a new file no. has been Created as shown in Figure 18.

The screenshot displays a success message on the ONLINE NATIONAL DRUGS LICENSING SYSTEM interface. The message is as follows:

Your Application has been submitted successfully. Kindly note your file no. [JK/WHOGMP/2026/00014](#) for future correspondence.

Figure 18: Application Number