THE OFFICIAL WEBSITE OF DIRECTORATE HEALTH SAFETY & REGULATION
GOVT.OF HIMACHAL PRADESH

USER MANUAL

Drug Manufacturing License

Department Of Health Safety and Regulations

URL Homepage: https://dcla.hp.gov.in/

GOVERNMENT OF HIMACHAL PRADESH

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SUPPORTING DOCUMENTS

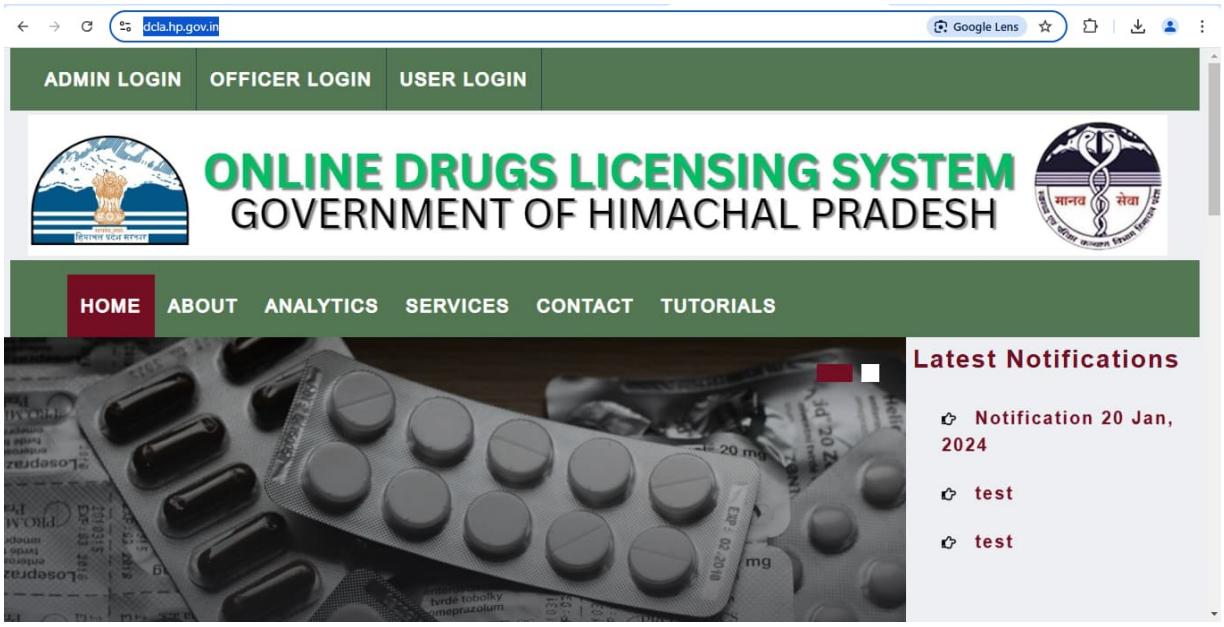
1) Covering Letter.
2) Specific Power of Attorney in favour authorized signatory for submitting application on behalf of the company
3) Site Plan and layout of the building with the name, address, scale, measurements of the area as per schedule- T requirement (For Ayurvedic, siddha, Unani) & as per Schedule –M Requirement (Allopathic Medicines) & as per Schedule-M-II requirement
4) Self-attested copies of documents pertaining to the possession of premises such as, register ownership /rent /lease/allotment letter /Possession Letter, Tax Receipt, (Documents should be Registered with appropriate Authority)
5) Consent to establish from State pollution control Board.
6) List of Directors, Partners, Trustees, along with ROC Copy Registered Partnership deed, Trust deed
7) List of Competent Technical Staff, with their qualification, Registration, Experience, previous FDA Approvals.
8) Appointment/Acceptance Letter of Competent Technical staff of manufacturing Section.
9) Appointment/Acceptance Letter of Competent Technical staff of Testing Section
10) Section wise List of plant and Machineries
11) NOC of department of industrial safety &Health
12) Details of manufacturing Process, Process Flow Chart
13) AHU installation and validation Certificate
14) Water System installation and validation Certificate
15) Site Master File
16) Form 29 Licensed issued by SLA
17) Form 10 Issued by CDSCO where required
18) Constitution details of firms
19) A copy of New Drug permission if applicable. If not, justification.
20) Supporting data for BA/BE study where required
21) Stability studies data
22) Form 51 Undertaking
23) List of SOPs
24) Copy of Draft Labels
25) Challan of Fees Paid to Be Upload
26) Self-declaration of technical person
27) Any Other Document
28) Application in Form 24
29) self-declaration of directors

Applicable Fee

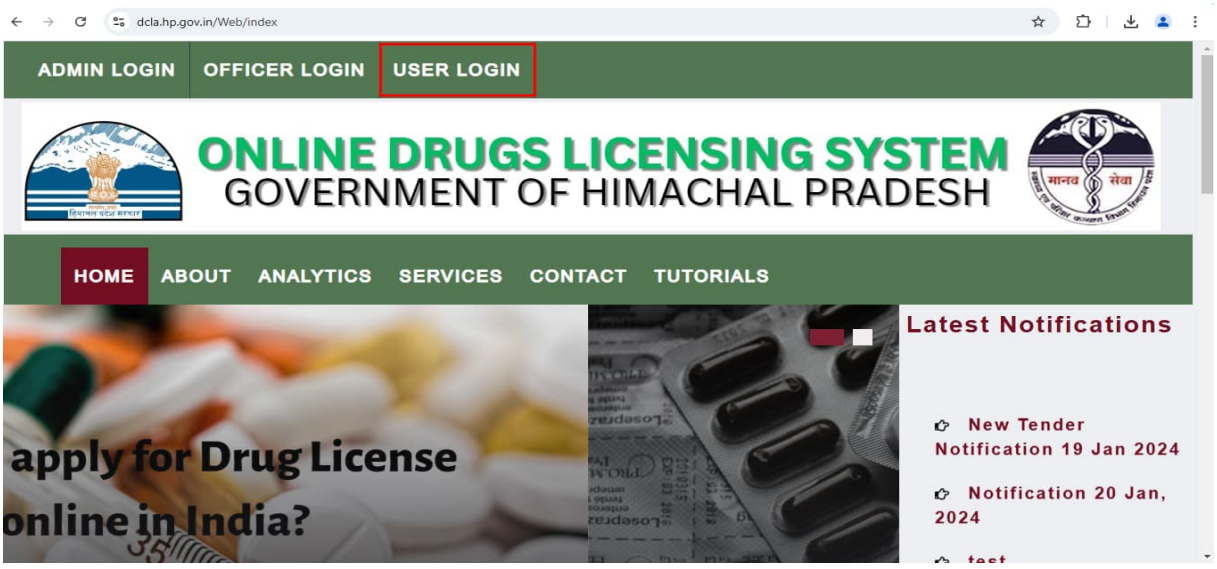
Sr. No	Name of the certificate	Existing Fees (In rupees)
1.	Grant/Retention of Drugs Manufacturing License/ Loan License	7500/-
2.	Grant/Retention of Cosmetics Manufacturing License/ Loan License	10000/-
3.	Grant/Retention of Retail/Wholesale License	1500/-
4.	Grant/Retention of Medical Devices (Class A & B)	5000/-
5.	Grant/Retention of Additional Product of Medical Devices	500/ Product
6.	Grant/Retention of Additional Product in Drugs License	300/ Product
7.	Grant/Retention of Additional Product in Cosmetics License	500/ Product
8.	GMP/ GLP Certificate	500/-
9.	Production Certificate, Non-Conviction Certificate, Capacity and Quality Certificate, Manufacturing and Marketing Certificate, Market Standing Certificate, Validity Certificate and any other certificate related to tender process.	500/-
10.	Grant of Test License on Form- 29	250/ Product
11.	Certificate as per WHO Guidelines	2000/-
12.	Certificate of Pharmaceutical Products (CoPP's)	300/ Product

ONLINE SUBMISSION OF APPLICATION

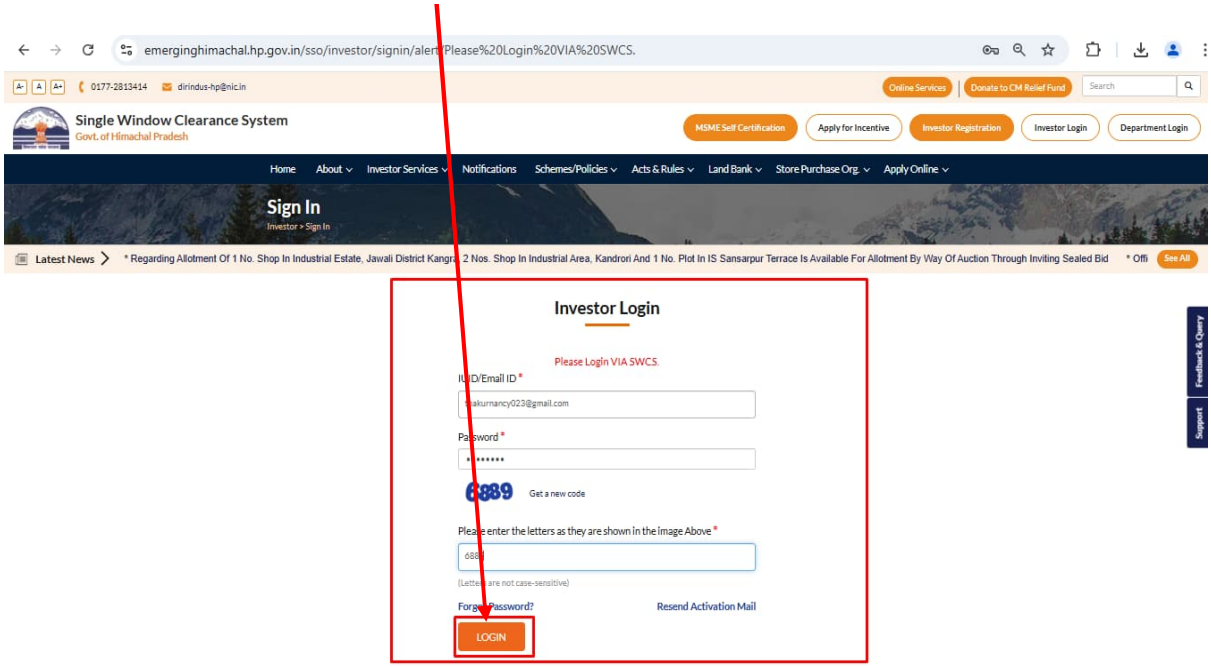
Step-1: Go to URL: https://dcla.hp.gov.in/ as highlighted below



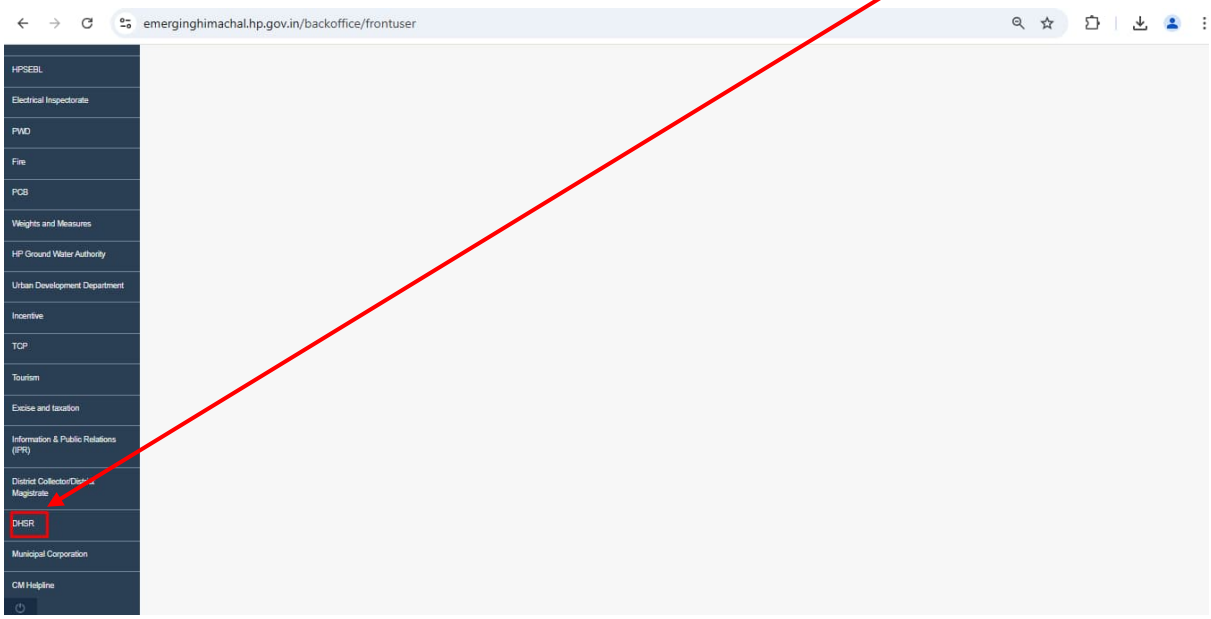
Step-2: Hover to "**User Login**" in the home page and click as shown in the picture below.



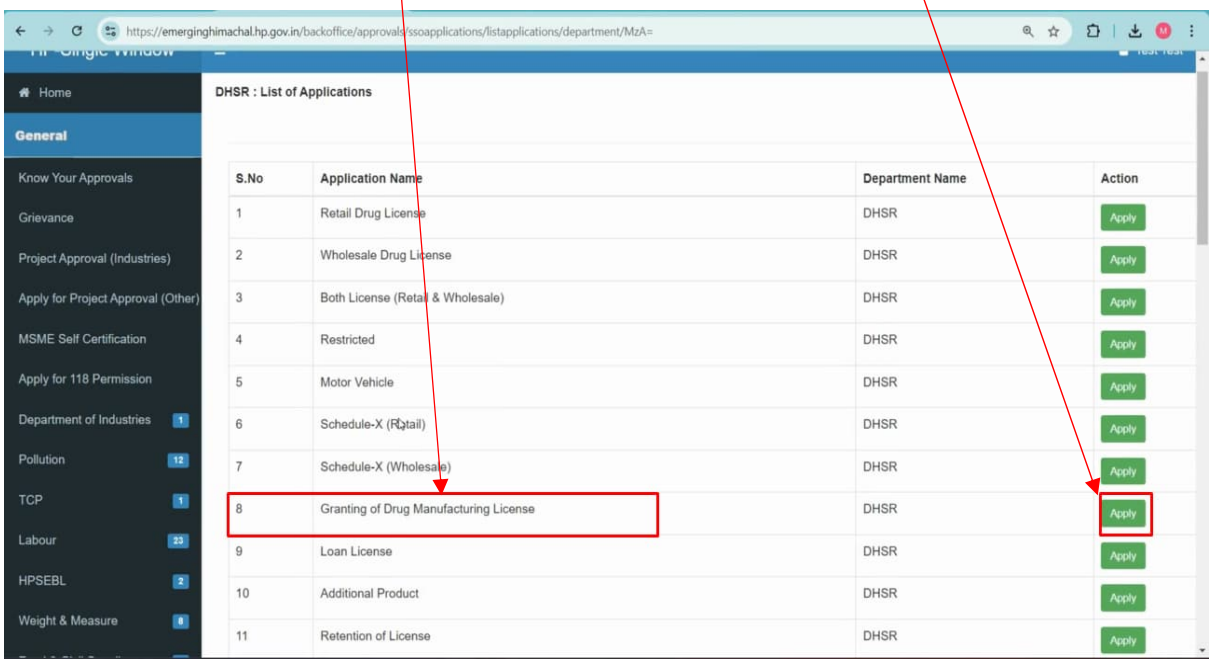
Step-3: Once user has clicked on user login, he/she will get redirected to a new webpage where he has to fill login details and click on '**Login**'



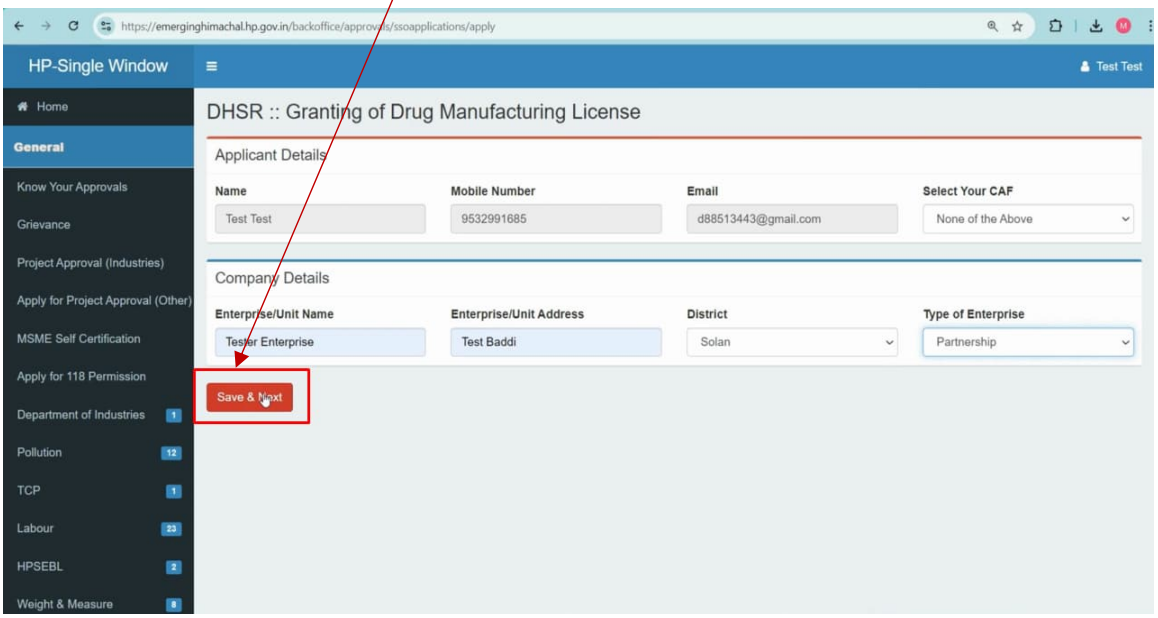
Step-4: Once user has logged in, he/she will scroll down the webpage and Click on **DHSR**.



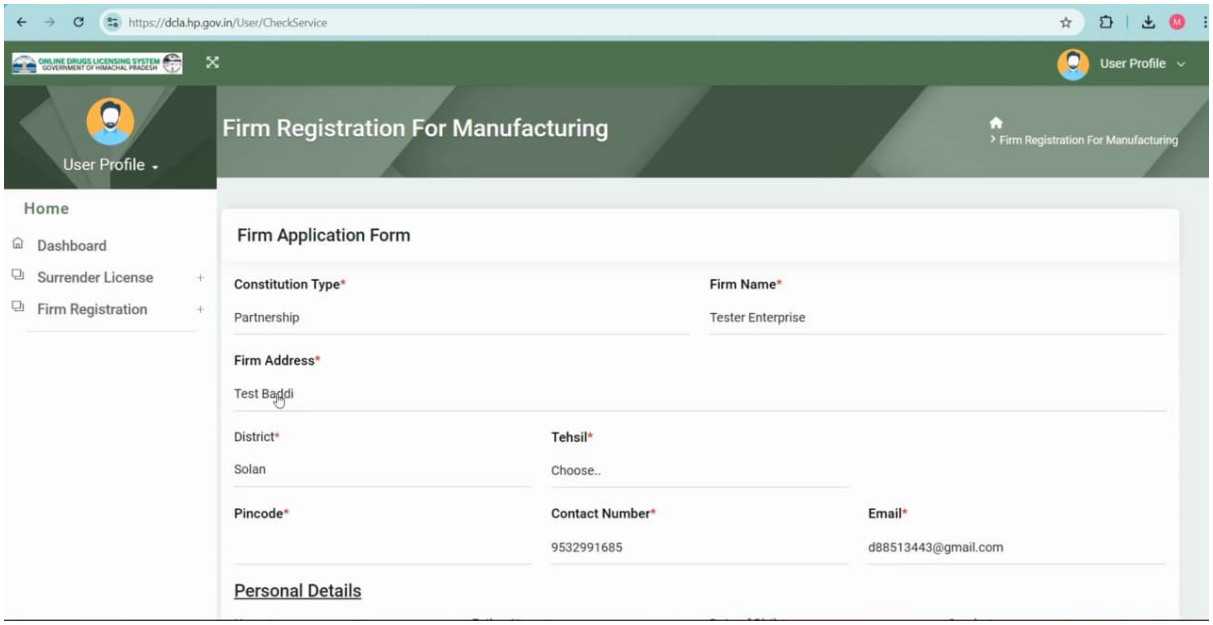
Step-5: Once user has clicked on DHSR he/she will get redirected to a new webpage where he selects service related to **Grant of Drug Manufacturing License** and click on **Apply**.



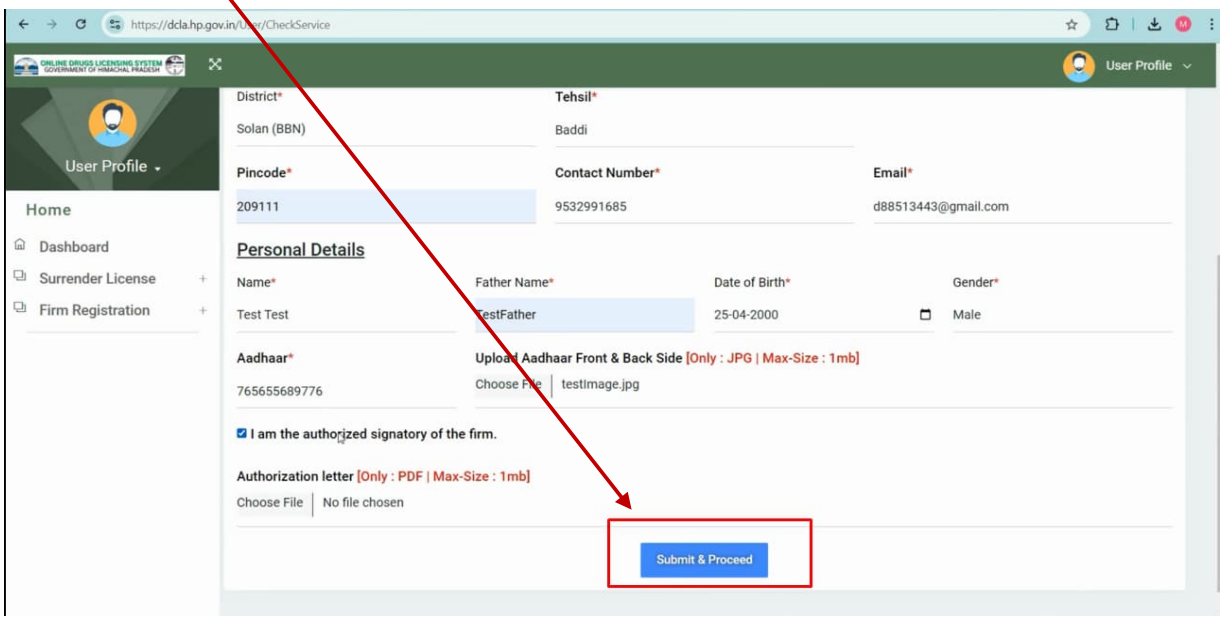
Step-6: Once the user has clicked on apply, he/she will get redirected to a new web page where he has to fill in the details and click on **'save & next'** as shown below.



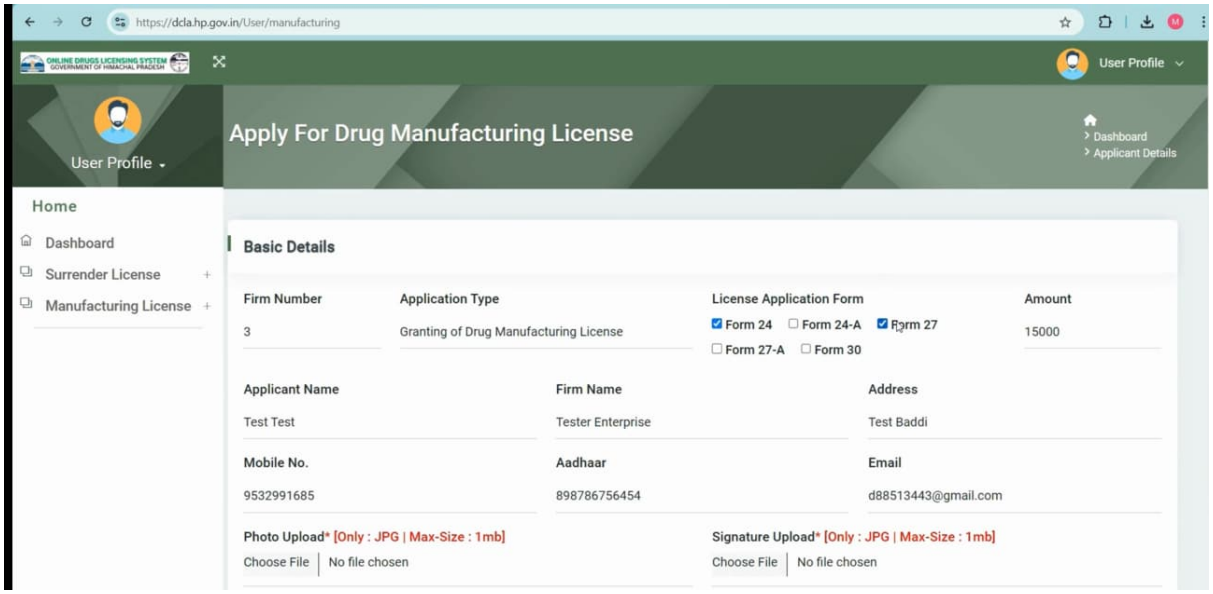
Step-7: Once the user has clicked on save and next, he/she will get redirected to a new web page where he has to fill in the details.



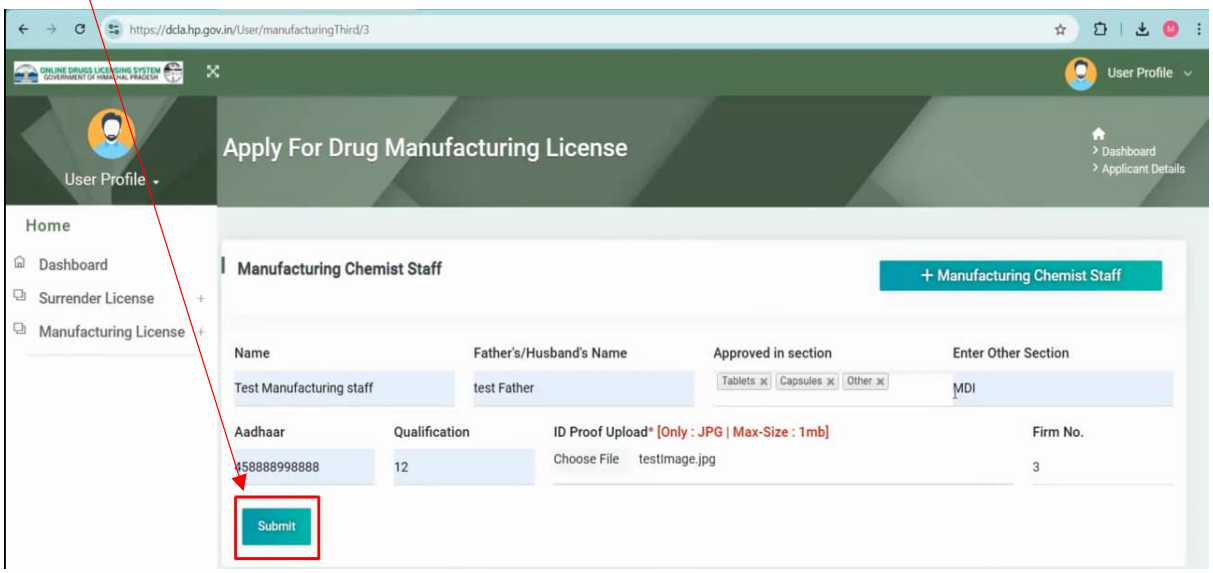
Step-8: Once the user has filled all information required in the application form, he/she will click on **Submit & Proceed**



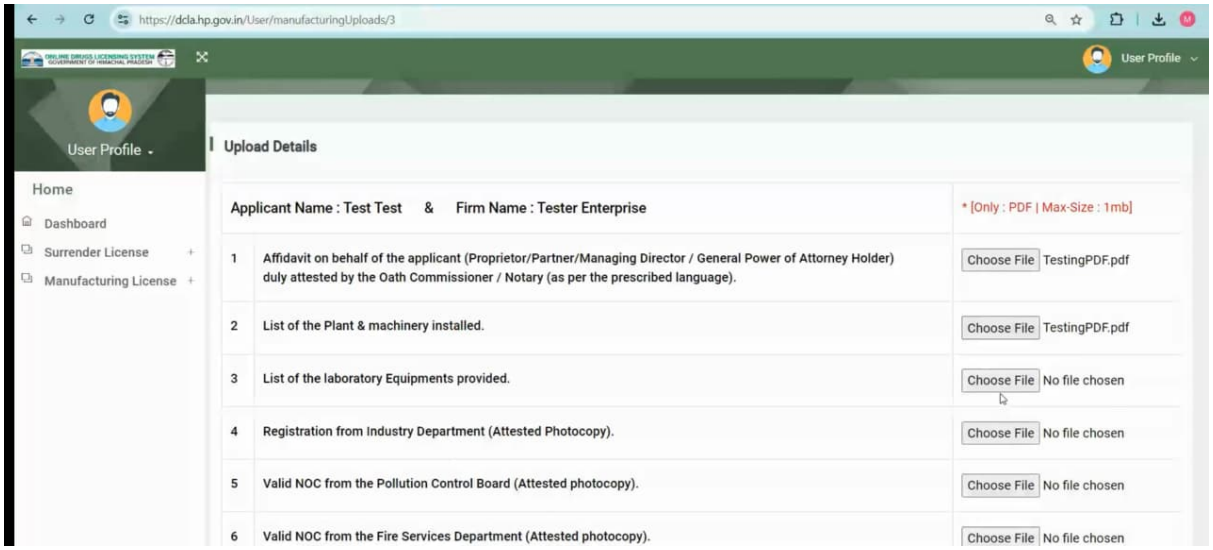
Step-9: Once the user has clicked on Submit & Proceed, he/she will get redirected to new webpage where the applicant fills the application form



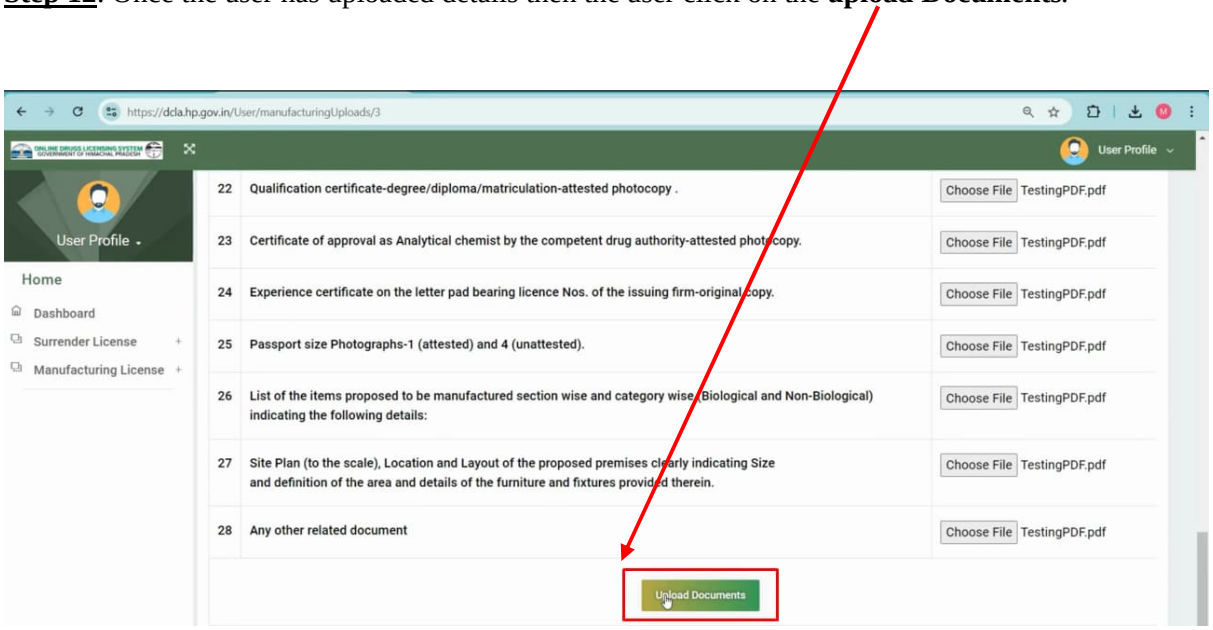
Step-10: Once the user has filled all information required in the application form, he/she will click on **Submit**



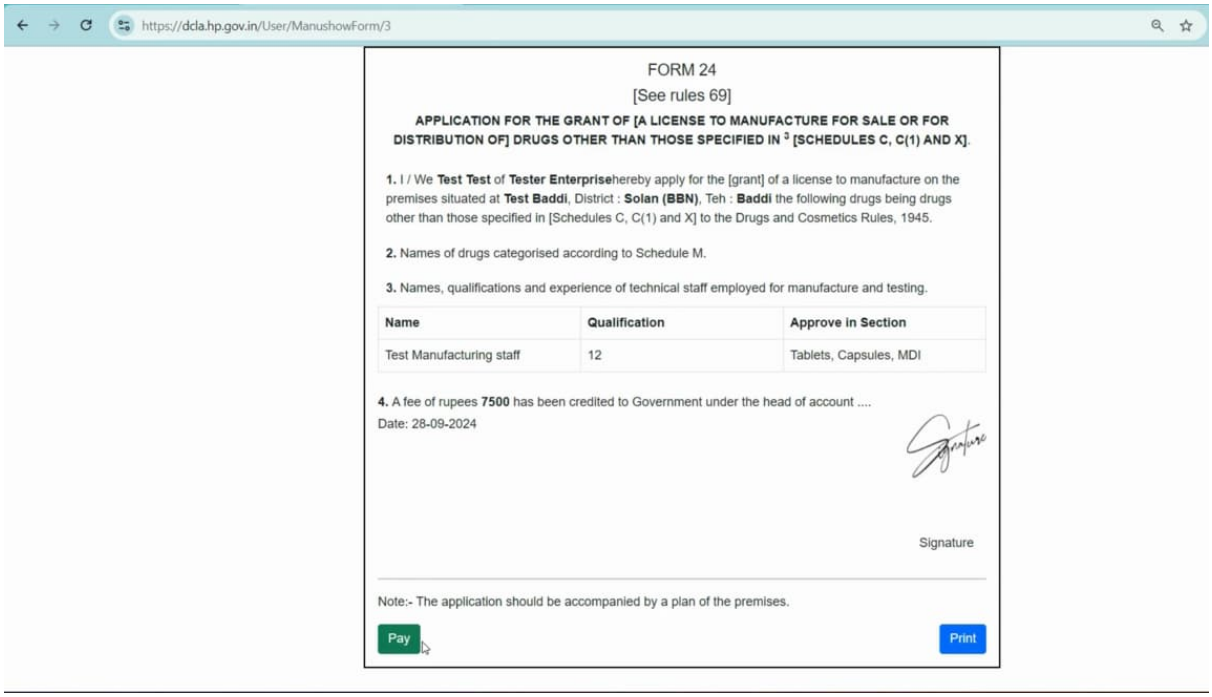
<u>Step 11</u>: Once the user has clicked on submit he/she will get redirected to new webpage where he has to upload details as shown below



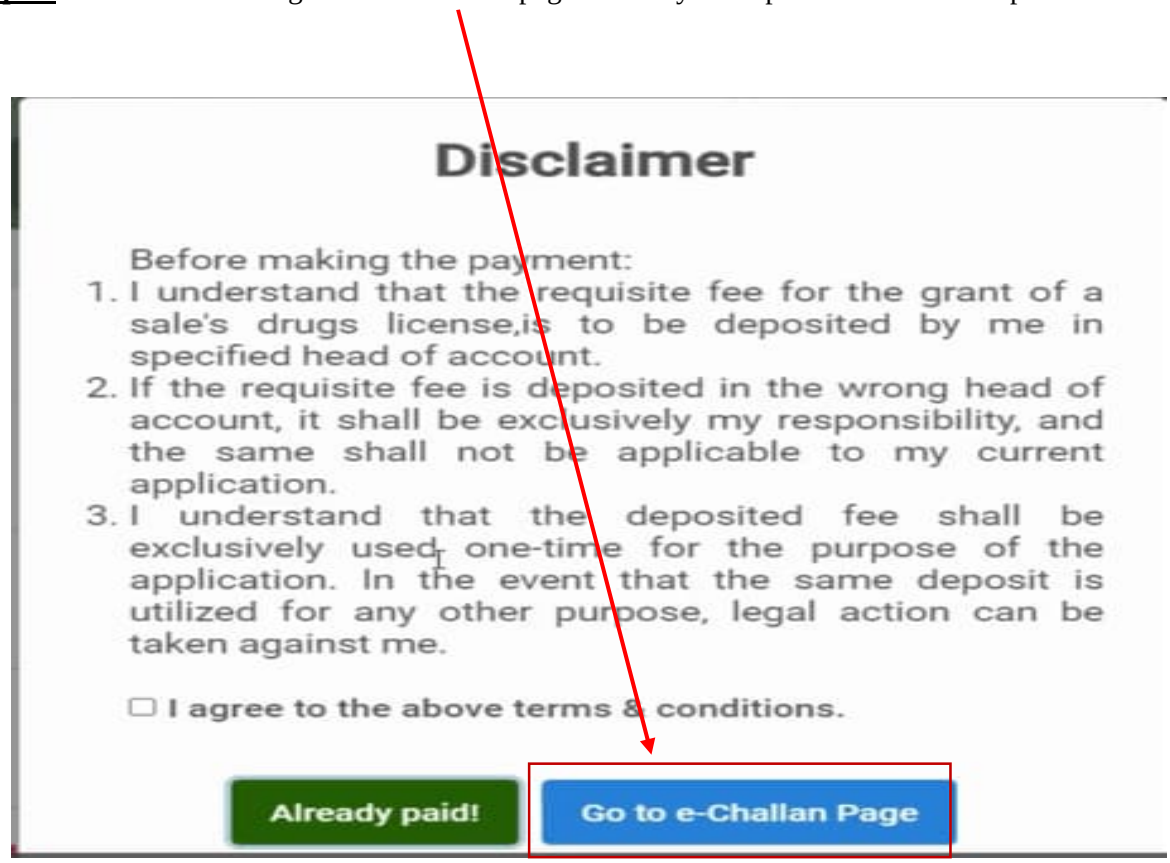
<u>Step 12</u>: Once the user has uploaded details then the user click on the **upload Documents**.



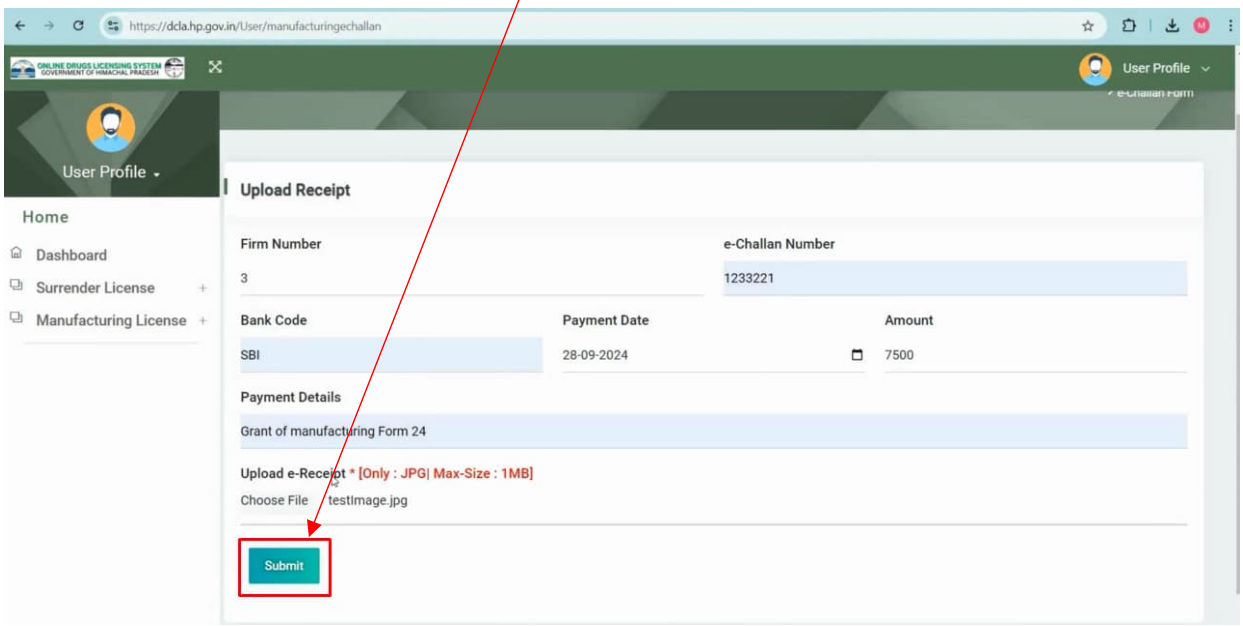
<u>Step 13</u>: Once the user has clicked on upload Documents, he/she will get redirected to a new web page where he will click on **Pay**.



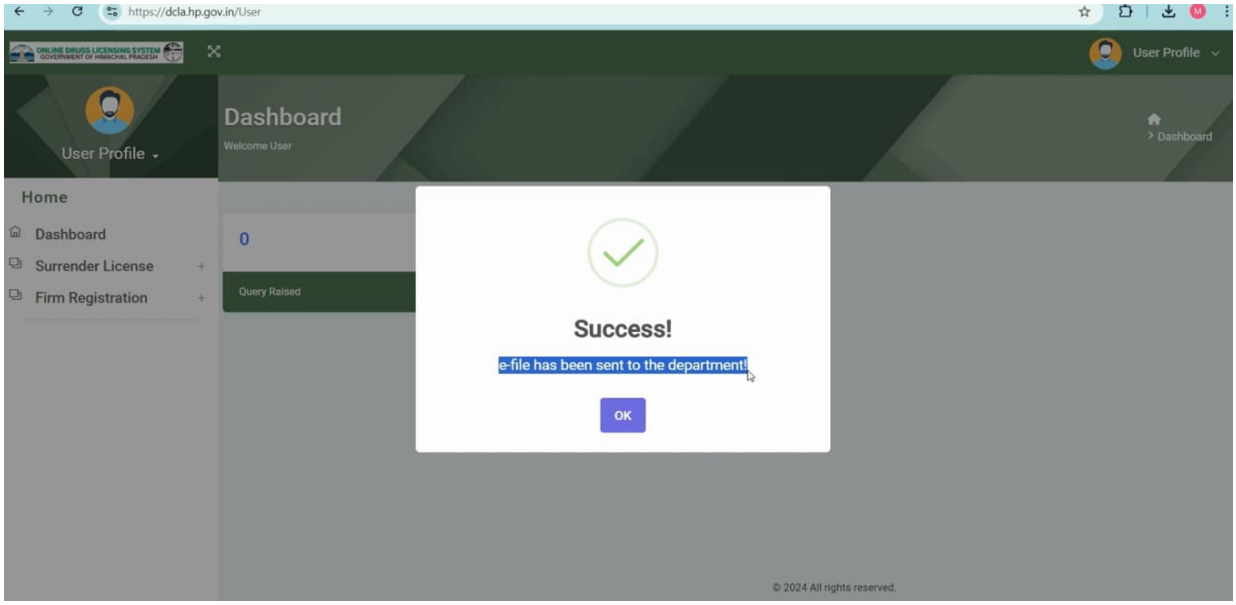
<u>Step 14</u>: Once the user has go to the **e-challan** page then they will upload the detail receipt .



<u>Step 15</u>: Once the user has clicked on e- challan he/she will get redirected to a new web page where he will fill the challan detail and click on **submit**



<u>Step 16</u>: Once the user has paid the e-challan fee fill will be send to the department for approval



Approved Certificate

FORM 25

(See rule 70)

[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN [SCHEDULES C, C(1) AND X]

1. Number of License: **HP-MNB-00001** Date of Issue: **22/11/2024**

2. **Dwarka Global Lifesciences** is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at **Plot No. 89,Industrial Area,Lodhi Majra,Manpura,Baddi, Solan (BBN), Nalagarh** under the direction and supervision of the following [competent technical staff]

(a) [Competent technical staff] (Names)

Manufacturing Chemist		
Name	Qualification	Approved in Section(s)
Jitendra Kumar	Bsc	Tablets, Capsules, External Preparations
Analytical Chemist		
Name	Qualification	Approved in Section(s)
Manohar Lal Verma	bsc	Chemical Testing, Instrumentation, Microbiological Testing

(b) Names of drugs (each item to be separately specified) : **Tablets, Capsules, External Preparations (Ointment) (General)**

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license, subject to the conditions applicable to license for sale.

4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the condition of licence and the provisions of the Drugs & Cosmetics Act 1940 (23 of 1940) and the Drugs Rules 1945 shall be assessed not less than once in three years or as needed per risk-based approach.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs & Cosmetics Act 1940.

Date **22/11/2024**

Dr. Kamlesh Naik
Licensing Authority

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.

3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69(5). This licence will be deemed to extend to the categories so endorsed.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.

FORM 28

(See rule 76)

[LICENCE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF DRUGS SPECIFIED IN SCHEDULES C AND C(1) EXCLUDING THOSE SPECIFIED IN SCHEDULES X]

1. Number of License: **HP-MB-00002** Date of Issue: **22/11/2024**

2. **Dwarka Global Lifesciences** is hereby licensed to manufacture at the premises situated at **Plot No. 89,Industrial Area,Lodhi Majra,Manpura,Baddi, Solan (BBN), Nalagarh** the following drugs being drugs specified in Schedules C and C(1) [excluding those specified in Schedules X] to the Drugs and Cosmetics Rules 1945.

(a)Names of Drugs : **Tablets, Capsules, External Preparations (Ointment) (General)**

(b) Name of approved [Competent technical staff]. (Names)

Manufacturing Chemist		
Name	Qualification	Approved in Section(s)
Jitendra Kumar	Bsc	Tablets, Capsules, External Preparations
Analytical Chemist		
Name	Qualification	Approved in Section(s)
Manohar Lal Verma	bsc	Chemical Testing, Instrumentation, Microbiological Testing

3. The licence authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence subject to the conditions applicable to licences for sale.

4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the condition of licence and the provisions of the Drugs & Cosmetics Act 1940 (23 of 1940) and the Drugs Rules 1945 shall be assessed not less than once in three years or as needed per risk-based approach.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs & Cosmetics Act 1940.

Date **22/11/2024**

Dr. Kamlesh Naik
Licensing
Authority

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.

2. If the licensee wants to undertake during the currency of the licence the manufacture of any drug specified in Schedules C and C (1) [excluding those specified in Schedule X] not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in rule 75(3). This licence will be deemed to extend to the items so endorsed.

3. Any change in the [competent technical staff] shall be forthwith reported to the Licensing Authority.

4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.