



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/>

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SUPPORTING DOCUMENTS

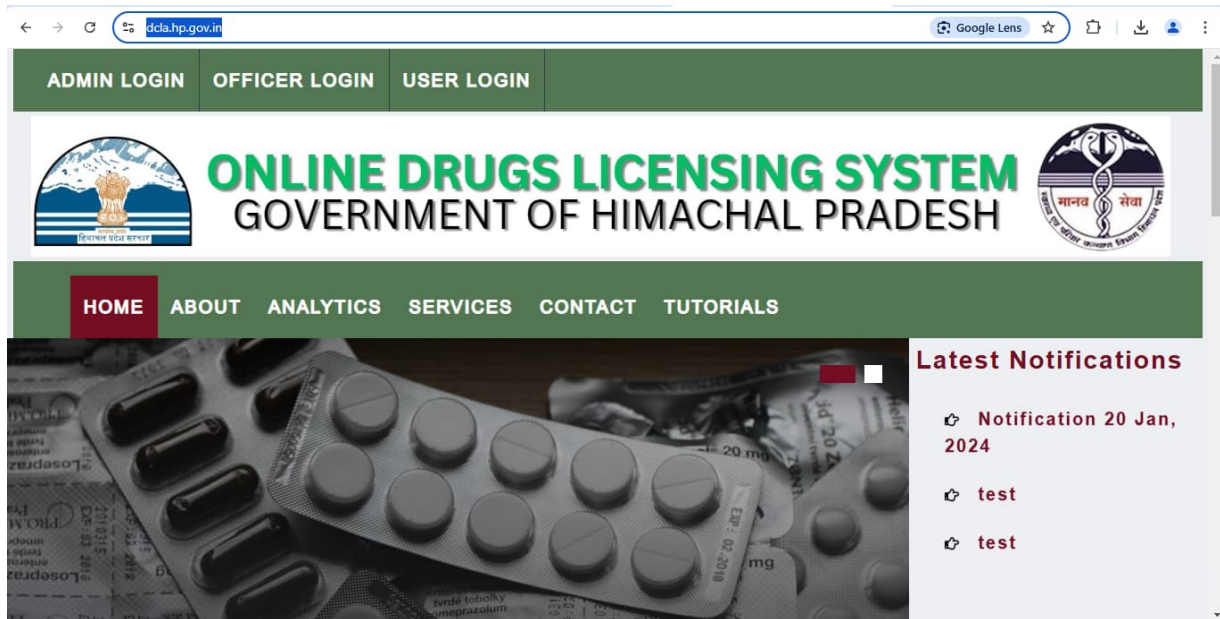
- 1) Covering Letter.
- 2) Specific Power of Attorney in favour authorized signatory for submitting application on behalf of the company
- 3) Site Plan and layout of the building with the name, address, scale, measurements of the area as per schedule- T requirement (For Ayurvedic, siddha, Unani) & as 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

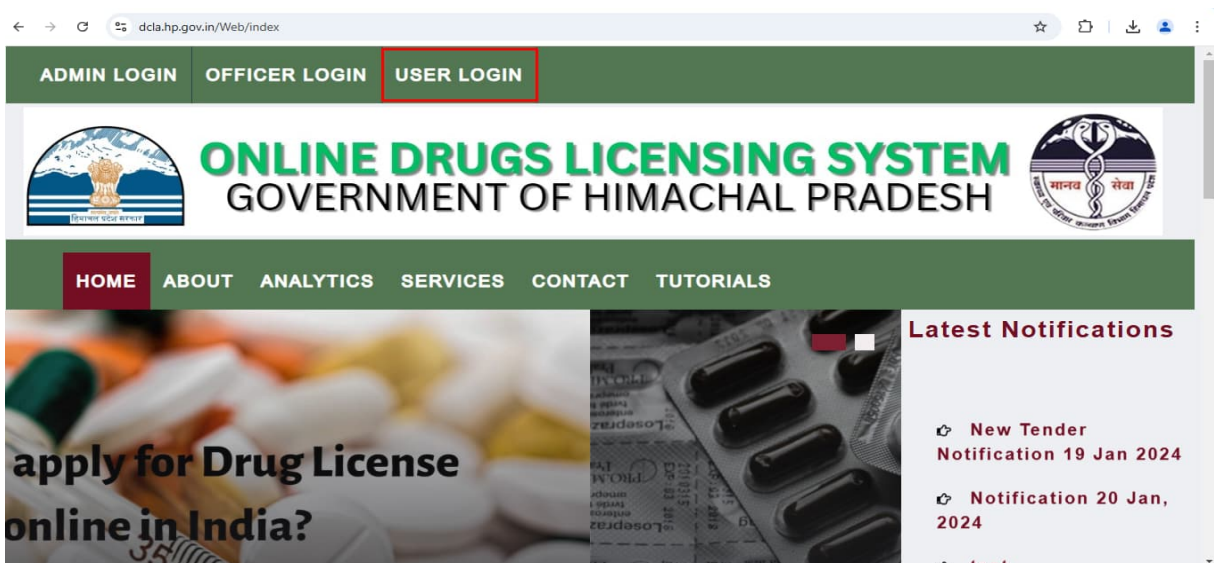
Sr. No	Name of the certificate	Existing Fees (In rupees)
1.	Grant/Retention of Drugs Manufacturing License/ Loan License	7500/-
2.	Grant/Retention of Cosmetics Manufacturing License/ Loan License	10000/-
3.	Grant/Retention of Retail/Wholesale License	1500/-
4.	Grant/Retention of Medical Devices (Class 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'

emerginghimachal.hp.gov.in/sso/investor/signin/alertPlease%20Login%20VIA%20SWCS.

0177-2813414 | dirindus-hp@nic.in | Online Services | Donate to CM Relief Fund | Search

Single Window Clearance System
Govt. of Himachal Pradesh

MSME Self Certification | Apply for Incentive | Investor Registration | Investor Login | Department Login

Home | About | Investor Services | Notifications | Schemes/Policies | Acts & Rules | Land Bank | Store Purchase Org. | Apply Online

Sign In
Investor > Sign In

Latest News > * Regarding Allotment Of 1 No. Shop In Industrial Estate, Jawali District Kangra, 2 Nos. Shop In Industrial Area, Kandrori And 1 No. Plot In IS Sansarpur Terrace Is Available For Allotment By Way Of Auction Through Inviting Sealed Bid * Off | See All

Investor Login

Please Login VIA SWCS.

ID/Email ID *

Password *

6889 Get a new code

Please enter the letters as they are shown in the image Above *

(Letters are not case-sensitive)

[Forgot Password?](#) | [Resend Activation Mail](#)

LOGIN

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

emerginghimachal.hp.gov.in/backoffice/frontuser

- HPSEBL
- Electrical Inspectorate
- PVID
- Fire
- PCB
- Weights and Measures
- HP Ground Water Authority
- Urban Development Department
- Incentive
- TCP
- Tourism
- Excise and taxation
- Information & Public Relations (IPR)
- District Collector/District Magistrate
- DHSR**
- Municipal Corporation
- CM Helpline

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**.

S.No	Application Name	Department Name	Action
1	Retail Drug License	DHSR	Apply
2	Wholesale Drug License	DHSR	Apply
3	Both License (Retail & Wholesale)	DHSR	Apply
4	Restricted	DHSR	Apply
5	Motor Vehicle	DHSR	Apply
6	Schedule-X (Retail)	DHSR	Apply
7	Schedule-X (Wholesale)	DHSR	Apply
8	Granting of Drug Manufacturing License	DHSR	Apply
9	Loan License	DHSR	Apply
10	Additional Product	DHSR	Apply
11	Retention of License	DHSR	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.

HP-Single Window

DHSR :: Granting of Drug Manufacturing License

Applicant Details

Name: Test Test Mobile Number: 9532991685 Email: d88513443@gmail.com Select Your CAF: None of the Above

Company Details

Enterprise/Unit Name: Testor Enterprise Enterprise/Unit Address: Test Baddi District: Solan Type of Enterprise: Partnership

[Save & Next](#)

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.

The screenshot shows a web browser at the URL <https://dda.hp.gov.in/User/CheckService>. The page title is "Firm Registration For Manufacturing". The left sidebar contains a "User Profile" dropdown and a navigation menu with "Home", "Dashboard", "Surrender License", and "Firm Registration". The main content area is titled "Firm Application Form" and contains the following fields:

Constitution Type*		Firm Name*	
Partnership		Tester Enterprise	
Firm Address*			
Test Bagdi			
District*		Tehsil*	
Solan		Choose..	
Pincode*		Contact Number*	Email*
		9532991685	d88513443@gmail.com

Below the form is a section titled "Personal Details".

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

The screenshot shows the "Personal Details" section of the form. A red arrow points from the text "Submit & Proceed" in the previous step to a blue button labeled "Submit & Proceed" at the bottom of the form. The form fields are as follows:

District*		Tehsil*	
Solan (BBN)		Baddi	
Pincode*		Contact Number*	Email*
209111		9532991685	d88513443@gmail.com
Personal Details			
Name*	Father Name*	Date of Birth*	Gender*
Test Test	TestFather	25-04-2000	Male
Aadhaar*		Upload Aadhaar Front & Back Side [Only : JPG Max-Size : 1mb]	
765655689776		Choose File testimage.jpg	
<input checked="" type="checkbox"/> I am the authorized signatory of the firm.			
Authorization letter [Only : PDF Max-Size : 1mb]			
Choose File No file chosen			

The "Submit & Proceed" button is highlighted with a red box.

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

ONLINE DRUGS LICENSING SYSTEM
GOVERNMENT OF HIMACHAL PRADESH

Apply For Drug Manufacturing License

User Profile

Dashboard
Applicant Details

Home

Dashboard
Surrender License
Manufacturing License

Basic Details

Firm Number	Application Type	License Application Form	Amount
3	Granting of Drug Manufacturing License	<input checked="" type="checkbox"/> Form 24 <input type="checkbox"/> Form 24-A <input checked="" type="checkbox"/> Form 27 <input type="checkbox"/> Form 27-A <input type="checkbox"/> Form 30	15000

Applicant Name	Firm Name	Address
Test Test	Tester Enterprise	Test Baddi
Mobile No.	Aadhaar	Email
9532991685	898786756454	d88513443@gmail.com

Photo Upload* [Only : JPG | Max-Size : 1mb]
Choose File | No file chosen

Signature Upload* [Only : JPG | Max-Size : 1mb]
Choose File | No file chosen

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

ONLINE DRUGS LICENSING SYSTEM
GOVERNMENT OF HIMACHAL PRADESH

Apply For Drug Manufacturing License

User Profile

Dashboard
Applicant Details

Home

Dashboard
Surrender License
Manufacturing License

Manufacturing Chemist Staff + Manufacturing Chemist Staff

Name	Father's/Husband's Name	Approved in section	Enter Other Section
Test Manufacturing staff	test Father	Tablets x Capsules x Other x	MDI

Aadhaar	Qualification	ID Proof Upload* [Only : JPG Max-Size : 1mb]	Firm No.
458888998888	12	Choose File testImage.jpg	3

Submit

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

Applicant Name : Test Test & Firm Name : Tester Enterprise * [Only : PDF | Max-Size : 1mb]

Sl. No.	Document Description	File Name / Status
1	Affidavit on behalf of the applicant (Proprietor/Partner/Managing Director / General Power of Attorney Holder) duly attested by the Oath Commissioner / Notary (as per the prescribed language).	Choose File TestingPDF.pdf
2	List of the Plant & machinery installed.	Choose File TestingPDF.pdf
3	List of the laboratory Equipments provided.	Choose File No file chosen
4	Registration from Industry Department (Attested Photocopy).	Choose File No file chosen
5	Valid NOC from the Pollution Control Board (Attested photocopy).	Choose File No file chosen
6	Valid NOC from the Fire Services Department (Attested photocopy).	Choose File No file chosen

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

22 Qualification certificate-degree/diploma/matriculation-attested photocopy . Choose File TestingPDF.pdf

23 Certificate of approval as Analytical chemist by the competent drug authority-attested photocopy. Choose File TestingPDF.pdf

24 Experience certificate on the letter pad bearing licence Nos. of the issuing firm-original copy. Choose File TestingPDF.pdf

25 Passport size Photographs-1 (attested) and 4 (unattested). Choose File TestingPDF.pdf

26 List of the items proposed to be manufactured section wise and category wise (Biological and Non-Biological) indicating the following details: Choose File TestingPDF.pdf

27 Site Plan (to the scale), Location and Layout of the proposed premises clearly indicating Size and definition of the area and details of the furniture and fixtures provided therein. Choose File TestingPDF.pdf

28 Any other related document Choose File TestingPDF.pdf

Upload Documents

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

FORM 24
[See rules 69]
APPLICATION FOR THE GRANT OF [A LICENSE TO MANUFACTURE FOR SALE OR FOR DISTRIBUTION OF] DRUGS OTHER THAN THOSE SPECIFIED IN 3 [SCHEDULES C, C(1) AND X].

1. I / We **Test Test of Tester Enterprise** hereby apply for the [grant] of a license to manufacture on the premises situated at **Test Baddi**, District : **Solan (BBN)**, Teh : **Baddi** the following drugs being drugs other than those specified in [Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945.

2. Names of drugs categorised according to Schedule M.

3. Names, qualifications and experience of technical staff employed for manufacture and testing.

Name	Qualification	Approve in Section
Test Manufacturing staff	12	Tablets, Capsules, MDI

4. A fee of rupees 7500 has been credited to Government under the head of account
Date: 28-09-2024

Signature

Note:- The application should be accompanied by a plan of the premises.

[Pay](#) [Print](#)

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

Disclaimer

Before making the payment:

1. I understand that the requisite fee for the grant of a sale's drugs license, is to be deposited by me in specified head of account.
2. If the requisite fee is deposited in the wrong head of account, it shall be exclusively my responsibility, and the same shall not be applicable to my current application.
3. I understand that the deposited fee shall be exclusively used, one-time for the purpose of the application. In the event that the same deposit is utilized for any other purpose, legal action can be taken against me.

I agree to the above terms & conditions.

[Already paid!](#) [Go to e-Challan Page](#)

Step 15: 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**

ONLINE DRUGS LICENSING SYSTEM
GOVERNMENT OF HIMACHAL PRADESH

User Profile

User Profile

Home

Dashboard

Surrender License

Manufacturing License

Upload Receipt

Firm Number: 3

e-Challan Number: 1233221

Bank Code: SBI

Payment Date: 28-09-2024

Amount: 7500

Payment Details

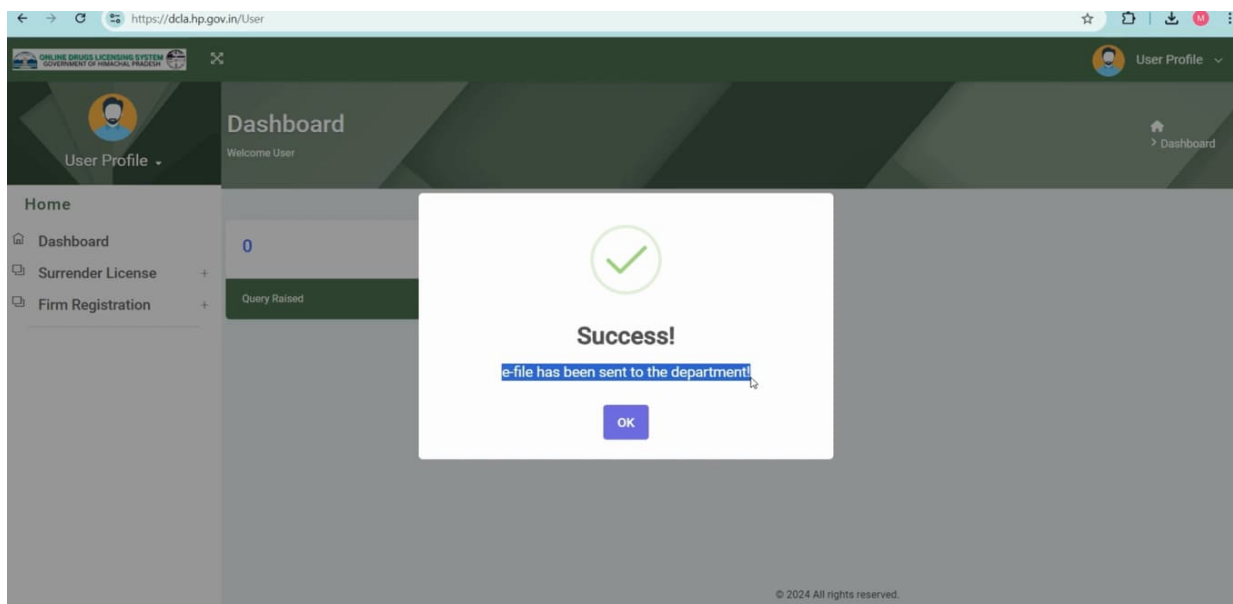
Grant of manufacturing Form 24

Upload e-Receipt * [Only : JPG] Max-Size : 1MB

Choose File: testImage.jpg

Submit

Step 16: 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 Maja, Manpura, Badli, Solan (BNI), Nalagarh** under the direction and supervision of the following [competent technical staff]

(a) [Competent technical staff] (Name)

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 licence, subject to the conditions applicable to licence 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

- 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.
- Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority.
- 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.
- 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 Maja, Manpura, Badli, Solan (BNI), 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] (Name)

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

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