Guidelines, Procedure, Checklist & Fee

Drug / Cosmetic Manufacturing License (ONDLS)

Health & Medical Education (State Drug Controller)

Government of J&K

Name of Service

Issuance of **Drug / Cosmetic Manufacturing License** through "Online National Drug Licensing System" (ONDLS)

Name of Department

Health & Medical Education Department (Office of State Drug Controller)

Policy/Government Order

Drugs & Cosmetic Act, 1940 & Rules thereunder

Introduction to Online National Drug Licensing System (ONDLS)

The National Drug Authority of the Country viz CDSCO has designed & developed an Online Module/Portal in collaboration with Centre for Development of Advanced Computing, Noida. The said portal is extended to all types of Regulatory Clearances in terms of Licensing / Certifications for Manufacturing, Blood Centres & Sales.

Guidance for Applicant Stakeholders

The module is based on the principle of self – registration on the portal by Firm / Blood Centre & Technical Person.

Accessibility to the ONDLS module: -

- The individual / firm intending to register on the portal may logon at https://statedrugs.gov.in
- On the Homepage of the Module at top right corner, click on Sing on /up.
- Enter Mobile No. & OPT will be sent on Mobile Number. Enter OTP with 60 seconds.
- Enter email ID. OTP will be sent on email ID. Enter OTP within 60 seconds.
- New Page will open up which provides below tiles: Firm : Technical Person : Firm & Technical Person
- The Firm / Individual has to select one tile as per requirement. The selection of tiles is simplified as below:

    - ✓ a) If user is a Firm or Corporate, Tile "Firm" is required to be selected & proceed accordingly.

- ✓ b) If user is an individual & intends to register as a Technical Person, Tile "Technical person" is required to be selected & proceed accordingly.

  Note : If applicant firm intending to obtain Manufacturing / cosmetic License & have a separate Registered Corporate address & Manufacturing Site address , then Corporate & Site are required to be registered on portal separately through different email IDs & Mobile No. by using Firm Tile in both cases. The Corporate is advised to be registered first followed by site. Once site is registered , a link will be sent to corporate & corporate need to approve the proposed site. Registered Corporate shall use CIN during registration & individual based firm have the option to initiate registration on the basis of PAN.

Submission of Application by Firm / Uploading of Details by Technical Person:

- A person who has registered himself / herself as technical person (Manufacturing Chemist or Analytical Chemist / Microbiologist) has to update below details along with uploading of relevant documents.

  A) Add Academic Qualification
  B) Add Professional Experience
  C) Add Technical Registration.

  After completing the details, System generated Technical Registration Number is allotted to Technical Person which is available in the profile option.

Application Submission by Firm/Blood Centre

- The firm after successful Registration / Approved by Coporate as the ccase may be shall hire technical person (Manufacturing Chemist / Analytical Chemist) through add technical member tile by using Technical registration Number to be provided by Technical Person. After hiring , the technical person will be available in Hired Technical Member.
- The user has to click on Fresh Application & update basic details about the premises, add technical person details & selection of License Forms.
- Proceed to checklist of documents related to type of License Form(s) selected
- Upload documents against the checklist & proceed.
- Fill Payment details form.
- Download Legal Form viz Form 24 / 27

- Sign the legal form & proceed to upload.
- Submit the application & message will be displayed that your application has been submitted successfully. Kindly note your File No. for future correspondence.

Note: *The module provides option of hiring of technical person by the firm. The Technical person has to share his system generated Technical Registration Number with the firm. The firm searches this number in the Hiring of Technical Staff option. After completion of offer & acceptance by & between firm & technical person, the hiring process is complete & the services of such hired person can be utilised as Competent Technical Staff on Licenses if fulfilling eligibility criteria for same.*

Further, the technical person already approved by any Licensing Authority of the Country under D& C Act, 1940 is eligible for registration over the portal.

Procedure to obtain Technical registration Document by a proposed competent person is as below:

The proposed technical person (Physically hired by applicant firm) having requisite qualification & experience as provided under D& C Act, 1940 but do not possess any sort of documentary approval from the Competent Authority need to apply before State Drug Controller through proper channel . The application is then referred to empowered committee for examining his / her eligibility & experience so as to dispose of his / her application on merits.

Guidance for Official Stakeholder (Department Workflow)

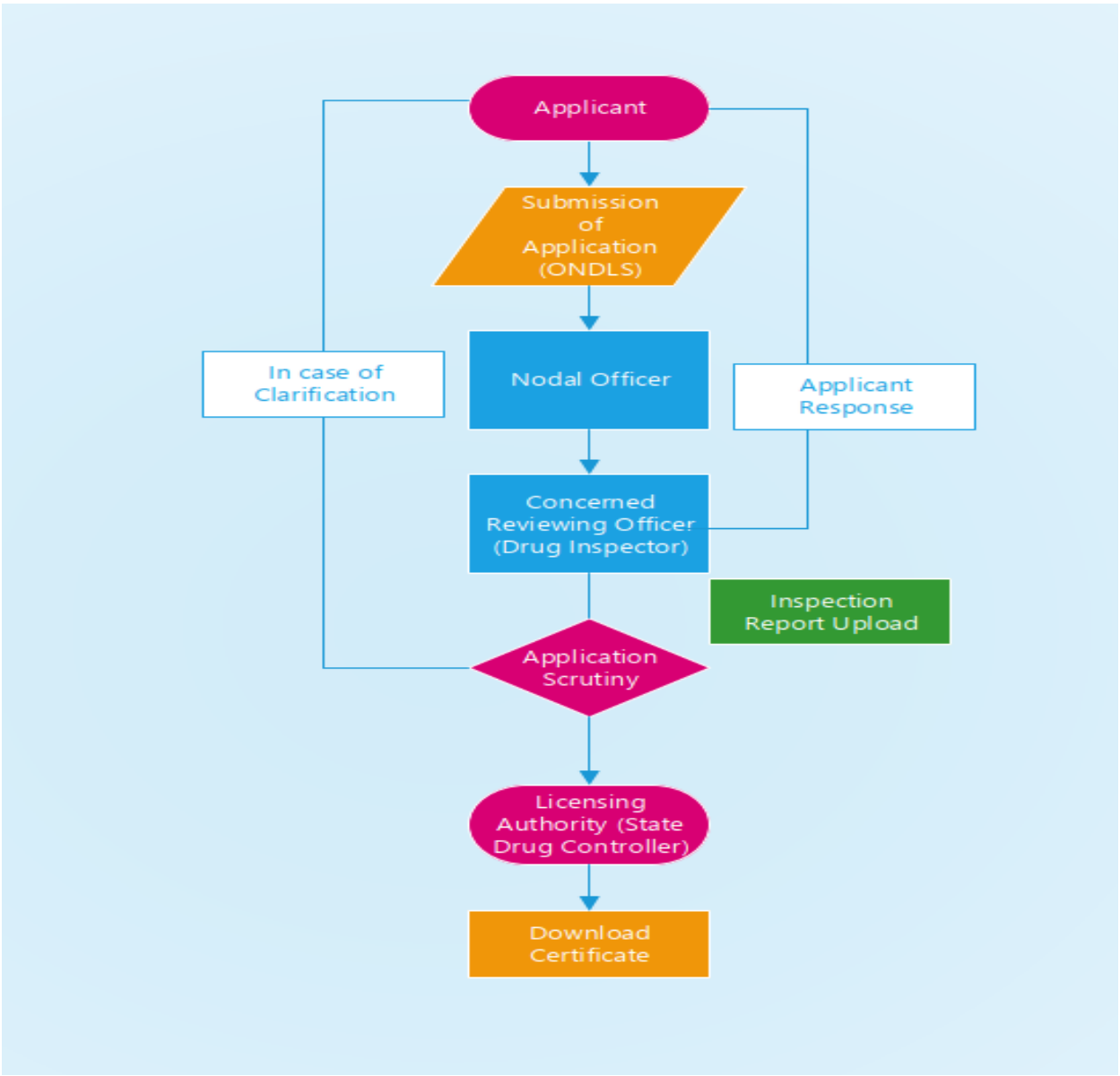
The working principle for official users is based on Mobile Number & Email ID based Registration of Officials on the portal, Creation of Application Type Zones, & Mapping of registered Officials with Created Zones. Three tier hierarchy system is customized for UT of J&K.

a) **Reviewing Officer (Drug Inspector)**
b) **Nodal Officer**
c) **Licensing Authority**

- The applications submitted by the stakeholders are received on the dashboard of Nodal Officer.
- Nodal Officer assigns the application to concerned Reviewing Officer.

- Reviewing Officer after scrutiny of uploaded documents & uploading of Inspection Report forwards the application to Licensing Authority with specific recommendation.
- Based on recommendations, Licensing Authority shall dispose off the application. The approved application is downloaded & uploaded along with Cover Letter.
- The applicant can download the final certificate from his /her user Id credentials.

- **Department Level Processing of Application**



1. Procedure, Checklist & Fee of Grant of Drug Manufacturing License

The step wise procedure for grant of Drug / Cosmetic Manufacturing is given as below:

Step 1: Application for grant of a licence on Form 25 / 28 / 28C / 28D / Cos-8 , shall be made in Form-24 / 27 / 27C / 27D / Cos-5 respectively accompanied by "**a fee as per below details :**

For Form 24 : Rs 7,500/= (Inclusive of First 10 Products) & Rs 300/= each & above 10 Products.

For Form 27 : Rs 7,500/= (Inclusive of First 10 Products) & Rs 300/= each & above 10 Products.

For Form 27C : Rs 7,500/= (For Whole Human Blood I.P) & Rs 300/= for each component.

For Form 27D : Rs 7,500/= (Inclusive of First 10 Products) & Rs 300/= each & above 10 Products

For Form Cos-5 : Rs 10,000/= for each category of Cosmetics (Inclusive of First 10 Products) & Rs 500/= each & above 10 Products for each category of Cosmetics.

The statutory / supportive requirements to the Form-24 / 27 / Cos-5 is as:

1. Constitution of the Firm / RoC / MoA.
2. Details of Directors & Authorised Signatory
3. Documentary evidence in respect of the ownership or occupation on rental or other basis of the premises.
4. Site Plan of the Premises / Lay out as per Schedule M for Drugs & QMS for Cosmetics.
5. Appointments / Acceptance of competent technical staff.
6. Pollution Control Certificate
7. DIC Registration / NOC.
8. Prescribed fee as detailed above.
9. List of Machinery & Equipments /
10. List of SoPs
11. Site Master File
12. Water Validation
13. AHU Validation
14. Stability Studies of product s
15. Form 29 in case of drugs

16. Form 51 in case of Drugs.

Note -I : Before filing of application / uploading of documents , applicant is required to upload details of intended products.

Note-II : For more clarification on checklist documents , Please visit homepage of https://statedrugs.gov.in & browse "Service" tab at the top of the page & download checklist of required documents available against each type of application form.

Step 2 : The application complete in all respects is forwarded to concerned area inspector by the Licensing Authority for on spot inspection of the facility .

Step 3 : The concerned inspector of Drugs / Joint Inspection Team inspect the facility & upload the inspection report with specific observations / recommendations. .

Step 4 : The Licensing Authority after being satisfied with the recommendations of concerned inspector for grant of license issue the License/s in favor of the applicant on Form 25 / 28 / Cos-8

Online Mandate Order for ONDLS

OFFICE OF THE STATE DRUGS CONTROLLER
DRUGS & FOOD CONTROL ORGANIZATION
PATOLI MANGOTRIAN J&K (JAMMU)

Regd. Post / Email / WAP

Sub: Adoption of "Online National Drug Licensing System" for Manufacturing & Sales Licensing in the UT of J&K – Regarding.

ORDER No. DFO of 119, 2021
Dated : 02 - 12 - 2021

Whereas , XLN Online Module for Licensing System (Sales) was adopted by this UT on 13.08.2018 in terms of Notification bearing No. HD/Drugs/69/2017 , dt: 13.08.2018 ;

Whereas , Apex Drug Authority of the Country viz Central Drugs Standard Control Organization , New Delhi **(herein referred to as CDSCO)** in collaboration with Centre for Development of Advanced Computing , Noida **(herein referred to as CDAC)** has developed a PAN India Portal under the banner **"Online National Drug Licensing System (ONDLS)"** for all states which shall extend to all regulatory clearances related to Manufacturing ; Blood Centers , Retail Sale & Wholesale under the provisions of Chapter IV of Drugs & Cosmetics Act, 1940 ;

Whereas , in order to ensure smooth transition , XLN Module was shut down vide this office Order No. DFO 105 of 2021 dt : 10.11.2021 ;

Whereas , the procedural trial / validation of ONDLS Module has been completed by the CDAC Authorities ;

Whereas , the said portal / module bearing URL as https://statedrugs.gov.in has been launched on 30th November, 2021 ;

Whereas, under **XLN Module** , Wholesale Licensing (Fresh) were disposed off as per ***"Guidance Manual for issuance of Drug Sale Licenses on Form 20B &21B"*** issued vide this office Communication No. DFO/D-845/7418-20 , dt: 04.02.2019 ;

Whereas, **XLN Module** & Newly adopted Module **(ONDLS)** are different in operation design & therefore necessary amendment is required in the existing Guidance Manual ;

Now , therefore in light of the contents explained herein above , all the statutory authorities appointed by the Government of J&K to carryout statutory duties under the provisions of the Drugs & Cosmetics Act, 1940 & Drugs Rules 1945 thereunder are hereby ordered to adopt Online Module viz **"Online National Drug Licensing System" (ONDLS)** with immediate effect for regulatory clearances under the said Act & Rules.

No. DFO/D-936/ 4193-4242
Dt: 02-12-2021

(Lotika Khajuria)
State Drugs Controller
Drugs & Food Control Organization
J&K (Jammu)

Copy To :

1. The Additional Chief Secretary to Government , H&ME Department, Civil Secretariat (J&K) for favor of information.
2. Drugs Controller General (I) , CDSCO (HQ) , FDA Bhawan , Kotla Road , New Delhi for favor of information.
3. Commissioner, FDA (J&K) –Drugs & Food Control Organization J&K for favor of information.
4. Jt. Director Planning (H&ME) Department , Civil Secretariat , J&K for information. Process of integration of Portal with UT specific SWC System has been already taken up with concerned quarters for necessary action at an earliest convenience.
5. SIO-NIC (J&K) for information.
6. Dy. Controller –Drugs & Food Control Organization Jammu / Kashmir for information & necessary action with the request to ensure implementation of revised guidelines in letter & spirit. The revised Guidance Manual is attached herewith as Annexure A.
7. All Assistant Controller Drugs / All Licensing Authorities for necessary compliance.
8. Assistant Controller Drugs (I), CDSCO Sub Zone Jammu for information.
9. Mr. Rahul Gautam –CDAC , Noida for information.
10. ***All Drug Control Officers (Enforcement) for strict compliance.***
11. Mr. Surinder C/o M/s Saytechnologies , Jammu with the request to upload the document on our official website by today only.

Weblink for the Notification: - ONDLS.pdf (dfcojk.org)

Notified Timelines Under Jammu & Kashmir Public Service Guarantee Act

(69)

GOVERNMENT OF JAMMU AND KASHMIR
GENERAL ADMINISTRATION DEPARTMENT
(Public Services Management Cell)
Civil Secretariat, Jammu/Srinagar

NOTIFICATION

Srinagar, the 13th September, 2013

SRO 400 - In exercise of the powers conferred by section 4 read with section 8 of the Jammu and Kashmir Public Services Guarantee Act, 2011 (Act No. IX of 2011), the Government hereby specify the following services and the designated officers/appellate authorities as under:-

I. Health and Medical Education Department

Issuance of Drug Licenses under Drugs and Cosmetics Act-1940/Rules

S. No.	Name of the Service	Designated Officer (the officer who will provide the service)	Stipulated time frame for providing the service	First Appellate Authority	Second Appellate Authority
01	License to sell, stock or exhibit (or offer) for sale, or distribute drugs by retails (Allopathic /Homeopathic drugs) on various forms viz. Form 20, Form21 and Form 20F (Rule 64), Form 20A and Form 21A (Rule 62B), Form 20 C (Rule 67F)	Assistant Controller Drugs of the concerned District	1 Month	Deputy Controller Drugs and Food Control Organization of the respective Division	Controller, Drugs and Food Control Organization J&K, Jammu/ Srinagar
02	License to sell, stock or exhibit (or offer) for sale, or distribute drugs by wholesale (Allopathic/Homeopathic drugs) on various forms viz. Form20 B, Form 21B and Form 20G (Rule 64), Form 20BB and Form 21BB (Rule 62D), Form 20D (Rule 67F).	Deputy Controller Drugs and Food Control Organization of the respective Division	1 Month	Controller, Drugs and Food Control Organization J&K, Jammu/ Srinagar	Administrative Secretary to Government, Health & Medical Education Department
03	License to manufacture for sale or for distribution of drugs/cosmetics/ Ayurvedic (including Siddha or Unani drugs) on various forms viz. Form 25 and Form 25F (Rule 71), Form 25A (Rule 71 B), Form 25 B (Rule 71A), Form 25C (Rule 85E), Form 25D (Rule 157), Form 25E (Rule 154A), Form 26 (Rule78), Form 26A (Rule 76A), Form 26 B (Rule 76), Form 29 (Rule 89), Form 32 (Rule 139), Form 32 A(Rule 142 B).	Controller, Drugs and Food Control Organization J&K, Jammu/ Srinagar	1 Month	Divisional Commissioner, Jammu/ Kashmir	Administrative Secretary to Government, Health & Medical Education Department