Online Application Procedure

Visit Drug Control Administration website "www.dca.telangana.gov.in" And select the tab "Online Drug Licensing System"

Online Registration Select "Apply Online" - First Time Applicants need to Register Under "New Users" by filing in the details including the license information, and obtain a User ID and password for login.

Confirmation to New Users/Applicants will be sent to their mail-id/ through SMS on the registered mobile number. Registered Applicant can now Log-in to proceed with the online application.

Select the service category and type of License from the drop down list. For e.g - Under Sales License - Retail or Wholesale, then the type i.e Grant /Renewal / Amendment

Filing
Application,
Uploading
Documents
and Fees
Payment

Checklist / Documents to be submitted for each services are available under "How to Apply" tab at home page. Checklist as per the License selected is also provided during the application process. Applicant need to prepare the soft copies of all the documents required for desired licences.

Applicant need to fill in the - firm details, constitution details, RP/CP and other required information, and upload documents as per the checklist. (Application can be saved and pages can be revisited to make any changes before submission)

License Fee to be Paid and Application Submitted (Acknowledgement of Fee Payment & Application Submission Confirmation will be sent to the Applicant's registerd maid ID / through SMS

Application Scrutiny and Inspection Scrutiny of the application/documents by DCA Official, clarification / query (if any) will be communicated to the applicant through mail or SMS alert. Alternatively, applicant can track the status on their login dashboard. Applicant can reply to the queries online.

Inspection of the Unit / Premises by DCA Official (Applicant will be informed in advance). Submission of Inspection Report to Senior Officials.

Once approved, Applicant can download the License from the Online Portal after Signing-In. A copy of the License also be sent to the registered e-mail ID.

Inspection Procedure for Manufacturing & Sales License's Application

- a) The inspector shall verify the following aspects at the time of inspection of the facility for *grant/renewal of manufacturing licences:*
- ➤ Production area of the facility to verify the uni-flow of various operations carried out in the respective modules.
- > Design of the facility for proper segregation of areas meant for various activities.
- Installation of the required equipment along with the qualification status.
- > Purified water generation and distribution system and the status of validation.
- Air Handling Units validations along with the zoning classification (air classification), pressure differentials in various areas of the production modules.
- ➤ Material movement and men movement in the production areas to ensure regarding the no chance of cross contamination/ mix up.
- ➤ Quality Control laboratory to verify the instruments & calibration status (analytical capabilities of firm).
- Warehousing facilities of the firm for raw materials and finished products.
- ➤ Required capabilities of Technical Staff for manufacturing and testing.
- ➤ To verify the compliance of the facility with the provisions of Good Manufacturing Practices as per Schedule M (general requirements and specific requirements) and Good Laboratory Practices as per Schedule L-1 of Drugs and Cosmetics Act 1940 and Rules made thereunder.
- b) The inspector shall verify the following aspects at the time of inspection of the outlet/premises for *grant/renewal of sales licences* as per Rule 64 of Drugs and Cosmetics Act 1940 and Rules made thereunder:
- Area of the outlet to verify the compliance with the statutory limits.
- ➤ Capabilities to provide good storage conditions for the drugs stocked in the premises such as racks, refrigerator (for cold storage drugs) etc.