DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

Standard Operating Procedure – Manufacturing Licence for Allopathic Drugs

Name of Department	**Drugs Control Department**

1. Standard Operating Procedure for Applicant

Application for	**Manufacturing Licence for Drugs**
Mandatory supporting documents required	1. Application in Form 24/24A/24B//27/27A 2. Licence fee via online payment receipt of Rs. 7500/- for application received in Form 24/24A//27/27A. Licence fee remitted is for approval of 10 products. For products beyond 10, additional fee of Rs.300 is to be remitted for each product. 3. Licence fee via online payment receipt of Rs. 700/-for application received in Form 24B. Licence fee remitted is for approval of 10 products. For products beyond 10, additional fee of Rs.100 is to be remitted for each product. 4. Constitutional details of the firm (Proprietorship/Partnership including Limited Liability Partnership/ Private or Public company/ Society/Trust) 5. Document from local authority to prove ownership of premises 6. Plan of the premises 7. Declaration of technical staffs for manufacturing and testing 8. Documents to prove their qualification and experience 9. Details of products applied with their master formula records, SOPs, Specimen labels, Stability study data, Bioequivalence study data for oral dosage form of drugs specified under Category II & IV of Biopharmaceutical classification system. 10. By remitting Rs. 7500/- as the licence fee along with application of allopathic drugs (form 25,25A, 28, 28A) a maximum of approval of 10 products could be obtained. For products beyond 10 numbers additional fee of Rs. 300/- is to be remitted. 11. For retention of licences, fee of Rs. 6000/- is to be remitted online for approval of 10 products. For products beyond 10 numbers additional fee of Rs. 300/- is to be remitted
Process description	1. Submission of the entire application via ONDLS portal which is then forwarded to Office of Deputy Drugs Controller (India), Central Drugs Standard Control Organisation, Chennai 2. Verification of the documents by the concerned Regional/Senior Drugs Inspector 3. Pre-licensing inspection to be conducted jointly by the Drugs Inspector, CDSCO, Chennai & Concerned Regional/Senior Drugs Inspector of Assistant Drugs Controller Office. 4. Issue of Manufacturing Licence for Drugs by the State Drugs Controller (In case of biologicals by State & Central Licensing authority)
Procedure for Fees payment	Payment can be done through e-treasury

List of Reference Documents	Drugs & Cosmetics Act,1940 & Rules,1945
Time line for completing the process	28 days
Checking of Application Status	Online provision currently available
Key Contact Person from department	Drugs Controller

2. Standard Operating Procedure for Approver

Application for	**Grant or Retention of Licence for Manufacturing Drugs**
Mandatory supporting documents required	1. Application in Form 24/24A//27/27A 2. Registration fee via online payment receipt of Rs. 7500/ 3. Plan of the premises 4. Declaration of technical staffs on manufacturing and testing 5. Documents to prove their qualification and experience 6. Details of products applied with their master formula records & SOPs (In the case of renewal details of products approved is also to be submitted) 7. By remitting Rs. 7500/- as the licence fee along with application of allopathic drugs (form 25,27) a maximum of approval of 10 products could be obtained. For products beyond 10 numbers additional fee of Rs. 300/- is to be remitted
List of Reference Documents	Drugs & Cosmetics Act, 1940 & Rules, 1945
Time line for completing the process	28 days
Departmental Work Flow	1. Application submitted to Drugs Controller Office will be forwarded to Deputy Drugs Controller(India), CDSCO, Chennai for joint inspection. 2. After completion of pre-licensing joint Inspection, Joint inspection report will be forwarded by the DDC (I), Chennai to the Office of Drugs Controller, either recommending or the grant of licence or rejecting the application as the case may be. 3. Licence for Manufacturing Drugs is then issued by the Drugs Controller based on the recommendations in the inspection report. In case of biologicals, licence is issued by state & Central Licensing Authority

3. Verification/Inspection Procedure:

Verification – Verification of application form and supporting documents
Inspection – Inspection of the premises by the concerned Drugs Inspector