DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

Standard Operating Procedure and Checklist

Name of Department	**Drugs Control Department**

1. Standard Operating Procedure for Applicant

Application for	Grant or Renewal of Retail/Bulk Drug Licence
Mandatory supporting documents required	1. Application in Form 19/19A/19B/19C 2. Registration fee via online payment receipt of Rs. 3000/ 3. Document from local authority to prove ownership of premises 4. Pharmacist registration certificate 5. Declaration of the pharmacist 6. Option request 7. Affidavit in prescribed form 8. Attested copies of documents of constitution of the proposed firm 9. Covering letter with court fee stamp worth Rs.5/- 10. Proof for identity of the applicant 11. In the case of renewal application in addition to the above documents the previous renewal certificates in original/copy of original Drugs Licences are also to be attached 12. In the case of application made in form 19AA the attested copy of RC book of the vehicle is to be provided along with application 13. In the case of application in form 19A the questionnaire, Chelan, affidavit and attested copies of documents of constitution of the proposed firm , proof of identity etc are to be provided
Process description	1. Registration with XLN software for obtaining ID and password 2. Uploading of documents into the software 3. E-submission of application 4. Submission of hardcopy of entire application to the concerned Assistant Drugs Controller/ Drugs Inspector office(Not mandatory) 5. Verification of the documents by the concerned Drugs Inspector 6. Pre-licensing inspection by Concerned Drugs Inspector 7. Issue of drug licence by Assistant Drugs Controller
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	30 days
Checking of Application Status	Online provision available
Key Contact Person from department	Drugs inspector

Application for	Grant or Renewal of wholesale Drug Licence

Mandatory supporting documents required	1. Application in Form 19/19B/19C 2. Registration fee via online payment receipt of Rs. 3000 3. Document from local authority to prove ownership of premises 4. Copy of SSlC/Degree Certificate or pharmacy Registration Certificate of Competent Person. 5. Declaration of the Competent Person 6. Declaration regarding the maintenance of Cold Chain and supporting documents, if drugs requiring cold storage are intended to be stocked/distributed 7. Affidavit in prescribed form 8. Attested copies of documents of constitution of the proposed firm 9. Covering letter with court fee stamp worth Rs.5/- 10. Proof for identity of the applicant 11. In the case of renewal application in addition to the above documents, the previous renewal certificates in original/copy of original Drugs Licences are also to be attached
Process description	1. Registration with XLN software for obtaining ID and password 2. Uploading of documents into the software 3. E-submission of application 4. Submission of hardcopy of entire application to the concerned Assistant Drugs Controller /Drugs inspector office(Not mandatory) 5. Verification of the documents by the concerned Drugs Inspector 6. Pre-licensing inspection by Concerned Drugs Inspector 7. Issue of drug licence by Assistant Drugs Controller
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	30 days
Checking of Application Status	Online provision available
Key Contact Person from department	Drugs inspector

Application for	Manufacturing Licence for Drugs & Cosmetics
Mandatory supporting documents required	1. Application in Form 24/24A/24B/24C/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. In the case of renewal of licences the previous renewal certificate in original © of original Drugs Licences are to be attached.

	8. 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
Process description	1. Submission of hardcopy of entire application to the concerned Assistant Drugs Controller office, which is then forwarded to the Drugs Controller Office. (In case of notified medical devices & biologicals, application is then forwarded to CDSCO, Chennai/Delhi) 2. Verification of the documents by the concerned Regional/Senior Drugs Inspector 3. Pre-licensing inspection by Concerned Regional/Senior Drugs Inspector (In case of notified medical devices & biological, joint inspection from office of State Drugs Controller & CDSCO) 4. Issue of Manufacturing Licence for Drugs by the Drugs Controller (In case of notified medical devices & 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 not available
Key Contact Person from department	Drugs Controller

Application for	Manufacturing Licence for Cosmetics
Mandatory supporting documents required	1. Application in Form 31/31A 2. Registration fee via online payment receipt of Rs. 3500/ 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. In the case of renewal of licences the previous renewal certificate in original or copy of original Drugs Licences are to be attached. 8. By remitting Rs. 3500/- 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. 100/- is to be remitted

Process description	1. Submission of hardcopy of entire application to the concerned Assistant Drugs Controller office, which is then forwarded to Drugs Controller Office 2. Verification of the documents by the concerned Regional/Senior Drugs Inspector 3. Pre-licensing inspection by Concerned Regional/Senior Drugs Inspector 4. Issue of Manufacturing Licence for Cosmetics by the Drugs Controller
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 not available
Key Contact Person from department	Drugs Controller

Application for	Blood Bank Licence
Mandatory supporting documents required	1. Application in Form 27C 2. Registration fee via online payment receipt of Rs. 7500/- 3. Plan of the premises 4. Declaration of technical staffs 5. Documents to prove the qualification and experience of technical staffs 6. List of equipment provided 7. List of blood products required 8. Details of labels 9. Standard operating procedures for processing of whole blood/ preparation & testing of blood components 10. In the case of renewal of licences the previous renewal certificate in original/ copy of original Blood Bank Licences are to be attached.
Process description	1. Submission of hardcopy of entire application to the Assistant Drugs Controller Office & Drugs Controller Office, which is then forwarded to CDSCO, Chennai/Delhi 2. Verification of the documents by concerned Regional/Senior Drugs Inspector of Office of State Drugs Controller & CDSCO 3. Pre-licensing joint inspection by concerned Regional/Senior Drugs Inspector of Office of State Drugs Controller & CDSCO 4. Issue of blood bank licence by Central & State 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 is currently not available

Key Contact Person from department	Drugs Controller

2. Standard Operating Procedure for Approver

Application for	Grant or Renewal of Retail/Bulk Drug Licence
Mandatory supporting documents required	1. Application in Form 19/19A/19B/19C 2. Registration fee via online payment receipt of Rs. 3000/ 3. Document from local authority to prove ownership of premises 4. Pharmacist registration certificate 5. Declaration of the pharmacist 6. Bill book request form 7. Affidavit in prescribed form 8. Self addressed envelope with postal stamps of Rs.27/- 9. Attested copies of documents of constitution of the proposed firm 10. Covering letter with court fee stamp worth Rs.5/- 11. Proof for identity of the applicant 12. In the case of renewal application in addition to the above documents the previous renewal certificates in original/copy of original Drugs Licences are also to be attached 13. In the case of application made in form 19AA the attested copy of RC book of the vehicle is to be provided along with application 14. In the case of application in form 19A the questionnaire, Chelan, affidavit and attested copies of documents of constitution of the proposed firm , proof of identity etc are to be provided
List of Reference Documents	Drugs & Cosmetics Act, 1940 & Rules, 1945
Time line for completing the process	30 days
Departmental Work Flow	1.After pre licensing Inspection is completed, Drugs Inspector prepares the report in the software itself, either recommending the grant of licence or rejecting the application as the case may be and forward the application to the Assistant Drugs Controller 2.The hard copy of the application submitted to the Assistant Drugs Controller is also forwarded to the Drugs Controller 3. Assistant Drugs Controller checks the data in the software, which if found satisfactory, issues the drug licence 4. The licensee can take the print out of the e-signed licence from the software as and when he/she receives the automatically generated sms.

Application for	Grant or Renewal of Wholesale Drug Licence
Mandatory supporting documents required	1. Application in Form 19/19B/19C 2. Registration fee via online payment receipt of Rs. 3000 3. Document from local authority to prove ownership of premises 4. Copy of SSlC/Degree Certificate or pharmacy Regn Certificate of Competent Person. 5. Declaration of the Competent Person 6. Declaration regarding the maintenance of Cold Chain and supporting documents, if drugs requiring cold storage are intended to be stocked/distributed

	7. Affidavit in prescribed form 8. Attested copies of documents of constitution of the proposed firm 9. Covering letter with court fee stamp worth Rs.5/- 10. Proof for identity of the applicant 11. In the case of renewal application in addition to the above documents, the previous renewal certificates in original/copy of original Drugs Licences are also to be attached
List of Reference Documents	Drugs & Cosmetics Act, 1940 & Rules, 1945
Time line for completing the process	30 days
Departmental Work Flow	1.After pre licensing Inspection is completed, Drugs Inspector prepares the report in the software itself, either recommending the grant of licence or rejecting the application as the case may be and forward the application to the Assistant Drugs Controller 2.The hard copy of the application forwarded to the ADc also forwarded to the Drugs Controller 3. Assistant Drugs Controller checks the data in the software, which if found satisfactory, issues the drug licence 4. The licensee can take the print out of the e-signed licence from the software as and when he/she receives the automatically generated sms.

Application for	Grant or Renewal of Licence for Manufacturing Drugs
Mandatory supporting documents required	1. Application in Form 24/24A/24B/24C/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. In the case of renewal of licences the previous renewal certificate in original © of original Drugs Licences are to be attached. 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 Assistant Drugs Controller Office is forwarded to Drugs Controller Office. In case of notified medical devices & biologicals, application is forwarded from Drugs Controller Office to CDSCO, Chennai/ Delhi for joint inspection. 2. After verification of the documents, inspection of the premises is conducted by the concerned Regional/ Senior Drugs Inspector. In case of notified medical devices joint inspection by Office of State Drugs Controller & CDSCO

	3. After completion of pre-licensing Inspection, Regional / Senior Drugs Inspector prepares the report, either recommending the grant of licence or rejecting the application as the case may be and the report is then forwarded to the Drugs Controller 4. Licence forManufacturing Drugs is then issued by the Drugs Controller based on the recommendations in the inspection report. In case of notified medical devices & biologicals, licence is issued by state & Central Licensing Authority

Application for	Grant or Renewal of Licence for Manufacturing Cosmetics
Mandatory supporting documents required	1. Application in Form 31/31A 2. Registration fee via online payment receipt of Rs. 3500/ 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. In the case of renewal of licences the previous renewal certificate in original/ copy of original Drugs Licences are to be attached. 8. By remitting Rs. 3500/- 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. 100/- 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 Assistant Drugs Controller Office is forwarded to Drugs Controller Office. 2. After verification of the documents, inspection of premises is conducted by the concerned Regional/ Senior Drugs Inspector 3. After completion of pre-licensing Inspection, concerned Regional/Senior Drugs Inspector prepares the report, either recommending the grant of licence or rejecting the application as the case may be and the report is forwarded to Drugs Controller 4. Licence for manufacturing cosmetics is then issued by State Licensing authority based on the Inspection report

Application for	Grant or Renewal of Blood Bank Licence
Mandatory supporting documents required	1. Application in Form 27C 2. Registration fee via online payment receipt of Rs. 7500/ 3.Plan of the premises 4.Declaration of technical staffs 5.Documents to prove the qualification and experience of technical staffs 6.List of equipments provided

	7.List of blood products required 8.Details of labels 9.Standard operating procedures for processing of whole blood/ preparation & testing of blood components 10. In the case of renewal of licences the previous renewal certificate in original/ copy of original Blood Bank Licences are to be attached.
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 Assistant Drugs Controller Office & Drugs Controller Office is then forwarded to CDSCO, Chennai/ Delhi. 2. After verification of the documents, Joint inspection of premises is conducted by the office of State Drugs Controller & CDSCO 3. After completion of pre-licensing Inspection, inspection report, either recommending the grant of licence or rejecting the application as the case may be and the report is forwarded by CDSCO to State Drugs Controller 4. Licence issued by State Licensing authority based on recommendation in joint inspection report, is then forwarded to CDSCO, New Delhi for countersignature by DCG(I).

3. Verification/Inspection Procedure:

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

4. Checklist (for supporting documents)

- Document 1 – Grant/renewal of Retail/Bulk Drug Licence
- Document 2 – Grant /Renewal of Wholesale Drug Licence
- Document 3 – Grant/Renewal of Licence for Manufacturing Drugs
- Document 4 – Grant/Renewal of Licence for Manufacturing Cosmetics
- Document 5 – Grant/Renewal of Blood Bank Licence