

DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

Standard Operating Procedure – Grant/Retention of Wholesale & Retail Sale licences

Name of Department	Drugs Control Department
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1. Standard Operating Procedure for Applicant

Application for	<u>Grant or Retention of Retail Drug Licence</u>
Mandatory supporting documents required	<ol style="list-style-type: none"> 1. Application in Form 19/19A/19B/19C 2. Registration fee via online payment receipt of Rs. 3000/ 3. Constitutional details of the firm (Proprietorship/Partnership including Limited Liability Partnership/ Private or Public company/ Society/Trust) 4. Document from local authority to prove ownership of premises 5. Pharmacist registration certificate 6. Declaration of the pharmacist 7. Option request 8. Affidavit in prescribed form 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 retention application, only requisite fee need to be remitted by the user 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
Process description	<ol style="list-style-type: none"> 1. Registration of the firm & technical person has to be done via ONDLS Portal 2. Uploading of documents into the software 3. E-submission of application 4. Verification of the documents by the concerned Drugs Inspector 5. Pre-licensing inspection by Concerned Drugs Inspector 6. 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	<u>Grant or Retention of Wholesale Drug Licence</u>
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DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

Mandatory supporting documents required	<ol style="list-style-type: none"> 1. Application in Form 19/19B/19C 2. Registration fee via online payment receipt of Rs. 3000/- 3. Constitutional details of the firm (Proprietorship/Partnership including Limited Liability Partnership/ Private or Public company/ Society/Trust) 4. Document from local authority to prove ownership of premises 5. Copy of SSLC/Degree Certificate or pharmacy Registration Certificate of Competent Person. 6. Declaration of the Competent Person 7. Declaration regarding the maintenance of Cold Chain and supporting documents, if drugs requiring cold storage are intended to be stocked/distributed 8. Affidavit in prescribed form 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 retention application only requisite fee need to be submitted
Process description	<ol style="list-style-type: none"> 1. Registration of the firm and the technical person has to be done via ONDLS portal 2. Uploading of documents into the software 3. E-submission of application 4. Verification of the documents by the concerned Drugs Inspector 5. Pre-licensing inspection by Concerned Drugs Inspector 6. 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

2. Standard Operating Procedure for Approver

Application for	Grant or Retention of Retail/ Drug Licence
Mandatory supporting documents required	<ol style="list-style-type: none"> 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

DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

	<ol style="list-style-type: none"> 6. Affidavit in prescribed form 7. Attested copies of documents of constitution of the proposed firm 8. Covering letter with court fee stamp worth Rs.5/- 9. Proof for identity of the applicant 10. In the case of retention, only requisite fee required to be paid by the user 11. 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 12. 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	<ol style="list-style-type: none"> 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. 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	<ol style="list-style-type: none"> 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 SSIC/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 retention, only requisite fee required to be paid by the user

DRUGS CONTROL DEPARTMENT
GOVERNMENT OF KERALA

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. 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.

3. Verification/Inspection Procedure:

Verification – Verification of application form and supporting documents

Inspection – Inspection of the premises by the concerned Drugs Inspector