

TABLE-I

SALE APPLICATIONS, LICENCES, FEES AND PENALTY

S. NO.	Category	Type Sale	Application Form	Licence Form	Fees for Grant/Renewal	Renewal Certificate Form No.	Penalty after expiry but within six months	Fees for duplicate copy of Org. Lic.
1.	Drugs other than those specified in Schedule C&C(1)&X	Whole Sale	19	20-B	Rs.1500	21 -C	Rs.1500+Rs.500p.m. or part thereof	Rs.150
		Retail Sale	19	20	Rs.1500	21 -C	Rs.1500+Rs.500p.m. or part thereof	Rs.150
2.	Drugs specified in Schedule C&C(1) but excluding those specified in Schedule X	Whole Sale	19	21B	Rs.1500	21 -C	Rs.1500+Rs.500 p.m. or part thereof	Rs.150
		Retail Sale	19	21	Rs.1500	21 -C	Rs.1500+Rs.500p.m. or part thereof	Rs.150
3.	Drugs specified in Schedule 'X'	Whole Sale	19-C	20-G	Rs.500	21 -C	Rs.500+Rs.250p.m. or part thereof	Rs.150
		Retail Sale	19-C	20-F R-61(1)	Rs.500 R-59(2)	21 -C	Rs.500+Rs.250p.m. or part thereof R-59(4)	Rs.150 R-59(3)

TABLE-II
MANUFACTURING FORMS, LICENCES, FEES AND PENALTY*

I- ALLOPATHIC DRUGS

S. No.	Category of drugs	Application Form No.	Licence Form No.	Fees for Grant/ Renewal	Renewal Certificate Form No.	Penalty after expiry but within six months	Fees for duplicate copy of Org. Lic.	Fee for addl. item for more than 10 item for each category
I	II	III	IV	V	VI	VII	VIII	IX
1.	Drugs other than those specified in Schedule C&C(I) &X (i) Repacking of drugs	24-B upto 10 items for each category R: 69(1) (a)	25-B R: 70	Lic. fees of Rs. 500+ Insp. fee of Rs. 200 for every inspection or for renewal of licence R: 69(2)(a)	26-B R: 73-B	Rs.500+Rs.250 p.m. or part thereof in addition to an inspection fee of Rs.200 R: 69(3)(i)	Rs. 1000 R: 69(4)	Rs. 100 for each addl. item R: 69(5)
	(ii) Drugs specified in Schedule X	24-F up to 10 items for each category R: 69 (1) (b)	25-F R: 70	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 69(2)(b)	26-F R: 73	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1000 R: 69 (3)(ii)	Rs. 1000 R: 69(4)	Rs. 300 per item R: 69(5)
	(iii) Any other	24-D up to 10 items for each category R: 69(1) (c)	25-D R: 70	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 69 (2) (c)	26 R: 73	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 69-A (1)	Rs. 1000 R: 69(4)	Rs. 300 per item R: 69(5)
	(iv) Loan Licence	24-A up to 10 items for each category R: 69-A(1)	25-A R: 70-A	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 69A(1)	26-A R: 73 A	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 69-A (1)	Rs. 1000 R: 69-A(4)	Rs. 300 per item R: 69-A (i)

* GSR No. 421 dated 24/08/2001

	Drugs specified in Schedule C&C(1) excluding those specified in Sch. X (i) Own unit	27 up to 10 items for each category R: 75(1)	28 R: 76	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 75(1)	26 R: 77	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 75(1)	Rs.1000 R: 75(4)	Rs. 300 per item R: 75(5)
	(ii) Loan Licence	27-A up to 10 items for each category R:75A(1)	28-A R: 76A	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 75A(1)	26-A R: 83-A	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 75 A (1)	Rs.1000 R: 75A(4)	Rs. 300 per item R: 75(5)
	(iii) Drugs specified in Schedule C&C(1) & X	27-B up to 10 items for each category R: 75(2)	28-B R: 76	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 75(2)	26-F R: 77	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 75(2)	Rs.1000 R: 75(4)	Rs. 300 per item R: 75(5)
	(iv) ♦ Drugs specified in Sch. C, viz. LVP and Sera & Vaccines	27-D up to 10 items for each category R: 75(3)	28-D R: 76	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 75(3)	26-H R: 77	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 75(3)	Rs. 1000 R:75(4)	Rs. 300 per item R: 75(5)
	(v) ♦ Whole Human Blood & Components	27-C R: 122F(1)	28-C R: 122G	Lic. fee of Rs. 6000 + Insp. fee of Rs. 1500 for every inspection or for renewal of licence R: 122 F (1)	26-G R: 122-H	Rs.6000+Rs.1000 p.m. or part thereof in addition to insp. fee of Rs.1500 R: 122 F (1)	Rs.1000 R: 122F(2)	Rs. 300 per item R: 75(5)
3.	Mfg. of drugs for purpose of examination, test/analysis	30 R: 90	29 R: 89	Rs.250 R: 90(2)				

PROCEDURE & Work Flow:

Application for Drugs Licence

(i) The application preferably in applicant's own handwriting and in standard size paper for Prescribed Application Form-19, 19-A should be obtained by the Drugs Inspector other than the Drugs Inspector-East Khasi Hills at the District Head Quarter from the applicant.

The Application should indicate the following:

- a) Full name of the Applicant,
- b) the Address of the Applicant,
- c) the Educational Qualification of the Applicant .
- d) the proposed location for Drugs Licence and
- e) the contact number of the applicant.

In case of the Retail and Wholesale Drugs Licence, the application should also indicate the
f) Name of the Person In-Charge /Registered Pharmacist
g) A copy of the valid Registration Certificate

ii) For applicants in the East Khasi Hills District, the application as stated above is to be obtained by the Senior Inspector of Drugs at the Directorate .

iii) The application obtained should be Registered, Numbered and signed with date.

Issuing of Prescribed Application Form:

After registration of written application, issue the Prescribed Form with Check List I, II, III etc accordingly depending on the type of Licence applied for by the applicant.

Sign each and every page of the Form Etc with date before issue to the applicant.

Pass the Treasury Challan for the Drugs Licence Fee with date. The applicant is to be instructed to submit the application issued within three months from the date of issue.

Receiving and Scrutinising of Application Form

After receiving the application form;

Check that all columns are duly filled up by the applicant.

Verify the signature of the applicant and that of the Registered Pharmacist / Competent person if any.

Check by putting tick mark in the column "for office use" , that the documents are enclosed as per check List issued.

Check that all the documents are duly attested including the specimen signatures of all concerned.

The incomplete application form be returned back to the applicant at the earliest.

Direct the applicant to comply and take remedial measures within the remaining period.

Forwarding of application to the SLA (State licensing Authority)

After thorough checking and scrutinizing of the application forms and all the documents submitted by the applicant, forward the complete, scrutinized application to the SLA within one week from the date of receipt.

CHECK LIST NO.1
FOR OBTAINING WHOLESALE DRUGS LICENCES

Sl. No.	Procedure/Detailed Papers to be enclosed (Duly attested wherever applicable)	For use by the applicant	For Office use.
	* Typed application in standard size paper requesting for the application form etc. to be addressed to the respective Inspector of Drugs at the District Head Quarter and to the Senior Inspector of Drugs for applicants in East Khasi Hills, District.		
1	Prescribed Application Form.		
2	Requisite fees Payment through Treasury Challan (non-refundable)		
3	Recent passport size photo of the applicant - 5 Nos		
4	Educational Qualification Certificate of the applicant.		
5	Age Certificate of the applicant.		
6	Specimen Signature of the Applicant		
7	No Objection Certificate from Municipal Board/ Local Durbar / Cantonment Board.		
8	(a) Scheduled Tribe Certificate for Khasi/Jaintia/Garo OR (b) T.N.T. Certificate for other than Khasi/Jaintia/Garo.		
9	P.R.C./EPIC/Bank Account/PAN Card/Current Electricity Bill/Current Telephone Bill / Driving Licence/Income Tax & Sale Tax Clearance Certificate.		
10	Appointment letter (s) from the Company (s) / Manufacturer (s)		
11	Complete product list of the appointing manufacturer (s) / Company (s)		
12	Documents pertaining to the legal tenancy of the premises (Own/Rental).		
13	Key and Site Plan of the premises showing the area in square metres (Min. 10 Sq.m Carpet area and 2.5m height).		
14	Purchase Invoice / Documents of cold storage facility.		
15	Duly filled in Undertaking I in Original (attach supporting documents).		
16	Duly filled in Undertaking II In Original (attach supporting documents).		
17	Provisional List of staff with complete biodata. (attach supporting documents, Qualification, Age and 1(one) Photo each.		
18	Recent passport size photos of the Registered Pharmacists / Experienced person - 5 Nos.		
19	Educational Qualification Certificate of the Registered Pharmacists / Experienced person.		
20	(a) Experience Certificate (s) of the Experienced person OR (b) Up to date Registration Certificate of the Pharmacists with Meghalaya Pharmacy Council.		
21	Age Certificate of the Registered Pharmacist / Experienced person.		
22	Specimen Signature of the Registered Pharmacist / Experienced person.		
23	(a) Partnership Deed / Agreement for Partnership Firm / Ltd. Company (b) Declaration of Sole proprietorship.		
24	Complete self addressed stamp envelope (with Pin Code)		
25	Check List No. 1.		
	* The Prescribed application Form alongwith enclosures to be submitted to the respective Inspector of Drugs or Senior Inspector of Drugs within 3 months from the date of Issue.		
	* Incomplete form will be summarily rejected.		

CHECK LIST NO. II

FOR OBTAINING RETAIL DRUGS LICENCES

Sl. No.	Procedure/Detailed Papers to be enclosed (Duly attested wherever applicable)	For use by the applicant	For Office use.
	* Typed application in standard size paper requesting for the application form etc. to be addressed to the respective Inspector of Drugs at the District Head Quarter and to the Senior Inspector of Drugs for applicants in East Khasi Hills, District.		
1	Prescribed Application Form.		
2	Requisite fees Payment through Treasury Chalan (non-refundable)		
3	Recent passport size photo of the applicant - 6 Nos		
4	Educational Qualification Certificate of the applicant.		
5	Age Certificate of the applicant.		
6	Specimen Signature of the Applicant		
7	No Objection Certificate from Municipal Board/ Local Durbar / Cantonment Board.		
8	(a) Scheduled Tribe Certificate for Khasi/Jaintia/Garo OR (b) T.N.T. Certificate for other tha		
9	P.R.C./EPIC/Bank Account/PAN Card/Current Electricity Bill/Current Telephone Bill / Driving Licence/Income Tax & Sale Tax Clearance Certificate/Passport.		
10	Documents pertaining to the legal tenancy of the premises (Own/Rental).		
11	Key and Site Plan of the premises showing the area in square metres (Min. 10 Sq.m Carpet area and 2.5m height).		
12	Purchase Invoice / Documents of cold storage facility.		
13	Duly filled in Undertaking I in Original (attach supporting documents).		
14	Duly filled in Undertaking II in Original (attach supporting documents).		
15	Provisional List of staff with complete biodata, (attach supporting documents, Qualification, Age and 1(one) Photo each.		
16	Recent passport size photos of the Registered Pharmacists - 6 Nos.		
17	Educational Qualification Certificate of the Registered Pharmacists.		
18	Age Certificate of the Registered Pharmacist.		
19	Specimen Signature of the Registered Pharmacist.		
20	Up to date Registration Certificate of the Pharmacist with Meghalaya Pharmacy Council		
21	(a) Partnership Deed/Agreement for Partnership Firm/Ltd. Company OR (b) Declaration of Sole proprietorship.		
22	Complete self addressed stamp envelope (with Pin Code)		
23	This Check List No. II.		
	* The Prescribed application Form alongwith enclosures to be submitted to the respective Inspector of Drugs or Senior Inspector of Drugs within 3 months from the date of issue.		
	* Incomplete form will be summarily rejected.		

Check List -VFor setting up Drugs Manufacturing Unit

Sl.No.	Documents that are mandatorily required	For use by applicant	Office Use
1	Application in Prescribed Form (Refer Sch-A of the DCAR)		
2	Fees through Treasury Challan as per DCAR		
3	Site Master File		
4	Factory Licence from Commerce & Industries Department.		
5	Waste disposal agreements		
6	Consent of Pollution Control Board		
7	Consent/ Permission of State Electricity Board		
8	Land Deed		
9	Proposed Layout of Building manufacturing premises		
10	Company Memorandum /List of Directors and Company Registration Number		
11	Documents of the Overall in-Charge, Sectional In-Charge(s)		
12	Employees as per Rule 71 or & 71-A of the DCAR		
13	Medical test agreement for employee		
14	GST Number .		
15	List of Instruments and Equipments		