

**MANUFACTURING APPLICATIONS, LICENCES, FEES AND PENALTY
ALLOPATHIC DRUGS**

S. No.	Category of drugs	Application Form No.	Licence Form No.	Fees for Grant/ Retention / Renewal (Under Rule)	Renewal Certificate Form No. / Retention	Penalty after expiry but within six months (GSR 1337 (E) dated 27.10.2017)	Fees for duplicate copy of Original Licence (Under Rule)	Fee for addl. Item for more than 10 item for each category (Under Rule)
1.	Drugs other than those specified in Schedule C & C (1) & X (i) Repacking of drugs	24 B upto 10 items for each category	25 B	Lic. Fees of Rs.500+Insp. Fee of Rs. 200 for every inspection R: 69(2)(a)	Retention	Rs.500 + 2 % of Licence Fee p.m. or part thereof in addition to an inspection fee of Rs. 200	Rs. 1000 R: 69(4)	Rs.100 for each addl. item, R: 69(5)
	(ii) Drugs specified in Schedule 'X'	24 F upto 10 items for each category	25 F	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection R: 69(2)(b)	Retention	Rs.6000 + 2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1000.	Rs.1000 R: 69(4)	Rs.300 per item R: 69(5)
	(iii) Any other drugs	24 upto 10 items for each category	25	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection R: 69(2)(c)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R: 69(4)	Rs.300 per item R: 69(5)

	(iv) Loan Licence	24 A upto 10 items for each category	25 A	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection R: 69A(1)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R: 69A(4)	Rs.300 per item R: 69A(3)
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2.	Drugs specified in Schedule C&C (1) excluding those specified in Sch.X (i) Own unit	27 upto 10 items for each category	28	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection. R: 75(1)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs. 1000 R:75(4)	Rs.300 per item, R: 75(5)
	(ii) Loan Licence	27 A upto 10 items for each category	28 A	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection. R: 75A(1)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R: 75A(4)	Rs.300 per item R: 75(5)
	(iii) □ Drugs specified in Schedule C&C(1) &X	27 B upto 10 items for each category	28 B	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection. R: 75(2)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R: 75(4)	Rs.300 per item R: 75(5)
	(iv) ø Drugs specified in Sch. C, viz. LVP and Sera & Vaccines	27 D upto 10 items for each category	28 D	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection R: 75(3)	Retention	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R: 75(4)	Rs.300 per item R: 75(5)

	(v) Whole Human Blood & Components Or manufacture of Blood products for sale or distribution	27 C or 27 E or 27 F as the case may be	28 C	Lic. Fee of Rs. 6000+ Insp. Fee of Rs.1500 for every inspection or for renewal of licence. R: 122F(1)	Renewal on Form 26 G	Rs.6000+2 % of Licence Fee p.m. or part thereof in addition to insp. Fee of Rs. 1500.	Rs.1000 R:122F(2)	Rs.300 per item R-122F(3)
3.	Mfg. of drugs for purpose of examination, test/analysis	30	29	Rs. 250 R:90(2)	--	--	--	--

❑ Fee for further application after rejection Rs.250(R:82)

ø Fee for further application after rejection Rs. 250(R:122K)