LokLF; lsok egkfun'kky;] pUnj uxj] ngjknu
¼vk"kf/k d{k½

Mx ykblUl gsr pd&fyLV

1. आवेदन पत्र पूर्ण रूप से भरा जाना होगा।
2. वांछित शुल्क के संबंध में चालान की मूल प्रति।
3. गठन के संबंध में घोषणा कि आवेदक एक कम्पनी है अथवा सहभागिता युक्त फर्म है अथवा एकल स्वामित्व है के क्रम में आर्टिकिल ऑफ मेमोरेण्डम, सहभागिता पत्र की छाया प्रति मय अधिकृत व्यक्ति की घोषणा के यदि आवष्यक है/स्वामित्व के संबंध में शपथ पत्र जो कि नोटरी द्वारा प्रमाणित हो, होना चाहियें
4. प्रदूषण विभाग से अनापत्ति प्रमाण पत्र।
5. भवन का मानचित्र (ब्लू प्रिंट) जो कि किसी अधिकृत वास्तुविद द्वारा प्रमाणित हो तीन प्रतियों में वांछित होगा।
6. पेयजल के संबंध में पेयता की परीक्षण रिपोर्ट, कैमिकल तत्वों से सम्बन्धित परीक्षण रिपोर्ट तथा हानिकारक जीवाणुओं के सम्बन्ध में रिपोर्ट कि वे पेय योग्य है, किसी अनुमोदित प्रयोगषाला अथवा राज्य स्वास्थ्य संस्थान से प्रमाणित हो।
7. तकनीकी कर्मचारियों, निर्माण एवं विष्लेषण दोनों के सम्बन्ध में शैक्षिक योग्यता सम्बन्धी प्रमाणपत्र, जिस भी अनुज्ञापन प्राधिकारी से अनुमोदित की प्रमाणित प्रति, नियुक्ति पत्र एवं प्रभार ग्रहण करने की स्थिति जोकि शपथ पूर्वक प्रमाणित हो वांछित होगी। यहॉ यह भी उल्लेखनीय है कि निर्माण एवं विष्लेषण वेत्ताओं के तीन पासपोर्ट संलग्न के प्रमाणित फोटो भी वांछित होंगे।
8. भवन के संबंध में स्वामित्व के संबंध में प्रमाण पत्र कि वह किराये का है अथवा निजी है।
9. निर्माण उपकरणों की सूची।
10. विष्लेषण उपकरणों की सूची जो कि वर्गावार शड्यूल में दिये हुये विवरण के अनुसार होगी। यदि किसी वाहय प्रयोगषाला से किसी विषेष परीक्षण के लिये परीक्षण कराया जाना हो तो उसका उल्लेख।
11. प्रत्येक औषधि के संबंध में संलग्न परिषिष्ट पर वांछित सूचनाओं का पूर्णतया उल्लेख किया जाना।
12. निर्माणषाला के कर्मचारियों के सम्बन्ध में स्वास्थ्य परीक्षण की रिपोर्ट, उनके वैक्सीनेषन तथा इन आकुलेषन के सम्बन्ध में प्रमाणपत्र तथा सामयिक रूप से उनके चिकित्सकीय परीक्षण, वैक्सीनेषन, इन आकुलेषन किये जाने की शपथपूर्वक घोषणा।
13. अधिषमन के उपाय जोकि प्रदान किये गयें हों का विवरण।

14. ऊष्मा के लिए प्रयोग किये जाने वाले साधन कि विद्युत शक्ति से ऊष्मा का प्रयोग किया जायेगा अथवा कोयले के द्वारा किया जायेगा अथवा स्टीम के द्वारा किया जायेगा एवं इस सम्बंध में किस प्रकार के उपकरण प्रयुक्त होगे जैसे स्टीम के सम्बन्ध में व्वॉयलर अलग अन्य उपकरण डबलजैकेट वैसेटस आदि के द्वारा किया जायेगा।

यहॉ यह उल्लेखनीय है कि निम्न संवर्गो के सम्बंध में

1) वैक्सीन एवं सीरा

2) ब्लड बैंक एवं ब्लड प्रोडक्ट

3) लार्ज वॉल्यूम पेरन्टलस के सम्बंध में आवेदन पत्र की एक मूल प्रति आपके कार्यालय में लिया जाना समुचित होगा जिसमें कि सभी मूल अभिलेख होंगे तथा दो छाया प्रतियों सहित आवेदक को महाऔषिधि नियंत्रक, भारत सरकार, निर्माण भवन, नई दिल्ली तथा दूसरी प्रति सहायक औषधि नियंत्रक, भारत सरकार सब–जोन, लखनऊ, 364 चन्दलोक, अलीगंज लखनऊ को आवेदन द्वारा प्रेषित कराया जाना होगा।

फीस संलग्न सूची के अनुसार निम्नलिखित खाता शीर्षक में ट्रेजरी में जमा की जाएगी।

1– शहरी स्वास्थ्य सेवाएं

2– चिकित्सा एवं लोक स्वास्थ्य

3– लोक स्वास्थ्य

4– फीस/जुर्माना आदि

5– औषधि अधिनियम (ड्रग एक्ट) के अन्तर्गत अनुज्ञप्ति शुल्क।

Check List

1. Application Form 24, 27 etc
2. List of Items to be mnfd. (in triplicate)
3. Form XXF
4. Affidavit to the effect that so & so will be responsible for day to day conduct of the business of the firm or company etc. & the brand names of products does not infringe the trade mark Act in any way.
5. Treasury Chalan.
6. Map of the premises (Blue print)
7. Owner ship documents of the premises.
8. Partnership Deed or Article & Memo of association along with certificate of incorporation, and list of present Directors, Resolution of Board of Directors.
9. Power of attorney & authorization letter to Authorized signatory.
10. List of manufacturing Equipments.
11. List of Lab. Equipments
12. Appointment Letters, Joining Letters, Approval Certificates & affidavit of Manufacturing, Analytical Chemists.
13. NOC from UA Pollution Control Board
14. Medical Examination report (Freedom from contagious diseases) from qualified Doctor along with his consent for regular periodical health check up.
15. Portability test report of drinking water.
16. Consent letter from Approved 1ab. for sophisticated instrumental analysis
17. List of fire fighting equipments.
18. S.S.I Registration.

FORM 24
(See Rule 69)

Application for the grant of or renewal of a licence to manufacture of sale (or for distribution of drugs other than those specified in (Schedules C, C(1) and X)

1. I/We.....of. .....hereby apply for the grant/renewal of a licence to manufacture on the premises situated at..... ..... the following drugs, being drugs other than those specified in [Schedules C, C(I), and X] to the Drugs and Cosmetics Rules, 1945.
2. Name of drug categorized according to Schedule M
   .....
   .....
   .....
   .....
   .....
3. Names, qualifications and experience of technical/staff employed for manufacture and testing

4. A fee of rupees ..... has been credited to Government under the head of.....

Date..... Signature.....

Note: The application should be accompanied by a plan of the premises.

FORM 24

[See Rule 69-A]

Application for the grant of or renewal of a licence to manufacture of sale [or for distribution of] drugs other than those specified in [Schedules C, C(1) and X]

1. I/We .... of .... hereby apply for the grant/renewal of a loan licence to manufacture on the premises situated at ... .C/o **..... .....the undermentioned drugs, other than those specified in [Schedules C, C(1), and X] to the Drugs and Cosmetics Rules, 1945.

2. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.
   .....
   .....
   .....

3. I/We enclose
   (a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.
   (b) A true copy of a letter from the manufacturing concern that they agree lend the services of their expert staff, equipment and premises for the manufacture of each item required me/us and that they will analyse every batch of finished product and maintain the registers of raw rnaterials, finished products and reports of analysis separately in this behalf.
   (c) Specimens of labels, cartoons of the products proposed to be manufactured.
4. A fee of rupees……has been
   credited to Government under the head of
   account……..

   Date …… Signature……

---

* Enter here the name of the proprietor,partners or Managing Directors as the case may be.

@ Enter here the name of the applicant firm and the address or the principal place of business

** Enter here the name and address of the manufacturing concern where the manufacture will be actually be carried out and also the Licence number under which the letter operates.

FORM 24-B

[See Rule 69]

Application for the grant of or renewal of a licence to repack for sale [or for distribution of] drugs other than those specified in [Schedules C and C(1)]

[excluding those specified in sch. X]

1. I/We ..... of ..... hereby apply for the grant/renewal of a licence to repack the following drugs at the premises situated at ..... ……
2. Name of drugs to be repacked

.....
.....
.....
.....
.....

3. Names, qualifications and experience of competent staff ……...

.....
.....
.....
.....
.....

4. A fee of rupees forty has been credited to Government under the head of account .....

Date..... Signature of Applicant .....

Note: The application should be accompanied by a plan of the premises.

FORM 24-C

[See Rule 85-B]

Application for the grant of or renewal of a licence to manufacture for sale [or for distribution of] of Homeopathic medicines or a licence to manufacture preparations from back potencies by licenses in Form 20-C

1 I/We ....…… of .... holder of Licence No. ....in form 20- c hereby apply for the grant/renewal of licence to manufacture the under mentioned Homoeopathic Mother Tincture/Potentised and other preparations on the premises situated at……………………………………………………………….

2 Name of Homeopathic preparations ………………………… ....

3 Names, qualifications and experience of technical staff employed for manufacture and testing of Homeopathic medicines .... …………………………………………………………… ……………… ……………………………. ……………………………………………. ………

4 A fee of rupees……………………………………………………………….has been credited to Government under the head of

Date.................................. Signature of Applicant ....

Note: The application should be accompanied by a plan of the premises.

FORM 24-D
(See Rule 153)

Application for the grant/renewal of a licence to manufacture for sale of Ayurvedic/Siddha or Unani drugs

1 I/We ..... of .... hereby apply for the grant / renewal of a licence to manufacture Ayurvedic(including Siddha) or Unani drugs on the premises situated at ....

2 Name of drugs to be manufactured (with details)

.....

.....

.....

3.Names, qualifications and experience of technical/staff employed for manufacture and testing of Ayurvedic (including Siddha) or Unani drugs ....

.....

.....

.....

4. A fee of rupees .... has been credited to Government under the head of account..... .and the relevant treasury challan is enclosed herewith.

Date..... Signature of applicant.....

Note: The application should be accompanied by a plan of the premises.

FORM 24-E

(See Rule 154-A)

Application for the grant/renewal of a loan licence to manufacture for sale of Ayurvedic/Siddha or Unani drugs

1 I/We*.....of.....

.....hereby apply for the grant/renewal of a loan licence to manufacture on the premises situated at..... ..... C/o**.....

2 Name of drugs to be manufactured (with details)

.....
.....
.....
.....

3.Names, qualifications and experience of technical/staff actually connected with the manufacture and testing of Ayurvedic(including Siddha) or Unani drugs in the manufacturing premises

....
....
....
....

4.I/We enclose

(a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

(b) A true copy of a letter from the manufacturing concern that they agree lend the services of their expert staff, equipment and premises for the manufacture of each item required me/us and that they will analyse every batch of finished product and maintain the registers of raw rnaterials, finished products and reports of analysis separately in this behalf.

(c) Specimens of labels, cartoons of the products proposed to be manufactured.

5..A fee of rupees.....has been credited to Government under the head of account.....and the relevant treasury challan is enclosed herewith.

Date …… Signature…….

---

* Enter here the name of the proprietor,partners or Managing Directors as the case may be.

@ Enter here the name of the applicant firm and the address or the principal place of business

** Enter here the name and address of the manufacturing concern where the manufacture will be actually be carried out and also the License number under which the letter operates.

FORM 24-F

[See Rule 69]

Application for the grant of or renewal of a licence to manufacture for sale [or for distribution of] drugs other than those specified in Schedules Xand not specified[Schedules C and C(1)]

1.I/We... .... of .... hereby apply for the grant/renewal of a licence to manufacture on premises situated at .... …… ……..... the under mentioned drugs, specificed in Schedule X to the Drugs and Cosmetics Rules, 1945.

2. Name of drugs.

.....
.....
.....
.....
.....

3. Names, qualifications and experience of technical staff employed for manufacture and testing .....
.....
.....
.....
.....

4.A fee of rupees ..... has been credited to Government under the head of account ……..... ....

Date.....

Signature .....

Designation.....

FORM 27

Application for the grant or renewal of a lincence to manufacture for sale[of for distribution] drugs specified in Schedules C and C(1)[excluding those specified in [Part XB and]Sch .X]

1.I/We..... .... hereby apply

for the grant/renewal of a licence to manufacture on premises situated at

.....… …… …… …….. the undermentioned drugs, being drugs specified in Schedules C, C(1),)[excluding those specified in [Part XB]Sch .X] to the Drugs & Cosmetics rules, 1945.

2.Name of drugs(each item to be separately specified).

.....

.....

.....

.....

3.Names, qualifications and experience of the expert staff responsible for manufacture and testing of the above mentioned drugs.

(a)Name(s) of Staff responsible for test.... ....

(b) Name(s) of Staff responsible for manufacture ....

4.A fee of rupees .....and an inspection fee of rupees..... has been credited to Government under the head of account ……..... ....

Date.....

Signature .....

Designation.....

Note : The application should be accompanied by a plan of the premises.

FORM 27-A
(See Rule 75-A)

Application for the grant/renewal of a loan licence to manufacture for sale [or for distribution of] drugs specified in Schedules C and C(1)[Excluding those specified in [Part XB and] Sch X]

1. I/We*..... ....of @..... ....hereby apply for the grant/renewal of a loan licence to manufacture on the premises situated at..... .... C/o**..... ..... the under mentioned drugs, being drugs specified in Schedules C, C(1) [Excluding those specified in [Part XB and] Sch. X] to the Drugs and Cosmetics Rules, 1945.
2. Name of drugs (each substance to be separately specified)

   .....

   .....

   .....

3. Names, qualifications and experience of technical/staff actually connected with the manufacture and testing of specified products in the manufacturing premises.

   a. Names of Expert staff responsible for manufacture.....
   b. Name(s) of expert staff responsible for testing.....

4.We enclose

   (a) A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.
   (b) A true copy of a letter from the manufacturing concern that they agree lend the services of their expert staff, equipment and premises for the manufacture of each item required me/us and that they will analyse every batch of finished product and maintain the registers of raw rnaterials, finished products and reports of analysis separately in this behalf.
   (c) Specimens of labels, cartoons of the products proposed to be manufactured.

5..A fee of rupees .... has been credited to Government under the head of account ....

Date …… Signature of Applicant.....

---

* Enter here the name of the proprietor, partners or Managing Directors as the case may be.

@ Enter here the name of the applicant firm and the address or the principal place of business

** Enter here the name and address of the manufacturing concern where the manufacture will be actually be carried out and also the License number under which the letter operates.

FORM 27-B

Application for the grant or renewal of a license to manufacture for sale[of for distribution] drugs specified in Schedules C and C(1) and X]

1.I/We..... ....

..... of ....

..... hereby apply for the grant/renewal of a license to manufacture on premises situated at .....

.....…… …… …… ……..the under mentioned drugs, being drugs specified in Schedules C, C(1) and X to the Drugs & Cosmetics rules, 1945.

2.Name of drugs

.....

.....

.....

3.Names, qualifications and experience of the expert staff responsible for manufacture and testing of the above mentioned drugs.

(a)Name(s) of Staff responsible for manufacture.....

(b) Name(s) of Staff responsible for testing.....

4.A fee of rupees .....and an inspection fee of rupees..... has been credited to Government under the head of account

…….....

.

Date..... Signature .....

Note : The application should be accompanied by a plan of the premises.

Delete which ever is not applicable

FORM 27-B

[See Rule 122-F]

Application for the grant or renewal of a licence to manufacture for the operation of Blood Bank, processing of whole human blood for components and/or manufacture of blood products.

1.I/We .... of .... hereby apply for the grant/renewal of a license to operate a Blood Bank, processing of whole human blood for components and/or manufacture of blood products

2.The names of the Human Blood Components intended to be processed shall be specified.

.....

.....

.....

3.Names, qualifications and experience of the expert staff

(a) Name (s) of Medical Officer(s) .....

(b) Name(s) of Registered Nurse .....

(c) Name(s) of Blood Bank technician .....

4. The premises and plan* are ready for inspection/will be ready for inspection on.....

5.A fee of rupees .....and an inspection fee of rupees..... has been credited to Government under the head of account

…….....

.

Date.....

Signature .....

Designation..... .....

The applicant shall be accompanied by a plan of the premises

Delete whatever not applicable

FORM 27-D

Application for the grant or renewal of a licence to manufacture for sale [of for distribution] of Large volume Parenterals /Sera and Vaccines excluding those specified in Schedule X]

1.I/We .... of .... hereby apply for the grant/renewal of a licence to manufacture or distribution on premises situated at.....……..the under mentioned Large volume Parenterals/Sera and Vaccines, specified in Schedules C and C(1), to the Drugs & Cosmetics rules, 1945.

2.Name of drugs

.....
.....(each item to be separately specified)

3.Names, qualifications and experience of the expert staff responsible for manufacture and testing of the above mentioned drugs.

(a)Name(s) of Staff responsible for manufacture.....

(b) Name(s) of Staff responsible for testing.....

4. The premises and plan* are ready for inspection/will be ready for inspection on ....

5.A fee of rupees .....and an inspection fee of rupees..... has been credited to Government under the head of account …….....

Date.....

Signature .....

Designation.....

Note

1.The application should be accompanied by a plan of the premises; list of equipments and machinery to be employed for manufacture and testing; memorandum of association/constitution of the firm; copies of qualification and experience of competent technical staff and documents relating to ownership or tenancy of the premises

2.A copy of the application with relevant enclosures shall also be sent each to Central Licence Approving Authority and concerned Zonal/Sub Zonal Officers of Central drugs Standard Control organization.

INFORMATION DATA SUBMITTED WITH THE APPLICATION FOR GRANT OF DRUG MANUFACTURING LICENCE REGARDING ITEMS TO BE APPROVED

1.Name & Address of the Firm	:	_____
2.Licence No. and Date	:	New Licence Case
3.Categories of items permitted under the licence	:	Not Applicable (New Licence Case)
4.For Pharmacopoeial drugs	:	Not Applicable
(a) Name of the Product	:	_____
(b) Pharmacopoeial Reference (indicate the Edition & page of Pharmacopoeia)	:	_____
5.Patent and Proprietary Drugs	:	_____
(a) Name of the Drug	:	
(b) Complete formula	:	Kindly see overleaf.
(c) If the product is a combination, the data of the rational, efficacy and safety of each of the ingredient signally or in combination	:	Not applicable as similar product exists in the market
(d) Whether a similar product is being manufactured by any other firm in India	:	Yes
if so, details thereof	:	Mfd By m/s_____ _____ _____ _____
(e) Proposed Dosage	:	Nil
(f) The therapeutic claims proposed to made on the label/carton and insert literature	:	
(g) Certificate that the proposed name does not infringe the Trade Mark Act for the time being in force	:	It is certified that the proposed name does not infringe the Trade Mark Act for the time being in force. An affidavit in this regard is enclosed with the application

FORM 30

[See Rule 90]

Application for licence to manufacture drugs for purposes of examination, test or analysis

1. I/We..... ..... of

.....

by occupation.....

hereby apply for a licence to manufacture the drugs specified below for purposes of examination, test or analysis at ..... and I undertake to comply with the conditions applicable to the licence.

2.Name of Drugs

Date ..... Signature.....

FORM 31

[See Rule 138]

Application for the grant of or renewal of a licence to manufacture Cosmetics for sale [or for distribution]

1.I/We .... of .... hereby apply for the grant/renewal of a licence to manufacture on premises situated at ..... …… ……..... the following cosmetics

2.Name of Cosmetics

.....

3.Names, qualifications and experience of technical staff employed for manufacture and testing

.....

.....

.....

.....

4.A fee of rupees .... has been credited to Government under the head of account ……..... ....

Date..... Signature of Applicant.....

Note : The application should be accompanied by a plan of the premises

FORM 31-A

[See Rule 138-A]

Application for the grant of or renewal of loan licence to manufacture cosmetics of sale [or for distribution of]

1. I/We.....of

   .....hereby apply

   for the grant/renewal of a loan licence to manufacture of Cosmetics on the premises situated at..

   .....C/o.....the

   following Cosmetics.

2. Names of Cosmetics .....
3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

   .....

   .....

   .....

4. I/We enclose

   c. A true copy of a letter from me/us to the manufacturing concern whose manufacturing capacity is intended to be utilized by me/us.

   d. A true copy of a letter from the manufacturing concern that they agree lend the services of their expert staff, equipment and premises for the manufacture of each item required me/us and that they will analyse every batch of finished product and maintain the registers of raw rnaterials, finished products and reports of analysis separately in this behalf.

   e. Specimens of labels, cartoons of the products proposed to be manufactured.

3. A fee of rupees…… …… …… has been credited to Government under the head of account…… …… …… ……..

   Date …… Signature…….

Enter here the name and address of the manufacturing concern where the manufacture will be actually be carried out and also the Licence number under which the letter operates.

FORM 36
[See Rule 150-B]

Application for the grant of or renewal of approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/cosmetics

1.I/We. .... of

.... .hereby apply for the grant / renewal of approval for carrying out tests of identity, purity, quality and strengths on the following categories of drugs/items of cosmetics or raw materials used in the manufacture thereof on behalf of licensees for manufacture for sale of drugs/cosmetics

2. * Categories of drugs, items of cosmetics:

a] Drugs other than those specified in Schedule C and C(1) and also excluding Homeopathic Drugs :-

i. Crude Vegetable Drugs
ii. Mechanical Contraceptives
iii. Surgical Dressings
iv. Drugs requiring the use of ultraviolet/Infrared Spectro-Photometer or Chromatography
v. Disinfectants
vi. Other Drugs

b] Drugs Specified in Schedules C and C(1)

i. Sera, Vaccines, Antigens, Toxins, Antitoxins, Toxoids, Bacteriophages and similar Immunological products.
ii. Antibiotics
iii. Vitamins
iv. Parenteral Preparations
v. Sterilised Surgical Ligature/Suture
vi. Sterilised Surgical Ligature/Sulture.
vii. Drugs requiring microbiological tests
viii. Drugs requiring the use of ultraviolet/Infrared Spectro-Photometer or Chromatography
ix. Other Drugs
x.

c] Homeopathic Drugs

d] Cosmetics

3. The names, qualifications and experience of the expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.

.....

.....

.....

4. List of testing of equipment provided.....
.....

.....

.....

5. I/We enclose a plan of the testing premises showing the location and area of the different sections thereof.

6. A inspection fee of Rs. ..... has been credited to Government under the head of account.....

Date..... Signature.....

Delete which ever is not applicable

Schedule of Fees For Grant of Drugs/ Cosmetics Licenses

S. No	Form No	Rule	SCH	Fee Rs.	Requirement for Manufacture/ Testing/ Repacking etc.
1	24	Rule 69	'M'	7500/-	Application for the grant/renewal of a licence to manufacture for sale (or of distribution of) drugs other than those specified in Sch C,C (1) and X
2	24-A	**Rule 69-A**	'M'	**7500/-**	Application for the grant/renewal of a loan licence to manufacture for sale (or of distribution of) drugs other than those specified in Sch. C,C (1) and X
3.	24-B	**Rule 69**	'M'	**700/-**	Application for the grant/renewal of a licence to repack for sale of distribution of drugs, being drugs other than those specified in Schedule C and C (1) (Excluding those specified in Sch X)
4	24-C	**Rule 85-B**	"M'	**300/-**	Application for the grant/renewal of a licence to manufacture for sale (or of distribution of) Homeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensees holding licence in Form 20G
5	24-F	**Rule 75**	M + MIII	**7500/-**	Application for the grant/renewal of a licence to manufacture for sale (or of distribution of) drugs specified in Sch C,C (1) and excluding those specified in (Part XB and)Sch X)
6	27	**Rule 75 A**	M	**7500/-**	Application for the grant/renewal of loan licence to manufacture for sale (or of distribution of) drugs specified in Sch C,C (1) and excluding those specified in (Part XB and)Sch X)
7.	27-A	**Rule 75-A**	M	**7500/-**	Application for the grant/renewal of loan licence to manufacture for sale (or of distribution of) drugs specified in Sch C,C (1) and excluding those specified in (Part XB and)Sch X)
8.	27-B	**Rule 75**	M	**7500/-**	Application for the grant/renewal of a licence to manufacture for sale (or of distribution of) drugs other than those specified in Sch C,C (1) and X
9	27-C	**Rule 122 F**	M & MFXII	**7500/-**	Application for the grant/renewal of a licence for the operation of Blood Bank processing of whole human blood for components and/or manufacture of Blood Products

					components and/or manufacture of Blood Products
10	27-D	**Rule 75**	M & F	**7500/-**	Application for the grant/renewal of a licence to manufacture for sale (or of distribution of) Large volume Parenterals/sera and vaccines excluding those specified in Sch X
11	30	**Rule 90**	TESTL IC	**250/-**	Application for licence to manufacture drugs for purposes of examination, test or analysis
12	31	**Rule 138**	MII	**3500/-**	Application for grant/renewal of a licence to manufacture cosmetics for sale (or for distribution)
13	31 A	**Rule 138 A**	MII	**3500/-**	Application for grant/renewal of a licence to manufacture cosmetics for sale (or for distribution)
14	36	**Rule 150-B**		**7500/-**	Application for grant/renewal of approval for carrying out tests on drugs/cosmetics or raw materials used in the manufacture thereon behalf of licenses for manufacture for sale of drugs/cosmetics

"ENCLOSED " INFORMATION DATA TO BE SUBMITTED WITH APPLICATION FOR GRANT OF DRUG MFG LIC REGARDING ITEM TO BE APPROVED

Form – 19

See Rule 59(2)

Application for grant of a license to sell, stock or exhibit for sale, or distribute drugs.

1. I/We_____ (Mention Name, address of Prop. or partner of Director whichever is applicable)

   of M/s _____(name of the firm)

   Hereby apply for license to sell by Wholesale/Retail drugs specified in schedule C & C(i) excluding those specified in schedule x and /or drugs other than those specified in schedule C & C(i) and x to the Drugs & Cosmetics Rules, 1945 and also to operate a pharmacy on the premises situated.

   At_____ _____(Address of the Firm)

2. (Phone No. with STD Code)_____

3. The sale & dispensing of drugs will be made under the personal supervision of the qualified/competent person namely:-

   1. Name_____Qualification_____

   2. Name_____Qualification_____

   3. Name_____Qualification_____

   (Mention Pharmacist registration no. and date in case of wholesale mention Qualification + Experience)

4. Categories of drugs to by sold_____

5. Particulars of special storage:- Fridge/AC make_____ Capacity_____Lt. Cheese no._____

6. A fee of Rs._____(in words)_____has been credited to the Government of Uttaranchal under the head of accounts no. 0102100110302 vide Treasury challan no._____Dated_____on_____ _____(Name of Bank or Treasury).

   1. I/We opts that we shall maintain cash/credit memos/register of the entire sale and purchase of drugs.

   Date_____ Signature(s) of applicant

   For use of the reporting & licensing authority
   Recommended/Not Recommended (for the reasons given below)

   Signature of the Inspector (Drugs)

   Sanctioned/Refused (for the reasons given below)

   Signature of DLA

BEFORE DRUG LICENSING AUTHORITY, UTTARANCHAL

AFFIDAVIT

I_____S/o Sh._____

Aged about_____years, permanent R/o_____

_____

Presently residing at_____

_____

Do hereby solemnly affirm and state on oath as under: -

2. That the deponent has passed the following qualifications: -

   a) High School from_____Board, in the year_____with roll no._____(attested copy enclosed)

   b) Intermediate from_____Board, in the year___with roll no._____(attested copy enclosed)

   c) Graduation form_____University, in the year____with roll no. _____(attested copy enclosed)

3. That the deponent has joined his duties as a full time registered Pharmacist with M/s_____w.e.f._____

   (Self attested photocopies of my appointment & joining letters are enclosed)

10. That the deponent has _____years experience in sale purchase of medicine.

11. That the deponent and the ow

Spot Inspection Report (Sale Licence)

1. M/s_____

Address_____

_____ _____ _____

Tel. Nos. _____STD Code_____

2. Premises Type – Own ( ) or Rented ( ) or on Lease ( )

(Proof thereof) _____

Carpet area – Length_____Width_____= _____Sq.ft. Pucca well built( )

3. Special Storage facilities - Fridge/AC_____Make_____

Capacity_____Lt. Chasis No. _____

Furniture/Counter_____Signboard_____

4. Constitution – (Proprietor/Partners/Directors)

(Proof) – Affidevit/Partnership deed/Article of Asso. & Memorandum

Sl. No.	**Name, Parentage & Residential Address (Proof)**	**D.O.B. (Proof)**	**Qualification (Proof)**	**Others**

5. Technical Staff- Name

Sl.	**Name, DOB, Parentage, Original & Present Address**	**Edu. & Prof. Qualification**	**Registration No. & Dt. (Proof)**	**Experience/Renewed up to (Proof)**

6. D.L. applied for _____

7. Fee detail – Rs._____Ch. no. _____dt. _____Bank/Tr._____

8. Other Details _____

(Inspector of Drugs)

समक्ष – औषधि अनुज्ञापन प्राधिकारी, उत्तरांचल

मैं/हम––––––––––––––––––––––––––––––––पुत्र/पत्नी श्री––––––––––––––––––––––
उम्र–––वर्ष, निवासी––––––––––––––––––––––––––––––––––––स्वामी/भागीदार/प्रबन्ध निदेशक फर्म मै0––––––––––––––––––––––––––––पता––––––––––––––––––––––––
शपथ पूर्वक निम्न बयान करता हूँ/करते हैं :–

1. यह कि शपथी उपरोक्त फर्म का एकमात्र स्वामी/भागीदार (डीड संलग्न)/प्रबन्ध निदेशक (आर्टिकल ऑफ मैमोरेन्डम संलग्न) होने के कारण अन्य के साथ – साथ फर्म के दिन प्रतिदिन के व्यवसाय के संचालन के लिये उत्तरदायी होगा/होंगे।
2. यह कि शपथी की शैक्षिक योग्यता बी0फार्मा है तथा वह उत्तरांचल फार्मेसी रजिस्ट्रेशन ट्रिब्युनल से पंजीकृत है (प्रमाणपत्र संलग्न)। शपथी उक्त फर्म में स्वयं एक कम्पीटेन्ट परसन के रुप में कार्य करेगा तथा इस कार्य के लिये वह स्वयं उत्तरदायी होगा। शपथी वर्तमान में किसी भी सरकारी अथवा गैर सरकारी संस्था में कार्यरत नही है।
3. यह कि शपथी ने उक्त फर्म के लिये एक परिसर/दुकान जिसका क्षेत्रफल––––––––वर्गफुट है, जो पक्का बना हुआ है तथा जिसमें साईन बोर्ड, काउन्टर, रैक्स, बिजली तथा फ्रिज (मेक––––––––––कैपिसिटी––––लीटर, चेसिस न0–––) आदि की व्यवस्था कर ली गयी है जो किराये पर (रसीद संलगन)/अपने स्वामित्व में (प्रमाण पत्र संलग्न) प्रदान कर लिया है। उक्त संस्थान का नक्शा संलग्न है। संस्थान की चौहद्दी निम्न प्रकार है :–
   1. पूरब––––––––––2. पश्चिम––––––––––3. उत्तर––––––––––4. दक्षिण––––––––––
   इसके अतिरिक्त उक्त संस्थान स्वच्छ एवं हाइजिनिक स्थान पर स्थित है।
4. यह कि शपथकर्ता उपरोक्त संस्थान पर रिटेल/होलसेल/गोदाम/सी0एण्डएफ0/स्थान परिवर्तन/संविधान परिवर्तन/नाम परिवर्तन हेतु आवेदन कर रहा है जिसमें एलोपैथिक/होम्योपैथिक औषधियों की बिक्री/भण्डारण का कार्य किया जायेगा। शपथी ने इस मद में रु0–––––––राजकीय कोषागार––––––––––––––में ट्रेजरी चालान सं0––––दि0––––––
   (मूल चालान संलग्न) के माध्यम से जमा करा दिये गये हैं। शपथी ने अपने संस्थान पर आयुर्वेदिक/वैटर्नरी/मियाद समाप्त औषधियों के लिये पृथक रैक्स की व्यवस्था कर ली है।
5. यह कि शपथी ने ड्रग्स एवं कास्मेटिक्स एक्ट व नियमावली खरीद ली है तथा उसका भली भांति अध्ययन कर लिया है। शपथी औषधियों की खरीद के रिकार्ड के रुप में खरीद बीजक तथा बिक्री के रिकार्ड के रुप में कैश/क्रेडिट मेमो की पठनीय कार्बन प्रतियां अपने संस्थान पर निरीक्षण हेतु नियमों के अन्तर्गत निर्धारित समायावधि तक सुरक्षित रखेगा।
6. यह कि शपथी, उसके भागीदारों, उसके अन्य निदेशकों के विरुद्ध आज दिन तक किसी भी न्यायालय द्वारा कोई भी दण्डात्मक कार्यवाही नही की गयी है और न ही उसे/उन्हें कोई सजा हुयी है (चरित्र प्रमाण संलग्न है)।
7. यह कि शपथी द्वारा ड्रग नियमावली के समस्त प्राविधानों का अनुपालन जो ड्रग लाइसेन्स प्राप्त करने से पूर्व आवश्यक हैं को पूरा कर लिया गया है।

इस शपथ पत्र के पैरा 1 से 7 तक मेरे ज्ञान में सत्य हैं। कुछ भी छिपाया नही गया है। ईश्वर मेरी सहायता करे।

दिनांक – शपथकर्ता के हस्ताक्षर

समक्ष – औषधि अनुज्ञापन प्राधिकारी, उत्तरांचल

मैं/हम––––––––––––––––––––––––––––––पुत्र/पत्नी श्री––––––––––––––––––––
उम्र–––वर्ष, निवासी––––––––––––––––––––––––––––––––––स्वामी/भागीदार/प्रबन्ध निदेशक फर्म मै0––––––––––––––––––––––––––पता––––––––––––––––––––––
शपथ पूर्वक निम्न बयान करता हूँ/करते हैं :–

8. यह कि शपथी उपरोक्त फर्म का एकमात्र स्वामी/भागीदार (डीड संलग्न)/प्रबन्ध निदेशक (आर्टिकल ऑफ मैमोरेन्डम संलग्न) होने के कारण अन्य के साथ – साथ फर्म के दिन प्रतिदिन के व्यवसाय के संचालन के लिये उत्तरदायी होगा/होंगे।
9. यह कि शपथी ने अपनी फर्म में औषधियों की खरीद व बिक्री के सुपरविजन हेतु एक पूर्णकालिक रजिस्टर्ड फार्मासिस्ट को नियुक्त कर लिया है जिसका शपथ पत्र, शैक्षिक योग्यता का प्रमाण पत्र, रजिस्ट्रेशन प्रमाण पत्र संलगन है।
10. यह कि शपथी ने उक्त फर्म के लिये एक परिसर/दुकान जिसका क्षेत्रफल––––––––वर्गफुट है, जो पक्का बना हुआ है तथा जिसमें साईन बोर्ड, काउन्टर, रैक्स, बिजली तथा फ्रिज (मेक––––––––कैपिसिटी––––लीटर, चेसिस न0–––) आदि की व्यवस्था कर ली गयी है जो किराये पर (रसीद संलगन)/अपने स्वामित्व में (प्रमाण पत्र संलग्न) प्रदान कर लिया है। उक्त संस्थान का नक्शा संलग्न है। संस्थान की चौहद्दी निम्न प्रकार है :–
    1. पूरब––––––––––2. पश्चिम––––––––––3. उत्तर––––––––4. दक्षिण––––––––––
    इसके अतिरिक्त उक्त संस्थान स्वच्छ एवं हाइजिनिक स्थान पर स्थित है।
11. यह कि शपथकर्ता उपरोक्त संस्थान पर रिटेल/होलसेल/गोदाम/सी0एण्डएफ0/स्थान परिवर्तन/संविधान परिवर्तन/नाम परिवर्तन हेतु आवेदन कर रहा है जिसमें एलोपैथिक/होम्योपैथिक औषधियों की बिक्री/भण्डारण का कार्य किया जायेगा। शपथी ने इस मद में रु0–––––––राजकीय कोषागार––––––––––––––में ट्रेजरी चालान सं0––––दि0––––––
    (मूल चालान संलग्न) के माध्यम से जमा करा दिये गये हैं। शपथी ने अपने संस्थान पर आयुर्वेदिक/वैटर्नरी/मियाद समाप्त औषधियों के लिये पृथक रैक्स की व्यवस्था कर ली है।
12. यह कि शपथी ने ड्रग्स एवं कास्मेटिक्स एक्ट व नियमावली खरीद ली है तथा उसका भली भांति अध्ययन कर लिया है। शपथी औषधियों की खरीद के रिकार्ड के रुप में खरीद बीजक तथा बिक्री के रिकार्ड के रुप में कैश/क्रेडिट मेमो की पठनीय कार्बन प्रतियां अपने संस्थान पर निरीक्षण हेतु नियमों के अन्तर्गत निर्धारित समायावधि तक सुरक्षित रखेगा।
13. यह कि शपथी, उसके भागीदारों, उसके अन्य निदेशकों के विरुद्ध आज दिन तक किसी भी न्यायालय द्वारा कोई भी दण्डात्मक कार्यवाही नही की गयी है और न ही उसे/उन्हें कोई सजा हुयी है (चरित्र प्रमाण संलग्न है)।
14. यह कि शपथी द्वारा ड्रग नियमावली के समस्त प्राविधानों का अनुपालन जो ड्रग लाइसेन्स प्राप्त करने से पूर्व आवश्यक हैं को पूरा कर लिया गया है।

इस शपथ पत्र के पैरा 1 से 7 तक मेरे ज्ञान में सत्य हैं। कुछ भी छिपाया नही गया है। ईश्वर मेरी सहायता करे।

दिनांक – शपथकर्ता के हस्ताक्षर

Check List for sale licence

1. Form 19
2. Affidavit of Proprietor, affidavit of Pharmacist (in case or retail)
3. Challan
4. Educational certificates of proprietor, experience certificate of proprietor (in case of wholesale)
5. Educational & registration certificates of pharmacist (in case of retail)
6. Map of premise in blue print
7. In case of c & f agent company's letter, memorandum of article of association of the company and power of attorney.
8. In case of partnership, partnership deed is required
9. Rent agreement or ownership proof.

BEFORE DRUG LICENSING AUTHORITY, UTTARANCHAL

AFFIDAVIT

I_____S/o Sh._____

Aged about_____years, permanent R/o_____

_____

Presently residing at_____

_____

Do hereby solemnly affirm and state on oath as under: -

4. That the deponent has passed the following qualifications: -
   a) High School from____Board, in the year___with roll no._____(attested copy enclosed)
   b) Intermediate from____Board, in the year___with roll no._____(attested copy enclosed)
   c) Degree/Diploma in Pharmacy from_____University. (Name of the institute_____) in the year____with roll no._____(atttested copy enclosed)
   d) Registration certificate no._____dt._____form Uttaranchal Pharmacist Registration Tribunal, Dehradun.(Attested photocopy enclosed)
5. That the deponent has joined his duties as a full time registered Pharmacist with M/s_____w.e.f._____

   (Self attested photocopies of my appointment & joining letters are enclosed)

6. That the deponent and the owner of the above firm are personally known to each other.
7. That the deponent is not working as registered Pharmacist in any Govt. or Private institution or any shop etc.
8. That whenever the deponent will leave the shop he will give one month notice to the owner of above firm and if the owner of the firm wants to do so he will also give one month prior notice to me.
9. That the deponent bears a good moral character and has never been convicted by any court of law.

   That para 1 to 5 of this affidavit are correct to the best of my knowledge, nothing is hidden. God help me.

Dated Deponent

समक्ष – औषधि अनुज्ञापन प्राधिकारी, उत्तरांचल

मैं/हम––––––––––––––––––––––––––––––––पुत्र/पत्नी श्री––––––––––––––––––––
उम्र–––वर्ष, निवासी––––––––––––––––––––––––––––––––––स्वामी/भागीदार/प्रबन्ध निदेशक फर्म मै0––––––––––––––––––––––––––पता––––––––––––––––––––––––

शपथ पूर्वक निम्न बयान करता हूँ/करते हैं :–

1. यह कि शपथी उपरोक्त फर्म का एकमात्र स्वामी/भागीदार (डीड संलग्न)/प्रबन्ध निदेशक (आर्टिकल ऑफ मैमोरेन्डम संलग्न) होने के कारण अन्य के साथ – साथ फर्म के दिन प्रतिदिन के व्यवसाय के संचालन के लिये उत्तरदायी होगा/होंगे।
2. यह कि शपथी उपरोक्त फर्म में स्वयं एक कम्पीटीशन परसन के रुप में कार्य करेगा। शपथी को औषधियों की खरीद एवं बिक्री का ––––––वर्ष का अनुभव है। (प्रमाण पत्र संलग्न)
3. यह कि शपथी ने उक्त फर्म के लिये एक परिसर/दुकान जिसका क्षेत्रफल––––––––वर्गफुट है, जो पक्का बना हुआ है तथा जिसमें साईन बोर्ड, काउन्टर, रैक्स, बिजली तथा फ्रिज (मेक––––––––कैपिसिटी––––लीटर, चेसिस न0–––) आदि की व्यवस्था कर ली गयी है जो किराये पर (रसीद संलगन)/अपने स्वामित्व में (प्रमाण पत्र संलग्न) प्रदान कर लिया है। उक्त संस्थान का नक्शा संलग्न है। संस्थान की चौहद्दी निम्न प्रकार है :–
   1. पूरब––––––––––2. पश्चिम––––––––––3. उत्तर––––––––4. दक्षिण––––––––––
   इसके अतिरिक्त उक्त संस्थान स्वच्छ एवं हाइजिनिक स्थान पर स्थित है।
4. यह कि शपथकर्ता उपरोक्त संस्थान पर रिटेल/होलसेल/गोदाम/सी0एण्डएफ0/स्थान परिवर्तन/संविधान परिवर्तन/नाम परिवर्तन हेतु आवेदन कर रहा है जिसमें एलोपैथिक/होम्योपैथिक औषधियों की बिक्री/भण्डारण का कार्य किया जायेगा। शपथी ने इस मद में रु0––––––राजकीय कोषागार––––––––––––––में ट्रेजरी चालान सं0––––दि0––––– (मूल चालान संलग्न) के माध्यम से जमा करा दिये गये हैं। शपथी ने अपने संस्थान पर आयुर्वेदिक/वैटर्नरी/मियाद समाप्त औषधियों के लिये पृथक रैक्स की व्यवस्था कर ली है।
5. यह कि शपथी ने ड्रग्स एवं कास्मेटिक्स एक्ट व नियमावली खरीद ली है तथा उसका भली भांति अध्ययन कर लिया है। शपथी औषधियों की खरीद के रिकार्ड के रुप में खरीद बीजक तथा बिक्री के रिकार्ड के रुप में कैश/क्रेडिट मेमो की पठनीय कार्बन प्रतियां अपने संस्थान पर निरीक्षण हेतु नियमों के अन्तर्गत निर्धारित समायावधि तक सुरक्षित रखेगा।
6. यह कि शपथी, उसके भागीदारों, उसके अन्य निदेशकों के विरुद्ध आज दिन तक किसी भी न्यायालय द्वारा कोई भी दण्डात्मक कार्यवाही नही की गयी है और न ही उसे/उन्हें कोई सजा हुयी है (चरित्र प्रमाण संलग्न है)।
7. यह कि शपथी द्वारा ड्रग नियमावली के समस्त प्राविधानों का अनुपालन जो ड्रग लाइसेन्स प्राप्त करने से पूर्व आवश्यक हैं को पूरा कर लिया गया है।

इस शपथ पत्र के पैरा 1 से 7 तक मेरे ज्ञान में सत्य हैं। कुछ भी छिपाया नही गया है। ईश्वर मेरी सहायता करे।

दिनांक –

शपथकर्ता के हस्ताक्षर