DRUGS CONTROL ORGANISATION

Medical & health Department, Swasthya Bhawan, Tilak Marg Jaipur

Email address- drugscontrolraj@gmail.com Phone - 01412221760

Check List for documents to be submitted for

Grant of Manufacturing Licences/ Blood bank.

(1) Application on prescribed form as per annexure table "A" along with requisite fees given in the same table , to be deposited in Bank through treasury challan duly attested by the office in Head-
0210- Medical & public Health
04- Public Health
800- Other receipt
(02) Miscellaneous receipt

(2) Affidavit of Proprietor/ Partners/ Director(s)/ Managing Director on Rs 10/= Non Judicial Stamp Paper duly attested by Notary Public (Annex. 'I-1&2')

(3) List of all the Partners/ Directors with age & complete postal & residential address.

(4) Specific Power of attorney in favor of Authorised Signatory for submitting Application on behalf of the Company on Rs 10/= Non-judicial Stamp paper duly attested by Notary Public (Annex. "J")

(5) Affidavit of Manufacturing Chemist & Analytical Chemist on Rs 10/= Non-judicial Stamp paper duly attested by Notary Public (Annex. "K-1&2")

(6) Attested Photostat Copies of qualification, experience and approval certificates of Manufacturing Chemist.& Analytical Chemist

(7) Original & Attested copies of Registration issued by Pharmacy Council in the name of Manufacturing Chemist &/or Analytical Chemists. (If any)

(8) Site Master File duly signed.

(9) Performa for approval of products (Annex. "L-1&2").

(10) Section wise list of Plant and machineries ,AHU's, water system, analytical instruments, apparatus for physico chemical, microbiological , biological along with their attested photocopies of purchase invoices provided.

(11) Medical examination Certificate of technical staff & employees includes absence of contagious disease,

(12) Registration from District Industries Center.

(13) Consent to establish & consent to operate from Rajasthan State Pollution Control Board.

(14) List of Reference books and literature provided.

(15) Document pertaining to ownership for the proposed site of the unit & documents in its support.

(16) Attested copies of partnership deed / Memorandum & article of Association.

(17) Specific resolution for commencing Drug/Cosmetic- Manufacturing activities (if not already included in Memorandum of Association)

(18) Section wise blue print of location of plant and machineries (dimensions in Metric system) , & site plan .

(19) Consent letter from government approved laboratory for sophisticated tests.

(20) Consent letter from principal manufacturing unit in case of loan license.

(21) For Blood Bank - Affidavits of Medical Officer, Blood Bank Technician, & Registered Nurse on Rs 10/= Non-judicial Stamp paper duly attested by Notary Public (Annex. "N-1&2")with attested Photostat Copies of qualification, experience and approval certificates.& No objection certificate from Rajasthan State Transfusion Council.

Annex. 'A'

Application	Type of License	License & inspection Fee
Form 24	Drugs other than those specified in Schedule C and C (1)	Rs 6000 +Rs 1500
Form 24-A	Loan manufacturing for other than those specified in Schedule C and C (1) and Schedule X	Rs 6000 + Rs 1500
Form 27	Drugs those are specified in Schedule C and C (1) excluding Part X-B and Schedule X.	Rs 6000 +Rs 1500
Form 27A	Loan manufacturing for those specified in Schedule C and C (1) excluding Part X-B and Schedule X.	Rs 6000 +Rs 1500
Form 27-B	Drugs those are specified in Schedule C, C(1) and X.	Rs 6000 +Rs 1500
Form 27-D	Drugs - Large Volume Parenterals and Sera and Vaccines.	Rs 6000 +Rs 1500
Form 24-C	Homoeopathic Drugs- Mother tinctures and Potentised preparations	Rs 600 +Rs 300
Form 27-C	Operation of Blood Bank and / or preparation of Blood Components	Rs 6000 +Rs 1500
Form 27-E	Blood Products	Rs 6000 +Rs 1500
Form 31	Cosmetics	Rs 2500 + Rs 1000

Annex. 'B'

FORM 24

[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 Schedule 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 Schedule C and C(1) and X to the Drugs and Cosmetics Rules, 1945.
2. Name(s) of drugs categorized according to Schedule M.
3. Name(s), qualifications and experience of technical staff employed for manufacture and testing.
4. A fee of Rs. ……... has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

Note- The application should be accompanied with a plan of premises.

FORM 24-A

[See Rule 69-A]

Application for grant of or renewal of a loan licence to manufacture for sale or for distribution of drugs other than those specified in Schedule 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 under mentioned drugs, other than those specified in Schedule C and C(1) and X to the Drugs and Cosmetics Rules.

   Name(s) of drugs (each substance to be separately specified)
2. The name(s), 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 encloses
   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 to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and they will analyze each batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.
   c) Specimens of labels, cartons of the products proposed to be manufactured.
4. A fee of Rs. ……... has been credited to the Govt. Account under the head of Account :

Date …….. Signature

Annex. D

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 Homoeopathic medicines or a licence to manufacture potentised preparations from back potencies by licensee holding licence in Form 20-C.

1. I/We……of ……..… holders of licence No. …… in Form 20-C hereby apply for the grant/renewal of a licence to manufacture the under mentioned Homoeopathic mother tinctures/ Potentised and other preparations on the premises situated at

   Name(s) of Homoeopathic preparation …….

   (Each item to be separately specified)

2. Name(s), qualifications and experience of technical staff employed for manufacture and testing of Homoeopathic medicines.
3. A fee of Rs. ……... has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

FORM 27

[See Rule 75]

Application for grant of or renewal of a licence to manufacture for sale or for distribution of drugs specified in Schedule C and, C(1) excluding those specified in Part XB and Schedule X.

1. I/We……..……,of ……. hereby apply for the grant/renewal of a licence to manufacture on the premises situated at …… ……..…… the under mentioned drugs, being drugs specified in Schedule C and C(1), excluding those specified in Part XB and Schedule X to the Drugs and Cosmetics Rules, 1945.

   Name(s) of drugs.

   (Each item to be separately specified)

2. Name(s), qualifications and experience of technical staff responsible for manufacture and testing of above-mentioned drugs:

   a) Name(s) of staff responsible for test ……

   b) Name(s) of staff responsible for manufacture ……

3. The premises and plan are ready for inspection/ will be ready for inspection on …….
4. A fee of Rs. ……... and an inspection fee of Rs. …….. has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

Annex. 'F'

FORM 27-A

[See Rule 75]

Application for grant of or renewal of a loan licence to manufacture for sale or for distribution of drugs specified in Schedule C and, C(1) excluding those specified in Part XB and Schedule 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 Schedule C and C(1), excluding those specified in Part XB and Schedule X to the Drugs and Cosmetics Rules, 1945.

   Name(s) of drugs.

   (Each substance to be separately specified)

2. Name(s), qualifications and experience of expert staff actually connected with the manufacture and testing of the specified products in the manufacturing premises.
   a) Name(s) of expert staff responsible for manufacture …….
   b) Name(s) of expert staff responsible for testing ……..
3. I/We encloses
   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 to lend the services of their expert staff, equipment and premises for the manufacture of each item required by me/us and they will analyse each batch of finished product and maintain the registers of raw materials, finished products and reports of analysis separately in this behalf.
   c. Specimens of labels, cartons of the products proposed to be manufactured.
4. A fee of Rs. ……... and an inspection fee of Rs. …….. has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

FORM 27-C

[See Rule 122-F]

Application for grant of or renewal of a licence for the operation of a Blood Bank for processing of whole blood and/or preparations of Blood Components.

1. I/We ……..……..……..…… proprietor / partners/ directors/ of M/s …… hereby apply for the grant/renewal of licence number …… dated …….. to operate a Blood Bank, for processing of whole blood and/or for preparation of its components on the premises situated at ……..…… Name(s) of item(s).
    1. ..
    2. ……
2. The name(s), qualifications and experience of competent technical staff are as under:
    a) Name(s) of Medical Officer
    b) Name(s) of staff Technical Supervisor.
    c) Name(s) of Registered Nurse.
    d) Name(s) of Blood Bank Technician
3. The premises and plan are ready for inspection/ will be ready for inspection on …….
4. A fee of Rs. ……... and an inspection fee of Rs. …….. has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

Note:

1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.
2. A copy of application together with the relevant documents shall also be sent to Central Licence Approving Authority and to the Zonal/Sub Zonal Officers concerned of the Central Drugs Standard Control Organisation.

FORM 27-D

[See Rule 75]

Application for the grant of or renewal of a licence to manufacture for sale or for distribution of Large Volume Parenterals/Sera and Vaccines excluding those specified inSchedule X

1. I/We …….. of…… hereby apply for the grant/renewal of licence to manufacture for sale or distribution on the premises situated at …… the under mentioned Large Volume Parenterals/Sera and Vaccines, specified in Schedule C and C(1) to the Drugs & Cosmetics Rules, 1945.
2. Name(s) of drugs(s). (Each item to be separately specified)
3. The name(s), qualifications and experience of the competent technical staff responsible for the manufacture of the above mentioned drugs.
    a) Name(s) of staff responsible for testing ……
    b) Name(s) of staff responsible for manufacturing …….
4. The premises and plan are ready for inspection/ will be ready for inspection on … .
5. A fee of Rs. ……... and an inspection fee of Rs. …….. has been credited to the Govt. Account under the head of Account :

Date …….. Signature ……..

Note:

1. The application is to be accompanied by a plan of the premises, list of equipment and machinery to be employed for manufacturing and testing; memorandum of association/constitution of the firm; copies of qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.
2. A copy of application together with the relevant enclosures shall also be sent each to Central Licence Approving Authority and Zonal/Sub Zonal Officers concerned of the Central Drugs Standard Control Organisation.

Form-31

(see rule 139)

Application for the grant or renewal of a license to manufacture cosmetics for sale or for distribution

1. I/we ……, of …… hereby apply for the grant / renewal of a license to manufacture on the premises situated at …… the following cosmetics:-
2. Name of cosmetics …….. .
3. Names , qualifications & experience of technical staff employed for manufacture & testing …….. .
4. A 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 premises.

Annex. 'I-1'

Affidavit of Proprietor/ Partners/ Director(s)/ Managing Director

(Performa to be submitted on Rs 10/= Non-judicial Stamp paper duly attested by the Notary Public)

I, ---------- S/O, D/O Shri ----------, Age ---------, Caste ----------, Resident of ---------- declare solemnly on oath as under:-

1) That I am proprietor/partner/Managing Director/ Director of M/s ----------, (Name & Complete Address of manufacturing site) ---------- by whom an application for grant of manufacturing licenses for manufacturing drugs/ medical devises/ cosmetics/ loan license has been made on Form Nos. ---------- to the Licensing Authority and Drugs controller, Rajasthan, Jaipur under the provision of Drugs & Cosmetics Act, 1940 and Rules, 1945.

2) That following are the other partners/ Directors of the firm:-

S.N.(1)	Name(s)& Father's name	Age	Residential address

3) That the building in which manufacturing activities are proposed are taken on rent/ lease from ----------/ are own premises which are adapted as per Schedule M/ M-I/M-II/M-III of the said rules.

4) That adequate qualified technical staff has already been appointed as per site Master file & other documents submitted along with the application.

5) That I will be solely responsible for the conduct of day-to-day activities of the firm for the purpose of Section 34 of the said Act as well as other prevailing enactments established by Law of Government of India & shall abide by all the provisions of Drugs & Cosmetics Act 1940 & Drugs Price Control Order 1995 as amended from time to time.

Witness No. 1 ----------

(Signature, Name and Address)

Witness No. 2 ----------

(Signature, Name and Address)

(DEPONENT) (Name)

VERIFICATION

I, ---------- verify that the contents of para 1 to 5 of this affidavit are true to the best of my knowledge and belief. So GOD help me.

Date ----------

Place ---------- (DEPONENT) (Name)

Annex 'J'

Performa of affidavit Power of Attorney to be executed by Partners/ Managing Director

I, ---------- s/o : w/o ; d/o Shri ----------, Age ---------, Caste ----------, Resident of ---------- declare solemnly on oath as under:-

1) That I am partner/Managing Director of M/s ----------, (Complete Address of manufacturing site) ---------- by whom an application for grant of manufacturing licenses for manufacturing drugs/ medical devises/ cosmetics/ loan license has been made to the Drugs controller, Rajasthan, Jaipur under the provision of Drugs & Cosmetics Act, 1940 and Rules, 1945.

2) That Shri ---------- s/o : w/o ; d/o ---------- Age ------, Caste --------- Resident of ---------- ---------- is authorized to sign and submit documents on behalf of the firm to the Licensing Authority and Drugs controller, Rajasthan, Jaipur.

3) That the signatures of Shri ---------- are hereby attested as under:

Signatures of Shri ----------

Witness No. 1 ---------- Witness No. 2 ----------

(Signature, Name and Address) (Signature, Name and Address)

(DEPONENT)

Name

VERIFICATION

I, ---------- verify that the contents of para 1 to 3 of this affidavit are true to the best of my knowledge and belief. So GOD help me.

Date ----------

Place----------

(DEPONENT)

Annex. 'K-1'

Performa of Affidavit to be submitted by Manufacturing & Analytical Chemist

I, ---------- s/o :; d/o Shri ----------, Age ---------, Caste ----------, Resident of ---------- declare solemnly on oath as under:-

1) That I have following qualification:-

S. N. (1)	Qualification (2)	University (3)

2) That I have following experience:-

S.No.(1)	Name and address of the firm(2)	Period of working with dates(3)

3) That I have been approved in the following sections for manufacturing / analysis of drugs:-

S.No.	Section in which approved	Approving Authority	Letter no. & date

4) That I have joined M/s ----------, (Complete Address of manufacturing site) ---------- on ---------- and will inform the Licensing Authority & Drugs Controller, Rajasthan, Jaipur as soon as I resign from this firm by registered post.

5) That I was working previously with M/s ----------, (Complete Address of manufacturing site) ---------- up to -------- and have informed the Licensing Authority on ---------- regarding my resignation from this firm.

6) That I will be responsible for the manufacturing/analytical activities of the firm for the purpose of Section 34 of the said Act as well as other prevailing enactments established by Law of Government of India

Witness No. 1 ---------- Witness No. 2 ----------

(Signature, Name and Address) (Signature, Name and Address) (DEPONENT) Name

VERIFICATION

I, ---------- verify that the contents of para 1 to 6 of this affidavit are true to the best of my knowledge and belief. So GOD helps me.

Date ----------

Place ---------- (DEPONENT) Name

Annex. 'L-1'

Performa for approval of products

(Name of firm & complete address)

- Name of Product:
- Pharmacopoeal Name

Edition & page no.

- Category:
- Composition:
- Dosage:
- Expiry:
- Packing:
- Similar Market Product:

(Name & signature of authorized Person)

Name of firm

Annex. 'L-2'

UNDERTAKING

1. I/We undertake that any addition there to or any deletion there from will not be done without prior permission of the Licensing Authority.

2. I/We undertake to comply with all the provisions of the law in force and the directions issued from time to time by the Licensing Authority and not to manufacture any drug/cosmetic under a name belonging to another manufacturer in the country. We also undertake that facility/ license to manufacture above category of drug from Licensing Authority is granted and available with me/us.

3. I/We undertake not to manufacture or sale or distribute any drug even if it is included in the approved list of product if it is or is as and when it will be banned by the Licensing Authority or by Drugs Controller General of India or by Government of India.

4. I/We undertake that all pharmaceutical aids used in the product shall be non-toxic, safe and non-hazardous.

5. I/We undertake to pack all the approved formulations as per Schedule P-1 and will assign expiry date not exceeding as per Rule 96 (1) (a) (vii) of Drugs & Cosmetics Rules, 1945. The label shall bear the specific storage conditions as per requirement of Schedule P and official Pharmacopoeia.

6. I/We undertake that formulation, for which approval has been sought for, has not been permitted to us/me under more than one brand name except for export or for contract manufacturing.

7. I here with under take that the thermo labile products which will be manufactured by me will be subjected to the stability studies for the period of at least one year with periodic testing (every three months) for three batches of every product & reports there of will be submitted to the licensing authority.

8. I undertake that we have manufacturing facilities as required vide schedule M to the Drugs & Cosmetics Rule 1945 for which application for aforesaid additional item has been made.

(Name & signature of authorized Person) Name of firm

Annex. 'M-1'

Performa of affidavit to be submitted by Proprietor/ Partners/ Director(s)/ Managing Director/Managing Trustee

I, ---------- s/o : w/o ; d/o Shri ----------, Age ---------, Caste ----------, Resident of ---------- declare solemnly on oath as under:-

1) That I am proprietor/partner/Managing Director/Managing Trustee/ Principle Medical Officer of M/s ----------, (Complete Address of manufacturing site) ---------- by whom an application for grant of license for the operation of a Blood Bank for processing of Whole Human Blood and preparation of Blood Components / manufacture of Blood Products has been made on Form Nos. 27-C, /27-E, to the Licensing Authority and Drugs controller, Rajasthan, Jaipur under the provision of Drugs & Cosmetics Act, 1940 and Rules, 1945.

2) That following are the other partners/ Directors/Trustees of the firm:-

S.No.(1)	Name(s)(2)	Age(3)	Residential address(4)

3) That the building in which manufacturing activities are proposed are taken on rent/ lease from ----------/ are own premises/ Government Building which are adapted as per Schedule F, Part XII-B/C of the said rules.

4) That adequate qualified technical staff has already been appointed.

5) That I will be responsible for the conduct of day-to-day activities of the firm for the purpose of Section 34 of the said Act as well as other prevailing enactments established by Law of Government of India.

Witness No. 1 ---------- Witness No. 2 ----------

(Signature, Name and Address) (Signature, Name and Address) (DEPONENT) Name

VERIFICATION

I, ---------- verify that the contents of para 1 to 5 of this affidavit are true to the best of my knowledge and belief. So GOD helps me.

Date ----------

Place ----------

(DEPONENT) Name

Annex. 'N-1'

Performa of affidavit to be submitted by Medical Officer, Lab Technician, Registered nurse

I, ---------- s/o : w/o ; d/o Shri ----------, Age ---------, Caste ----------, Resident of ---------- declare solemnly on oath as under:-

1) That I have following qualification:-

S. No.(1)	Qualification(2)	University(3)

2) That I have following experience:-

S. No.(1)	Name and address of the firm(2)	Period of working with dates(3)

3) That I have already been approved by Licensing Authority ---------- as Competent Technical staff for Operation of Blood Bank vide letter No. -------- Dated -------- /on the licences of Blood Bank issued to ---------- bearing Licence No. ------- granted on ----------.

4) That I am Registered with Medical Council of Rajasthan / Nursing Council of Rajasthan at No. ---------- on ---------.or That I have already been approved by Licensing Authority ---------- as Competent Technical staff for Operation of Blood Bank vide letter No. -------- dated -------- /on the licences of Blood Bank issued to ---------- bearing Licence No. ------- granted on ----------.

5) That I have joined M/s ----------, (Complete Address of manufacturing site) ---------- on ---------- and will inform the Licensing Authority & Drugs Controller, Rajasthan, Jaipur as soon as I resign from this firm.

6) That I was working previously with M/s ----------, (Complete Address of manufacturing site) ---------- up to -------- and have informed the Licensing Authority ---------- on regarding my resignation from this firm.

7) That I will be responsible for the manufacturing activities of the firm for the purpose of Section 34 of the said Act as well as other prevailing enactments established by Law of Government of India

Witness No. 1 ---------- Witness No. 2 ----------

(Signature, Name and Address) (Signature, Name and Address)

(DEPONENT) Name

VERIFICATION

I, ---------- verify that the contents of para 1 to 7 of this affidavit are true to the best of my knowledge and belief. So GOD help me.

Date ----------

Place ----------

(DEPONENT)

Name