

## **Documents for the Grant of Licence for Opening of New Blood Centre**

**(As per Part XIIB and/or XIIC of Schedule F of Drugs and Cosmetics Act 1940 and rules 1945)**

Licensing Authority :-

*Director (Drugs) State Drugs Control Directorate,  
Namkum, Ranchi  
e-mailid-directoratedrug.jharkhand@gmail.com*

Central Licence approving authority :-

*Drugs Controller General of India,  
New Delhi*

### **Documents to be submitted:**

1. Application In Form 27(C)
2. Applicant details:
  - Document relating to constitution of concerned Charitable Trust/firm/ Company/ LLP and others.
  - List of Trustees/Directors/partners and their Bio-data with their residential addresses and Photo, in case of proprietorship, bio-data with their residential addresses and Photo of proprietor.
  - Address/ ID proof of the applicant
3. Requisite Fees 7500/- should be deposited in Head -021001107010101 through **J-egras**
4. Premises details:
  - Ownership document of the premises.
  - Plan of the premises- with details of partitions, measurements (as per Part XIIB and/or XIIC of Schedule F of Drugs and Cosmetics Act 1945 as the case may be)
  - Rental agreement of the premises, if applicable
5. Municipal Tax receipt of the land/ Ownership of the land.
6. Constitution of the Firm.
7. Plan of the premises (total area 100sq mt. for whole Human Blood and additional area of 50 sq. mt for blood component.)

#### **Details of areas:-**

- Registration and Medical Examination
  - Blood collection (Air conditioned)
  - Laboratory for blood group Serology (Air conditioned)
  - Laboratory for blood Transmissible diseases ((Air conditioned)
  - Sterilization cum washing room
  - Refreshment cum rest room (Air conditioned)
  - Store cum Records Room
  - Counseling area with adequate privacy.
  - ❖ Blood Component preparation room(Air conditioned)
  - ❖ Identified quality control area with Component preparation area.
8. **Qualification & Experience, Consent and appointment letter of technical staffs** (Qualification & Experience should be as per Schedule F, Part XII-B of Drugs & Cosmetics Act along with their Passport size photo and photocopies of Qualification Certificate and experience certificate.)
    - Medical Officer-M.D. Path/ Post Graduate Degree in Transfusion Medicines/ MBBS with 1 year experience in Blood Banking/MBBS with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with Six month experience in Blood Bank/

MBBS with Diploma in Transfusion Medicines or Diploma in Immunohematology or Blood transfusion with Three months experience in Blood bank.

- Blood Bank Technicians- Degree in Medical Laboratory Technology (M.L.T) having 6 Month experience in Blood banking/DMLT with 1 year experience/B.Sc in hematology and transfusion medicine with Six month experience/ M.Sc in Transfusion Medicine with Six month experience/PGDMLT or PGDMLS with Six month Experience in Testing of blood and /or its Component in a Licenced Blood Centre.
- Registered Nurse
- Counselor of Medical Social worker- Master Degree in Social, Sociology, Psychology with Six month experience/Degree in Science or Health Science with One year Experience/Person with 10+2 having Three year of experience.
- ❖ Technical Supervisor- Diploma in Medical Laboratory Technology or Transfusion Medicine or Blood Bank technology with One year experience/ Degree in Medical Laboratory Technology or Transfusion Medicine or Blood Bank technology with Six month experience/ B.Sc in hematology and transfusion medicine with Six month experience/ M.Sc in Transfusion Medicine with Six month experience/ PGDMLT or PGDMLS with Six month Experience in Testing of blood or its Component or both in a Licenced Blood Centre.

## 9. List of Equipment make wise

### **General equipment and instruments**

- Refrigerators for Blood storage Type, capacity and number
- Temperature recorder in refrigerator
- Audible alarm system in refrigerator
- Balance for bag weighing
- Autoclave with temperature & pressure display
- Incinerator
- Emergency power supply(generator)
- Donor beds, chairs, tables/ Beside table
- Sphygmomanometer & stethoscope
- Recovery bed for donors
- Donor weighing scale

### **Emergency equipment:-**

- Oxygen cylinder, mask, gauge and pressure regulator
- 5% Dextrose or Normal Saline inj.
- Sterile Disposable Syringes and needles(various sizes)
- Sterile disposable I.V. Sets
- Adrenaline, Noradrenaline, Mephentin, Betamethasone (or dexamethasone), Metochlorpropamide injections.

### **Accessories**

- Blankets, emesis basins, haemostals, set clamps, sponge forceps, gauze, dressing jars, waste cans etc.
- Medium cotton balls, 1.25 cm adhesive tapes
- Denatured spirit, tinc, Iodine, green or liquid soap
- Paper napkins or towels

### **Laboratory Equipment**

- Refrigerator for kits and reagents storage
- Refrigerator make and Capacity
- Temperature display provided
- Compound microscope with low and high power objectives
- Table centrifuge
- Water bath 370 -570
- Rh viewing box
- Incubator with thermostat
- Mechanical shakers for serological test of syphilis test
- Hand lens
- Serological graduated pipettes of various sizes
- Pasteur pipettes
- Glass slides
- Test tubes of various sizes/ microplates

- Precipitating tubes(6x 50 mm) of various sizes
- Test tube racks
- Interval timer
- Material and equipment for glassware cleaning
- Blood transporting containers
- Wash bottles
- Filter papers
- Dielectric tube sealer
- Plain and EDTA vials
- Chemical balance
- Elisa reader with printer, washer and micro-pipettes
- Colorimeters/haemoglobinometer (strike off which is not applicable)for haemoglobin determination)

### **Equipment for Blood Component**

- Air conditioner
  - Laminar air flow bench
  - Refrigerator centrifuge
  - Plasma expresser
  - Dielectric sealer
  - Weighing device
  - Dry rubber balancing material
  - Artery forceps, scissors
  - Refrigerator (temperature between 2 degree cent. To 6 degree sent.)
  - Platelet agitator with incubator
  - Refrigerated Water bath for Plasma Thawing
10. **Statutory Registers** as per Drugs & Cosmetics Act.
    - Blood donor records
    - Master records for blood and its component.
    - Blood Stock Register
    - Issue register
    - Record of Blood bags
    - Cross matching records
    - Register of diagnostic reagents and kits
    - Adverse reaction record
    - Stock register of other consumable articles
    - Records of component supplies
  11. **Draft label** (labels of blood containers comply as per Schedule F, Part XII-B of Drugs & Cosmetics Act)
  12. **Specimen of Donor form** (bi-lingual), Transfusion Adverse report, Cross match reports, Donor consent form.
  13. **Standard Operating Procedures(SOP)**