

**Detail procedure obtaining a Blood Bank licence for Whole Human Blood IP  
& its components as well as Apheresis**

1. The authority shall apply to the Director of Drugs Control, WB for site & layout plan approval.
  - A) Minimum area of the Blood Bank is to be provided 100 sq. mtrs. for its operations collection, processing, storage & distribution along with ancillary area & an additional area of 50 sq. mtrs. For preparation of Blood Components & 10 sq. mtrs. for Apheresis comprising of the following rooms :
    - i) Registration & Medical examination with adequate furniture & facilities for registration & selection of donor's.
    - ii) Blood collection (Air-Conditioned)
    - iii) Blood component preparation (Air-Conditioned), temperature between 20 – 25 degree centigrade.
    - iv) Laboratory for blood group serology (Air-Conditioned)
    - v) Laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV, antibodies (Air-Conditioned).
    - vi) Sterilisation-cum-washing.
    - vii) Refreshment-cum-rest room (Air-Conditioned).
    - viii) Store-cum-record room.
2. After obtaining site approval from DDC, WB, who is also the State Licensing Authority (SLA), the Blood Bank Authority will apply for grant of licence in form 27C along with required documents and requisite fees (fees for whole human blood only is rupees 6000 + 1500 for inspection fee, total 7500 rupees + additional rupees 300 for each components where required) before SLA (DDC, WB) with a copy to Dy. Drugs Controller (India) CDSCO (East Zone), Nizam Palace, Kolkata & a copy to Member Secretary, SBTC, WB & Project Director, WBSAP&CS, Swasthya Bhawan for obtaining NOC from SBTC along with Format (G) & Annexure – V.
3. Simultaneously, the institution would provide proper manpower, machinery & equipments, reagents & kits etc. for the purpose of testing along with SOPs & others as guided in the Schedule-F, Part-XII B of Drugs & Cosmetics Act 1940 & Rules thereon.
4. Documents to be submitted for the grant of licence in Form 28C to operate a Blood Bank:
  - i) Application in Form 27C dully filled in & signed by the competent authority.

- ii) Original treasury challan as proof for depositing requisite fee of Rs.7500/- or more, where applicable under correct head of account.
- iii) A declaration / undertaking be obtained from the HOD.
- iv) A copy of Key – Plan of the building with relation to the nearby/adjoining roads, building, plots etc.
- v) A copy layout plan of the blood bank premises depicting the dimensions and position of various sections, doors, windows etc.
- vi) Attested photocopies of certificates of qualification, experience, Bio-date, appointment letter, letter of approval (in those cases where persons are already approved) and joining report of competent technical staff, viz. Medical Officer, Regd. Nurse and Technicians employed by the blood bank on regular basis.
- vii) List of machinery and equipment installed for blood collection/processing, giving full details viz. Make, capacity, material of which it is made and whether it is automatic or manual etc.
- viii) List of laboratory equipment/apparatus, reagents and reference book etc. Duly signed by an authorised person/medical officer.
- ix) List of Human Blood components intended to be processed and the method for their preparation, duly signed by an authorised person/medical officer.
- x) Draft specimen labels of whole human blood/blood components intended to be collected/processed.
- xi) SOP's for various procedures in blood banking duly signed by an authorised person/medical officer.
- xii) An undertaking from the Blood Bank that it will not draw blood from paid/professional donors.
- xiii) NOC from SBTC, WB.
- xiv) NOC from Pollution Control Board.
- xv) NOC from West Bengal Fire & Emergency Services.

To grasp the whole matter in a nut shell a flow-sheet diagram attached herein.