# FLOW SHEET DIAGRAM - FOR ESTABLISHING BLOOD BANK

**Location and surroundings**

Away from open sewage, drain, public lavatory or similar unhygienic surroundings.

**Building(s)**

Hygienic & avoid the entry of insects, rodents & flies, well-lighted, ventiliated & screened mesh, floors & walls shall be of smooth washable and drains of adequate size and traps to be provided for preventing back flow.

**Accommodation for a Blood Bank**

100 sq. mtrs. Minimum area for Whole Human Blood.

+

50 sq. mtrs. for Components.

+

10 sq. mtrs. for Apheresis.

+

Along with ancilliary areas.

**Site and Layout Plan Approval**

To be applied in plain paper for Site and Layout Plan approval before Director, Directorate of Drugs Control, W.B. (DDC, WB) KIT Building (5th Floor) P-16, India Exchange Place Extn., Kolkata - 700073.

(Model Layout Plan attached)

**Infrastructure Facility**

Personnel, Machinery, Equipments & Instruments, Reagents & Kits etc. & S.O.P.

(Details enclosed)

**Statutory Application**

To be applied in Form 27C along with requisite fees and relevant papers to Director, Directorate of Drugs Control, W.B. (DDC, WB)

Copy to Dy. Durg Controller (I), CDSCO(EZ), Nizam Palace, Kolkata.

Copy to M.S., SBTC, WB & P.D., WBSAP&CS, Swasthya Bhawan.

**Application for NOC from SBTC, WB**

To be applied for NOC at SBTC, WB in Format (G) with other annexures to M.S., SBTC, WB & P.D., WBSAP&CS at Swasthya Bhawan.

(Necessary forms and guidance will be available from WBSAP&CS, Swasthya Bhawan)

**Inspection**

Joint Inspection will be held by Joint Inspection team comprising of Officers of DDC, WB from SLA (State Licensing Authority) & CDSCO (EZ) (Central License Approving Authority i.e. CLAA) and expert where necessary.

**Report**

Satisfactory Report with recommendation by the Joint Inspection team.

**Licence - Stage 1**

Licence will be ready to sent to Drug Controller General of India (D.C.G.I., India) after maintaining formalities & approval of SLA (DDC, WB).

**Licence - Stage 2**

After processing and approval of DCGI, Licence (in Form 28C) will be returned to SLA.

**Licence - Stage 3**

Finally Blood Bank Licence will be issued from D.D.C., W.B. (SLA)