BLOOD BANK INSPECTION CHECK LIST

(use separate sheets, if necessary)

(Collect specimen forms, documents, labels, record copies wherever necessary)

Name of Institution: **M/s. Model Blood Bank , S.V.R.R. Government General Hospital Campus, Tirupati, Chitoor Distt. AP**			**Date of Inspection:** **27/03/2017**	
Address of the Institution	**M/s. Model Blood Bank , S.V.R.R. Government General Hospital Campus, Tirupati, Chitoor Distt. AP**			
Telephone No.: Fax No.: E-mail:	08772286290 e.mail. modelbloodbanktpt2010@gmail.com			
License number and date of issue	**18/CT/AP/95/BB/CP date of issue 10/10/2011 valid from 10/10/2011 to 09/10/2016**			
Inspected By	1. **Mr. Shyam Narayan Singh-**DI, CDSCO, Hyderabad. 2. **Miss Ruthu, DI, (FAC)DCA, Tirupathi (U)**			
Institution represented by	**Dr. M. Srinivasulu S/o M. Narasimhulu (Director)**			
Purpose of Inspection	Renewal of license **for Whole Human Blood IP**, **and blood Components with reference to the letter of Dy.DC(I), CDSCO, Hyderabad vide Ref. No. 5-2A(003)/HZ/2016-17/18126-18127 dated 24/03/2017**			
Type of Institution	**Government** ☑	Charitable	Red Cross	Others (specify) Registered Society.
Product(s) Licensed:	**A). Licenced for the following products, *viz*:** **1. Collection, store, distribute and processing of "Whole Human Blood IP"** **2. Preparation of Blood Components** **a. Fresh Frozen Plasma BP** **b. Packed Red Cells IP** **c. Cryoprecipitate** **d. Platelets Rich Plasma**			

Technical staff	Name	Qualification *(check documents)*	Experience *(check testimonials)*
Medical Officers	**Dr. M. Srinivasulu S/o M. Narasimhulu**	MBBS, MD (Pathology) Registration no 43320date 25/09/1999	. Appointed on 01/02/2016 till date **(To be Approved)**
	Dr. R. Ramanarayana Reddy	MBBS	Transfer to other department
Technical Supervisor	Sri. R. Suresh Babu	B.Sc.	**Transfer to kurnool**
Registered Nurse	Manas Devi Avula D/o Venkataswamy	DGNM	**Already Approved**
	Y. Thulasamma D/o Y. V. Nagi Reddy	DGNM Registration No.10311 dated 22/05/1992	**To be Approved, Working since 02/01/2001 till date**
	K. Manju Latha D/o Thimma Reddy	DGNM Registration No004255 dated 06/02/1998	**To be Approved, Working since 04/01/2001 till date**
	Premlatha Chalichemala D/O Nagaraju Naidu C	DGNM Registration No25696&25818 Dated.25/03/1998	**To be Approved, Working since 01/01/2009till date**
	N.Suseela D/o N. Venkata Ramana	DGNM Registration No008103 Dated11/06/199	**To be Approved, Working since 23/10/2004till date**
	Smt P. Vijayamma	……..	**Already Approved, left the blood bank**
	Smt. M. Sireesha	…….	**Already Approved, left the blood bank**
Technicians	Sri. A. Surendra Babu	DMLT	**Already Approved**
	P. Raghu Ram Chowdhary S/o P. Venkatesulu	DMLT	**Already Approved**
	P. Devamani D/oSubba Rayudu	DMLT	**Already Approved**
	K. Lakshmamma D/o Kavali Veeraswamy	DMLT Registration 02648/MLT/APPMB Dated.13/05/2011	**Working from 11/11/2010 till date In the model blood bank (to be Approved)**

A	Total Collection (for WHB + Components) *(Last two calendar years)*	Year	2017 (Till inspection date)	2016	2015
		Voluntary	1784	7508	7784
		Replacement	95	196	158
		Professional	Nil	nil	Nil
		Total	**1879**	**7704**	**7942**
	Distribution (of WHB + Components) *(Last two calendar years)*	Used in own Hospital	442	6755	5513
		Issued to others	41	530	1747
		Discarded	65	619	689
B	**Premises**	Total area			
	Details of Areas	**Sq. M.**	**Comments**		
1	Registration and Medical Examination	2.90x2.94=8.76 3.10x2.90=8.99	Already Approved		
2	Blood Collection (A/C?)	5.78x5.70=32.94	Already Approved, A/C Provided		
3	Refreshment & Rest Room (A/C?)	5.78x5.70=32.94	Already Approved, A/C Provided		
4	Serology Lab. (A/C?)	7.7x2.93=22.56	Already Approved A/C Provided		
5	Transmissible diseases Lab. (A/C ?)	7.70x2.84=21.86	Already Approved, A/C Provided		
6	Sterilization & Washing	7.62x2.84=21.64	Already Approved		
7	Stores and Records	7.62x2.84=21.64	Already Approved		
	General comments on Area	Blood bank has provided **total 171.33 Square Meters (**for the activities of Whole Human Blood IP .			
1	**Standard Books? (obtain list)**	Drugs & Cosmetics Act 1940.			
2	**Blood Bank Manual**	Blood bank manual 'Transfusion Medicine Technical manual', DGHS, Ministry of Health & Family Welfare, Govt. of India.			
3	**Standard operating procedures**				
A	Criteria to determine donor suitability		Yes		
B	Method of donor selection		Yes		
C	Preparation of phlebotomy site		Yes		
D	Product to Donor traceability		Yes		
E	Collection procedures, precautions etc.		Yes		
F	Method of components preparation		Yes		
G	Test methods		Yes		

H	Pre-transfusion Testing	Yes	
I	Adverse reaction management	Yes	
J	Storage temperature & its control	Yes	
K	Expiry date Assignment	Yes	
L	Returned Blood Management	NA	
M	QC for reagents & supplies	Yes	
N	Maintenance, calibration & validation of equipment	Yes	
O	Labeling Procedures	Yes	
P	Apheresis Procedures	No	
Q	Any other SOPs	No	
D	Procedure for disposal of blood (expired, clotted, improperly collected, HIV, etc).	Yes	
E	Donor education/ motivation material	Yes	
F	Donor selection	Yes	
1	Donor record	Yes	
2	Selection/rejection manual	Yes	

3	**Donor record details:**		
A	Age	Yes	
B	Interval between donations	Yes	
C	Last pregnancy/ delivery/ abortion	Yes	
D	Immunization details	Yes	
E	Recent drug intake	Yes	
F	Major surgery	Yes	
G	Malaria	Yes	
H	Jaundice	Yes	
I	Other viral infection	Yes	
J	Fever & common cold	Yes	
K	History-cancer, TB, Diabetes, Drug addiction, etc.	Yes	
L	Alcohol intake	Yes	
M	Transfusion history	Yes	
4	Donor Examination	Yes	
A	Weight	Yes	
B	Veinpuncture site	Yes	
C	Haemoglobin	Yes	Performing by CuSO4/Haemocue method
D	Blood pressure	Yes	
E	Pulse	Yes	
F	Temperature	Yes	

G	**Collection of Blood**		
A	Preparation of phlebotomy site	Yes	Cotton swabs with Betadine followed by Spirit.
B	Type and amount of anti-coagulant used	Yes	CPDA single-350 ml; CPDA double bags-350 ml without SAGM; 49 ml of CPDA in 350 ml of blood bag

C	Amount of blood collected (random wt.)	Yes	350 ml
D	Blood collected in bags/bottles	Yes	Bags only
E	Pediatric Bags?	No	
F	Is mixing done during collection? How?	Yes	Through BCM
G	Is new bag used in case of 2nd puncture?	No	
H	How is sample tubes labeled?	Yes	Donor samples stored in segments & patient samples in vials with rubber stopper.
I	Emergency kit available?	Yes	
H	**Storage of blood**		
A	Temperature recording graph preserved?	Yes	Blood bank recorded by thermograph
B	Alarm system checks done?	Yes	
C	Physical Verification done? Frequency?	Yes	Every 30 mins.
D	How is blood transported? outside, towards?	Yes	In thermocol box with ice packs
I	**Blood Testing**		
A	Sterility Testing	No	
B	Haemoglobin Estimation method	Yes	By Colorimeter method
C	Method for ABO Grouping	Yes	Forward & reverse grouping method
D	Procedure for grouping	Yes	Tube method.
E	Method of pooled cell Preparation	Yes	Collecting from three different bags of known group after washing with normal Saline & diluting by 2-5% with normal Saline.
F	Du test done on D-samples?	Yes	By tube method using Coomb's reagent.
G	Test for unexpected antibodies done?	Yes	By indirect Coomb's test
H	Hepatitis test done? Describe method and Name of kit manufacturer	Yes	ELISA method using Name of kits – ErbaELISA Mfg – M/s. Transasia biomedical ltd, Daman
I	Syphilis test done? Describe method and Name of kit manufacturer	Yes	Card Method, Name of kits mfg – M/s. Tulips ,Mfg. Beacoiagnostics
J	HIV test done? Describe method and Name of kit Manufacturer	Yes	ELISA method using Name of kits – ErbaELISA Mfg – M/s. Transasia biomedical ltd, Daman
K	HCV test done? Describe method and Name of kit Manufacturer	Yes	ELISA method using Name of kits – ErbaELISA Mfg – M/s. Transasia biomedical ltd, Daman
L	Malaria test done? Describe method	Yes	Leishmann Stain method.
M	Donor informed in case of +ve results?	Yes	In case of HIV positive sending to ICTC, Govt Hospital.Tirupathi.

N	In case of HbsAg/HIV +ve results, Donor debarred permanently	Yes	maintained
O	Are HbsAg/HIV +ve donors followed up?	Yes	
P	Cross matching. (Describe method)	Yes	Saline, Albumin & indirect Coombs test.
J	**Testing of reagents etc.**		
A	Antisera tested?	Yes	
B	Method of Antisera Testing	Yes	Testing during receipt & before using for appearance, titer, sensitivity & specificity.
C	CPDA solution testing	Yes	COA maintained

K	**General equipment and Instruments**	
A	Refrigerators for Blood Storage Type, capacity and number	Yes, Blood bank has provided refrigerator **Screened** – 2 in No. 1. Jevetsr.55618/295, Cap- 300 bags and 2. Remi BDBDIT/1072, Cap – 200 bags **Unscreened** – 1 in No. Remi BDIT/1125), Cap- 200 bags
B	Temperature recorder in refrigerator	Blood bank has provided thermograph for recording temperature of refrigerator continuously
C	Audible alarm system in refrigerator	Yes, provided
D	Balance for bag weighing	Provided 1 Blood Collection monitors in working condition.
E	Autoclave with temp. & pressure display	Yes, provided
F	Incinerator	Yes provided
G	Emergency power supply (generator)	Yes, provided Mahendra
H	Donor beds, chairs, tables	Yes, 7 donor couches provided in Phlebotomy room
I	Bedside table	Yes, provided
J	Sphygmomanometer & stethoscope	Yes, provided- 3 in No.
K	Recovery bed for donors	Yes provided
L	Donor weighing scale	Yes provided- 4 in nos.

L	**Emergency equipment**	
A	Oxygen cylinder, mask, gauge and pressure regulator	Yes provided
B	5% Dextrose or Normal Saline Inj.	Yes provided
C	Sterile Disposable Syringes and needles (various sizes)	Yes provided
D	Sterile disposable I.V. sets	Yes provided
E	Adrenaline, Noradrenaline, Mephentin, Betamethasone (or Dexamethasone), Metochlorpropamide injections	Yes provided

M	**Accessories**	
A	Blankets, emesis basins, hemostats, set clamps, sponge forceps, gauze, dressing jars, waste cans etc.	Yes provided
B	Medium cotton balls, 1.25 cm adhesive tapes	Yes provided
C	Denatured spirit, Tinc. Iodine, green or liquid soap	Yes provided.
D	Paper napkins or towels	Yes provided
N	**Laboratory Equipment**	
A	Refrigerator for kits and reagents storage Refrigerator make and Capacity	Yes provided-5 in No. 1. Remi (03) 2. Jeweet (01) 3. Electrolux(01)
B	Compound microscope with low & high power objectives	Yes
C	Table centrifuge	Yes, Provided-1 in No.,
D	Water bath- 37^0C & 57^0C	Yes, Provided
E	Rh-viewing box	Yes, Provided
F	Incubator with thermostat	Yes Provided
G	Mechanical shakers for serological test of syphilis test	Yes, Remi,
H	Hand lens	Yes
I	Serological graduated pipettes of various sizes	Yes, Provided
J	Pasteur pipettes	Yes, Provided
K	Glass slides	Yes, Provided
L	Test tubes of various sizes/ micropipettes	Yes, Provided 100-1000µl – 1 in No; 10-100 µl -1 in No.
M	Precipitating tubes (6x50 mm) of various sizes	Yes, Provided
N	Test tube racks	Yes, Provided
O	Interval timer	Yes, Provided
P	Material and equipment for glassware cleaning	Yes, Soap solution Provided
Q	Blood transporting containers	Yes, insulated containers provided
R	Wash bottles	Yes, Provided
S	Filter papers	Yes Provided
T	Dielectric tube sealer	Yes, Provided-2 tube sealers.
U	Plain and EDTA vials	Yes provided
V	Chemical balance	No
W	Elisa reader with printer, washer and micro-pipettes	**Plate reader**-Robonik -Sr. No. RTO260809RBK **Washer –** Robonik -Sr. No. AW0908RBK022

X	Colorimeters / Haemoglobinometer (strike off which is not applicable) for Haemoglobin determination.		Haemocue is being used for Hb determination.
O	**Records and Reports (***Comments on records, if any***)**		
A	Blood Stock/Master Register	Yes	Maintained
B	Blood donor record	Yes	Maintained
C	Issue register	Yes	Maintained
D	Record of Blood bags	Yes	Maintained
E	Cross matching records	Yes	Maintained
F	Register of diagnostic reagents and kits	Yes	Maintained
G	Adverse reaction Records	Yes	Maintained
H	Stock register of other consumable articles	Yes	Maintained
I	Are records destroyed?	Yes	Maintaining since 2010 TO TILL DATE
J	Labels of Blood containers as per Schedule F of the D & C act	Yes	Maintained as per Schedule F, Pt-XII B of D & C Rules.
P	**Outdoor camps:**		
A	Eligible to hold outdoor Camps	Yes	SBTC letter no. 734/BB/2017/AIDS/07 dated 20/03/2017.
B	Average number of camps held per month	Yes	2-4 camps per month
C	Vehicle available?	Yes	Provided by NACO
D	How are blood bags Transported	Yes	Thermocoal boxes with coolents gel packs
F	Proof sanitary conditions of camps	Yes	
G	Detailed statement of blood collected in camps	Yes	*Last year 3 camps conducted on following dates* *27-03-2017 (1054 bags) 2016 (3909 bags) 2015(4082)*

PROCESSING OF BLOOD COMPONENTS FROM WHOLE BLOOD.

Q.	ACCOMMODATION/PREMISES	Area in Sq. M.	COMMENTS
1.	Area provided for component preparation.	Prep.5.88x5.78=33.98 Preparation:5.75x2.90 =16.76 QC=5.78x2.39=13.35	**Total area = 64.09sq.m**
2.	Does an additional 10-sq.meter area provided for aphaeresis procedures.	**NA**	
(a)	Is Blood component room Air-conditioned?	YES	
(b)	Is Blood component room well lighted?	YES	
(c)	Are walls and floors are smooth & washable?	YES	

(d)	Is overall hygienic conditions maintained in the premises.	YES	
(h)	Comments on Area: Area provided for the preparation, storage & testing of Blood components & is adequate & complying Para I.B of Schedule F, Pt-XIIB of D&C Rules.		
R	PERSONNEL: Whether Technical Supervisor with adequate basic qualification and experience is available with blood bank.	No	**Comments:**
	Name, Qualifications & Experience	No	
S1	**Equipment (***As per GSR 245(E)dt.05.08.99***)**		**Make/Model/Capacity**
(i)	Air Conditioner.	YES	Split A/C
(ii)	Laminar air flow bench.	YES	
(iii)	Suitable refrigerated centrifuge.	YES	
(iv)	Plasma expresser	YES	
(v)	Clipper and clips and or dielectric sealer.	Yes	Provided-02 tube sealers.
(vi)	Weighing device.	YES	Electronic weighing balance.
(vii)	Dry rubber balancing materials.	Yes	**Provided**
(viii)	Artery forceps, scissors.	YES	
(ix)	Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply.	YES	**Screened** – 2 in No. 1. Jevetsr.55618/295, Cap-300 bags and 2. Remi BDBDIT/1072, Cap – 200 bags **Unscreened** – 1 in No. Remi BDIT/1125), Cap- 200 bags
(x)	Platelet agitator with incubator (*wherever necessary*)	Yes	Provided in 1 No. 1. Platelet agitator (Make: Jove) with incubator

(xi)	Deep freezers maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and	YES	Terumo-penpol-BF40U Capacity -300 bags
	Minus 75 degree centigrade to minus 80 degree centigrade.	Yes	Terumo-penpol-BF80U Capacity -300 bags
(xii)	Refrigerated water bath for plasma Thawing.	YES	Remi, IHCT/1015
(xiii)	Insulated blood bag containers with provisions for storing at appropriate temp for transport purposes.	YES	Insulated containers provided
(xiv)	Whether components are prepared only in a closed system using single, double, triple or quadruple plastic bags.	YES	BB has used double,plastic bags for preparation of components.
S2	**EQUIPMENT (GMP)**		**COMMENTS**
1.	Are equipment located in logical sequence and permit effective cleaning?	YES	
2.	Are equipment Calibrated/validated periodically?	YES	All equipments calibrated once in a six months by external agency. (M/s. TBS Banglore)

T	**PREPARATION OF BLOOD COMPONENTS.**		
1a	**Concentrated Human RBC's (Packed Red Blood Cells)**		**COMMENTS**
1b	**Washed Red Cells**		
A	Whether SOP is available for preparation of PRC? *Specify: Source material* Method RCF Speed Time	Yes	provided for verification during inspection (3500rpm -10 min – at 4^{o}C)
B	Is blood collected from suitable donor? (check the donor record).	Yes	
C	Are the packed red cells confirmed to the standard of I.P.2014	Yes	QC test reports are maintained with printouts.
D	How the Pilot tubes / samples are numbered?	Yes	Donor - Bag number. Patient – Stored in vials closed with rubber stoppers.
E	Whether pilot tube is attached in a tamper proof manner to the unit?	Yes	

F	Who is responsible for filling of pilot samples?	YES	Technician
G	Whether pilot samples are filled immediately after the blood is collected or at the time the final product is prepared?	YES	Pilot samples are filled immediately after the blood is collected.
H	Whether expiry is assigned as per norms? (specify the period)	YES	35 days
2	**Platelets concentrates**		**COMMENTS**
A	Whether SOP is available for preparation of Platelets concentrates? *Specify: Source material* Method RCF Speed Time	Yes	provided for verification during inspection (2000rpm -10 min – at 22ºC)
B	Whether the whole Blood /source material is stored at 20 degree to 24 degree centigrade after collection, before processing to platelet concentrates?	**Yes**	
C	Whether Platelet Concentrates are separated within 6 hours after the time of collection whole blood / source material	**Yes**	
D	Whether platelet concentrates are tested: Platelet count (Note the count), pH (not less than 6), measurement of Plasma volume, sterility (1% of total platelets prepared shall be tested for sterility, 'functional viability' (swirling movement)	**Yes**	
E	Whether compatibility test prepared on every unit before issue	Yes	
F	Whether platelet yield is calculated (1% of total platelets prepared shall be tested of which 75% of units shall confirm to standards)	Yes	
3.	**FRESH FROZEN PLASMA**		**COMMENTS**
a	Whether SOP is available for preparation of FFP? *Specify: Source material* Method RCF Speed Time	Yes	provided for verification during inspection (3000rpm -10 min – at 4ºC)
b	Whether deep freezers capable of maintaining temp between -75^{O}c to -80^{O}c and minus 30^{O}c to minus -40^{O}c are available	Yes	
c	Whether the source material/human blood stored at 4^{O}c till processed	YES	
d	Whether thawing facilities are provided (note the thawing temperature)	YES	Thawing temperature 37ºC
E	Lag time between collecting of blood and processing of FFP (check records)	YES	Yes maintained – Components Preparation Register is separately provided by it
4.	**CRYOPRECIPITATE:**		**COMMENTS**

A	Whether SOP is available for preparation of CRYOPRECIPITATE? *Specify: Source material* Method *RCF* Speed; Time	Yes	
B	Whether thawing facilities are available (note the temperature)	Yes	
c	Whether anti-hemophiliac factor activity is tested. (NLT 80 units/bag), (1% of total cryo prepared shall be tested of which 75% shall conform to specification)	Yes	
5.	**APHERESIS PROCEDURE(Platelet phresis)**		***COMMENTS:***
A	Whether cell separator facility is provided?	NA	
B	Whether donor is certified fit for apheresis (check the record)	NA	
C	Time allowed between successive aphaeresis on a single donor	NA	
D	Whether protein estimation of donor carried out if serial apheresis is to be conducted.	NA	
E	Whether inquiries about aspirin intake made before platelet apheresis.	NA	
F	Whether RBC's are re-transfused during platelet apheresis or leucopheresis. If not, what precautions are taken.	NA	
G	**Whether following tests are carried out before apheresis procedures** Name of the test Acceptance Criteria		**COMMEMTS**
	(i) Hemoglobin/Heamatocrit **(ii) Platelet count** **(iii) WBC count** **(iv) Differential count** **(v) Serum protein**	**Yes-**	

H	How much quantity of plasma is to be collected (Plasma apheresis):		
	DURATION **(I) Single sitting** (II) **Per months**	LIMIT Not exceeding 500 ml./1 sitting Not exceeding 1000 ml./1 months)	***COMMENTS:*** -

U	STORAGE OF BLOOD COMPONENTS		
S.No.	BLOOD COMPONENT	**TEMPERATIRE**	**DURATION/EXPIRY PERIOD**
1.	**FFP**	Below - 30^{o}C	1 Year
2.	**Cryoprecipitate**	NA	NA
3.	**Platelets concentrate**	20-24 ^{o}C	5 days
4.	**Red Cell concentrate**	2-6 ^{o}C	1day
5.	**Washed Red Cells**	2-6 ^{o}C	1day
V	**RECORDS AND LABELS**		**COMMENTS**

1.	Whether details of quantity supplied, compatibility report, details of receipts and signature of issuing person mentioned in the component record.	YES	
2.	Whether master record for component and issue register is mentioned as per norms (GSR 245 E dated 05.04.1999)	YES	
3.	Whether labels for components are prepared as per norms (GSR 245 E dated 05.04.1999)	YES	
4.	Whether all details on labels are filled by the responsible person on the final container	YES	

Observations,

M/s. Model Blood Bank , S.V.R.R. Government General Hospital Campus, Tirupati, Chitoor Distt. AP applied for Renewal of License in form 27-C for collection and processing of **Whole Human Blood I.P. and Blood Components. The Blood bank having drug licence bearing no. 18/CT/AP/95/BB/CP date of issue 10/10/2011 valid from 10/10/2011 to 09/10/2016 in Form 28C.** In this regard, the said Blood bank is jointly inspected on **27/03/2017** following observations were noticed.

1. The Blood bank has applied SBTC permission for renewal of license on 15/03/2017as required the Rule 122 G of Drugs and cosmetics Act 1940. *As per CDSCO, Hyderabad Lr. No. 5-2(g)/HZ/2015-16/7964 dated 10/09/2015 stated that "any application pending for grant or renewal of license for want of approval from SBTC, wherein application pending for more than a month in SBTC should not be an obstacle for grant or renewal of blood bank license as per supplementary agenda for 48th DCC meeting and a decision is taken in this regard*
2. The applicant has provided all the equipment necessary for the collection of Whole Human Blood I.P and Blood components per para E of Part XII B of schedule F of D&C Act &rules their under.
3. The Blood bank has appointed technical staff with necessary qualification as per D&C Act 1940(one Medical Officers, Five registered Nurse, four Technicians as per para C of Part XII B of schedule F of D&C Act &rules their under.
4. The applicant has submitted affidavit in original as required under section 34of D&C Act & Rules their under.
5. The applicant has submitted original plan copy in Blue Print as required in Para B of Schedule F of Part XII B of D&C Act and Rules thereunder.

6. The Blood bank has provided 171.3 Square Meters area for Whole Human Blood IP& 64.09 sq.m for blood componentsComplies as per the Schedule F of Drugs & Cosmetics Act 1940.
7. The applicant has submitted Medical fitness certificate for blood bank competent technical staff.
8. The applicant has submitted list of SOP's as required under para G of Sch F of part Xll B of Schedule F of D&C Act and Rules thereunder.
9. The applicant is maintaining all records and labels along with requisite column information as Para L of Schedule F of Part XII B of D&C Act and Rules thereunder.
10. The Blood Bank has applied in form 27C for grant Blood Bank with inspection Fee Rs. 7500 dated 03/10/2016 with challan no 39819.
11. The Blood bank has obtained 'No Objection Certificate' from AP Pollution Control Board As . . Required 122 P of D&C Act and rules there under.

Deficiencies

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1.The Blood Bank has not appointed Technical Supervisor required as per para C of Part XII B of . .. schedule F of D&C Act &rules their under.

2. The Blood Bank has not Sending the 1% of blood bags for sterility testing.
3. The Blood Bank Laminar Air flow Bench is not working
4. ELISA reader of blood bank is not working.
5. Thermograph of all equipments not working.
6. Calibration certificates of all equipments not provided.
7. In Components preparation room one AC is not working.

Remarks and Recommendations

In view of above **M/s. Model Blood Bank , S.V.R.R. Government General Hospital Campus, Tirupati, Chitoor Distt. AP** has provided area, equipments, technical staff and the documents meet the basic requirements as per the **Schedule F of Drugs and Cosmetics Act 1940** and Rules thereunder . Hence application may be consider for Renewal of license for ***after rectification of above deficiencies.***

Miss Ruthu,
DI, (FAC)DCA, Tirupathi (U).

Shyam Narayan Singh
DI, CDSCO, Hyderabad