

INSPECTIONS AND BLOOD CENTRE

UNDER DRUGS AND COSMETICS ACT 1940
AND RULES THEREUNDER

G.S.R. (66 E) Dated 11 March 2020 New Delhi In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in Part X B, in the heading, for the words —**Blood Banks**‡, the words —**Blood Centres**, shall be substituted

HISTORY OF BLOOD TRANSFUSION AND BLOOD BANKING (now BLOOD CENTRE)

1. 1260 AD. ARABIC SCRIBE ABOUT CIRCULATION OF BLOOD IN HUMAN BODY
2. 1616
 - William Harvey discovered that blood has a flow inside the animal body.
1. 1818 Dr. James Blund was successful in saving a man's life by direct transfusion from another man.
 -
1. 1875 Karl Landsteiner was first to notice that just any man's blood cannot be transfused to another.
2. 1900-1901 Karl Landsteiner's experiment revealed A, B and O group in human blood.
3. 1914-1918 Blood transfusion was used during the first world war,
4. 1937 World's first hospital blood bank was established on March 15, in Cook County Hospital of Chicago, U.S.A.
5. 1940 Rhesus Factor of Blood was discovered by Landsteiner and Weighner.
 - 1940 INDIA'S FIRST BLOOD BANK WAS SET UP IN THE SCHOOL OF TROPICAL MEDICINE, KOLKATTA (CALCUTTA) BY SIR UPENDRANATH BRAHMACHARI, THE

BLOOD BANKING IN INDIA.

- 1986 First AIDS patient due to blood transfusion in **Mumbai** was reported.
- **1992:** The National AIDS Control Organisation (NACO), established in 1992 is a division of India's Ministry of Health and Family Welfare
- **1993 FIRST ENTRY IN THE ACT: GSR 28 E DATED 22ND JAN 1993 PART X-B**Explanation : For the purpose of this rule a **Blood bank** means a centre for ... Although, unlicensed blood banks were running since world war -I
- 1996 Supreme Court's judgment on blood transfusion and blood banking in India; as a result of which National Blood Transfusion Council and State Blood Transfusion Councils are established for improvement of Blood Banking services in the country.
- 2000 World Health Day on 7th April 2000 was celebrated with, "Safe blood starts with me" as the slogan of the year.
- **THE SUPREME COURT ON NOVEMBER 13, 1995 UPHELD THE NATIONAL CONSUMER COMMISSION'S JUDGEMENT OF APRIL 1992**
- In accordance with the directive of the Supreme Court, NACO appointed an expert committee to revise the Drugs and Cosmetics Rules Pertaining to blood banking.

LICENSING OF BLOOD (CENTRES) BANKS UNDER THE ACT

- “Common Cause Vs Union of India” was filed in the Supreme Court of India in the year 1992. In a landmark judgement Supreme Court passed the following ruling;
 - (a) All blood banks to be licensed within 2 years.
 - (b) Eliminate professional donors within 2 years.
 - (c) Steps for starting special post-graduate courses (MD) in Transfusion Medicine be initiated.
- [Common Cause v. Union of India, 1996 SCC \(1\) 753](#)

HISTORY UNDER DRUGS AND COSMETICS ACT

- FIRST ENTRY IN THE ACT: GSR 28 E DATED 22ND JAN 1993 PART X-BExplanation : For the purpose of this rule a Blood bank means a centre for collection, storage, processing and distribution of Whole Human Blood Blood Components human donors" and | or from
- G.S.R. (66 E) Dated 11 March 2020 New DelhiIn the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in Part X B, in the heading, for the words —**BLOOD BANKS**!, THE WORDS —**BLOOD CENTRES**! SHALL BE SUBSTITUTED

NATIONAL BLOOD POLICY 2007

- THE POLICY AIMS TO ENSURE EASILY ACCESSIBLE AND ADEQUATE SUPPLY
- OF SAFE AND QUALITY BLOOD AND BLOOD COMPONENTS COLLECTED /
- PROCURED FROM A VOLUNTARY NON-REMUNERATED REGULAR BLOOD DONOR
- IN WELL EQUIPPED PREMISES, WHICH IS FREE FROM TRANSFUSION
- TRANSMITTED INFECTIONS, AND IS STORED AND TRANSPORTED UNDER OPTIMUM
- CONDITIONS. TRANSFUSION UNDER SUPERVISION OF TRAINED PERSONNEL FOR
- ALL WHO NEED IT IRRESPECTIVE OF THEIR ECONOMIC OR SOCIAL STATUS THROUGH

OFFICERS UNDER THE THE ACT

SR. NO.	DRUG MANUFACTURING	APPLICATION	OFFICER	OFFICER	GRANT OF LICENCE
1	1. BLOOD CENTRE WHOLE HUMAN COOLECTION STORAGE PROCESSING , DISTRIBUTION 2. HUMAN BLOOD COMPONENT	FORM 27-C RULE 122F	SLA DCO One or more	CLA	FORM 28-C RULE 122-8
2	BLOOD PRODUCTS	FORM 27-E RULE 122-F	SLA DCO One or more	CLA	FORM 28-E RULE 122-G
3	UMBELICAL CORD AND BLOOD STEM CELLS	FORM 27-F RULE 122-F	SLA Dco One or more	CLA	FORM 28-F RULE 122-F, 122-G, 122-H, 122-I, 122-K 122-P

PREMISES AREA REQUIREMENTS

AREA of 100 square metres for its operations and an

ADDITIONAL AREA of 50 square metres FOR PREPARATION OF BLOOD COMPONENTS.

It shall be consisting of A ROOM EACH FOR—

(1) REGISTRATION AND MEDICAL EXAMINATION with adequate furniture and facilities for registration and selection of donors;

(2) BLOOD COLLECTION (AIR-CONDITIONED);

(3) BLOOD COMPONENT PREPARATION. (This shall be air-conditioned to maintain Temperature between 20 degree centigrade to 25 degree centigrade);

(4) LABORATORY FOR BLOOD GROUP SEROLOGY (AIR CONDITIONED);

(5) LABORATORY FOR BLOOD TRANSMISSIBLE DISEASES like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned);

(6) STERILIZATION-CUM-WASHING;

(7) REFRESHMENT-CUM-REST ROOM (AIR-CONDITIONED);

(8) STORE-CUM-RECORDS

PERSONNEL

- **(a) MEDICAL OFFICER**, possessing the qualifications specified in condition (i) of RULE 122G.
- **(b) BLOOD CENTRE TECHNICIAN(s)**, possessing:—
 - (i) DEGREE IN MEDICAL LABORATORY TECHNOLOGY (M.L.T.) + 6 MONTHS' EXPERIENCE ; or
 - (ii) DIPLOMA IN MEDICAL LABORATORY TECHNOLOGY (M.L.T.)+ONE YEAR'S EXPERIENCE
- **(c) REGISTERED NURSE(s)**.
- **(d) TECHNICAL SUPERVISOR** (WHERE BLOOD COMPONENTS ARE MANUFACTURED), possessing—
 - (i) Degree in Medical Laboratory Technology (M.L.T.) with six month's experience in the preparation of blood components; or
 - (ii) Diploma in Medical Laboratory Technology (M.L.T.) with one year's experience in the preparation of blood components,
 - the degree or diploma being from a University/Institution recognised by the Central Government or State Government.
- **(e) CONSELLOR { FOR CAMPS}** !0+2 with 3years experience of concelling in Blood Center or Medical Social Worker

RULE 122 G QUALIFICATION OF MEDICAL OFFICER

- MBBS+ 1 year experience
- MBBS+ DIPLOMA IN CLINICAL PATHOTLOGY/BACTERIOLOGY + 6 MONTHS EXPEIENCE
- MBBS+ DIPLOMA IN TRANSFUSION MEDICINE+ 3 MONTHS EXPERIENCE
- POST GRADUATE DEGREE IN TRANSFUSION MEDICINE

MAINTENANCE

- 1. PRIVACY AND THOROUGH EXAMINATION OF DONOR
- 2. MINIMAL RISK OF CONTAMINATION WHILE COLLECTING BLOOD
- 3. STORAGE OF BLOOD/COMPONENT PENDING COMPLETE TESTING
- 4. DEDICATED QUARANTINE AND STORAGE ARRANGEMENTS
- 5. STORAGE OF FINISHED PRODUCTS BEFORE ISSUE
- 6. CORRECT PROCEDURES AS PER SOP
- 7. PROPER DISPOSAL OF BLOOD AND COMPONENTS NOT SUITABLE FOR USE

EQUIPMENT

- CLEAN
- PROPER
- SUITABLY PLACED
- OBSERVED, STANDARDISED AND CALIBRATED REGULARLY AS PER SOP AS PROVIDED IN THE TABLE GIVEN UNDER THIS HEAD

TABLE FOR CALIBRATION AND FREQUENCY

SR NO	EQUIPMENT	PERFORMANCE	CALIBRATION FREQUENCY	FREQUENCY
1	TEMPRATURE RECORDER	COMPARE AGAINST STANDARD THERMOMETER	DAILY	AS OFTEN AS NECESSARY
2	REFERIGERATED CENTRIFUGE	SPEED AND TEMPERATURE	EACH DAY OF USE	AS OFTEN AS NECESSARY
3	ABCD	EFGH	IJKL	MNOP
X-1				
X=18	MICROPIPETTE ELSA	VOLUME DELIVERY	EVERY YEAR	ONCE AN YEAR

SUPPLIES AND REAGNTS

SR.NO	REAGENT AND SOLUTIONS	FREQUENCY OF TESTING ALONG WITH CONTROLS
1	ANTI-HUMAN SERUM	EACH DAY OF USE
2	BLOOD GROUPING SERA	EACH DAY OF USE
3.	LECTIN	EACH DAY OF USE
4	ANTI BODY SCREENING AND REVERSE GROUPING CELLS	EACH DAY OF USE
5	HEPATITIS TEST REAGENTS	EACH RUN
6	SYPHILIS SEROLOGY REAGENTS	EACH RUN
7	ENZYMES	EACH DAY OF USE
8	HIV I AND HIV II REAGENTS	EACH RUN
9	NORMAL SALINE (LISS AND PBS)	EACH DAY OF USE
10	BOVINE ALBUMIN	EACH DAY OF USE

GMP

SOP FOR EACH CRITICAL OPERATION AVAILABLE AT THE SITE OF USE

SR NO		SR NO.	
a	Criterion determination of DONOR SUITABILITY	k	RETURNED BLOOD IF TO BE REISSUED THEN CRITERION
b	METHOD OF TESTING : FOR DONOR SELCT	l	PROCEDURE TO RELATE UNIT-DONOR-RECIPIENT
c	PHLEBOTOMY	m	QUALITY CONTROL SUPPLIES & REAGENTS
d	UID OF PRODUCTS VIS A VIS DONOR	n	PLANNED PREVENTIVE MAINTAINANCE _o
e	BLOOD COLLECTION PRECEDURE	o	LABELLING FOR PREVENTION OF MIXUP
f	METHOD COMPONENT PREPARATION	p	PLASMAPHERESISI, PLATELETSPHERESISI LEUCAPHAREISIS REINFUSION-DONOR
g	PRE TRANSFUSION TESTING	q	RECOVERED PLASMA
h	ADVERSE REACTION MANAGEMENT	r	REVIEW PROCEDURE BEFORE ISSUE
i	STORAGE TEMP CONTROL MANAGEMENT		
j	LENGTH OF EXPIRY DATE		

REFERENCE BOOKS

- Drugs and Cosmetics Act and Rules, SCHEDULE F PART XII-B
- DGHS : TRANSFUSION MEDICINE TECHNICAL MANUAL
- Dr. GP SALUJA AND Dr. GL SINGAL, Standard Operating Procedures and Regulatory Guidelines in Blood Banking
- Other standard text books

INSPECTION OF BLOOD CENTRE

Date of Inspection:Names of Inspecting Officers:	Name & Address of Blood Centre: Tel. No. E mail:
LEVEL State –S, District D Medical College – M, Taluk -T	Medical Officer In charge License No. Valid up to:
CONTROL: NAME OF ORGANIZRION	Applied for Grant / Licensed for
TECHNICAL STAFF	1. Whole Human Blood IP
Medical Officer :	2. Preparation of Blood Components:
Registered Nurse :	a. Packed Red Cells IP b. Washed Cells c. Fresh
Blood Bank Technician :	Frozen Plasma BP d. Pooled Plasma
Technical Supervisor :	e. Single Donor Plasma g. Platelets Rich Conc. h.
Social Workers :	Granulocyte Conc.
Attendants :	f. Platelets Rich Plasma
Others	i. Cryoprecipitate

WORK LOAD FOR PAST TWO YEARS

- **COLLECTION**

- **Voluntary Replacement Total**

- **Frequency of Reporting Monthly**
Quarterly
Half Yearly

- **MONTHLY**

- **QUATERLY**

- **HALF YEARLY**

- **ANNUALY**

- **DISPOSITION**

- **Used in their Hospital Issued Outside**
Discarded
Total

- **Details of Discarded Blood HBsAg +**
HIV +
HCV +

- **VDRL +**
Date Expired Insufficient Volume Haemolysed

OBSERVATIONS

- GENERAL EQUIPMENTS AND INSTRUMENTS
- Details Of Equipments/Instruments ...ObservationsRemarks
- LABORATORY EQUIPMENTS
- Details Of Laboratory Equipments ...Observations Remarks
- EQUIPMENT FOR COMPONENT PREPARATION
- Details Of Equipments/Instruments ...ObservationsRemarks

OBSERVATIONS ON GMP AND SOP

- IS WRITTEN STANDARD OPERATING PROCEDURES MAINTAINED DOES THE SOPS INCLUDE THE FOLLOWING?
 - A) CRITERIA TO DETERMINE DONOR SUITABILITY
 - B) METHODS OF PERFORMING DONOR QUALIFYING TEST
 - C) METHODS OF RELATING THE PRODUCT TO THE DONOR
 - D) BLOOD COLLECTION PROCEDURE WITH PRECAUTIONS TO ACCURATELY MEASURE
- THE QTY. OF BLOOD COLLECTED
 - E) METHODS OF COMPONENT PREPARATION
 - F) TESTS PERFORMED ON BLOOD & BLOOD PRODUCTS DURING PROCESSING
 - G) PRE-TRANSFUSION TESTING
 - H) PROCEDURES OF MANAGING ADVERSE REACTIONS

observations on GMP and SOP

- I) STORAGE TEMP. AND METHODS OF CONTROLLING STORAGE TEMP.
- J) EXPIRY DATE OF ALL FINAL PRODUCTS
- K) CRITERIA FOR ACCEPTING RETURNED BLOOD
- L) QUALITY CONTROL PROCEDURE FOR SUPPLIES AND REAGENTS
- M) SCHEDULES AND PROCEDURES FOR EQUIPMENT MAINTENANCE AND CALIBRATION
- N) LABELING PROCEDURES
- O) PROCEDURES FOR PLASMA/PLATELET/ LEUCOPHERSIS
- P) PROCEDURES FOR PREPARING RECOVERED PLASMA
- Q) PROCEDURES FOR REVIEW OF RECORDS

observations on GMP and SOP

CRITERIA FOR BLOOD DONATION:

- **DONOR REGISTRATION CARD showing**

1. Age (18 to 60) : Weight (not less than 45 kgs) : Temperature and pulse : Blood pressure : Hemoglobin (not less than 12.5g) – : indicate the test methods
Respiratory diseases : Skin diseases at the site of phlebotomy : Past medical history of TTD. : Precautionary observation to avoid professional donor :

2. **CRITERION FOR DEFERMENT OF BLOOD DONATION**

like abortion defer for six month

- 3. **CRITERION FOR REJECTION OF BLOOD DONATION**

- like, Cancer, endocrine disorders

ROUTINE TECHNIQUES USED FOR TESTS

CELL GR		Serum Groupin		Rh (D) Groupin					
SLIDE	D	SLIDE		SLIDE	D				
TILE		TILE		MODIFIED TUBE	M				
TUBE		TUBE		Du test	Du				
CROSS	MATCHING	CROSS		HBsAg		HCV		HIV	
SLIDE		SLIDE		Elisa-E	E	Elisa-E	E	ELISA	
TILE		TILE		Rapid	R	Rapid	R	RAPID	
SALINE		SALINE		Others	O	Others	O	WESTON BLOT	
								OTHERS	

ADDITIONAL OBSERVATIONS

- ODOROUS AMBIENCE
- RESPONSE OF DESK PERSON
- PRESENCE OF MEDICAL OFFICER ENGAGED FROM FAR CITY
- OXYGEN CYLINDER
- ANY SIGN OF EATABLE IN BLEEDING ROOM
- SIPPING MATTRESSES IN ROOM ADJACENT TO BLEEDING OR STORAGE ROOMS ESPECIALLY IN SUMMERS
- EXTRA BLOOD BAGS OVER THE STOCK
- SEROLOGICAL LAB WORKING OF AC
- MEDICAL SUPERVISIONS AT NIGHT
- SHORT CUTS IN TESTING
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THANKS

THE LEARNED AUDIENCE FOR PATIENT LISTENING