

GOVERNMENT OF WEST BENGAL
DEPARTMENT OF HEALTH & FAMILY WELFARE
DIRECTORATE OF DRUGS CONTROL

P-16, INDIA EXCHANGE PLACE EXTENSION, K.I.T. BUILDING- 5TH FLOOR, KOLKATA: -73

By Speed Post

No. DCWB/GBB/NRSMCH-8-96/Pt-II

Date:

To
The Drugs Controller General (India),
Central Drugs Standard & Control Organization (HQ)
Directorate General of Health Services
Ministry of H & F.W. FDA Bhawan, Kotla Road
New Delhi-110002

Sub: Renewal of licence No. DL-43-MB/SLA/CLAA/WB dtd.30.12.1996 for the period 01.01.2022 to 31.12.2026 of M/s. N.R.S. Medical College & Hospital Blood Centre , 138, A.J.C.Bose Road,Kolkata -700014.

Enclosed please find herewith an application in Form 27-C dtd. 17.12.2021 & Revised application on 10.06.2024 alongwith Joint Inspection Report dtd. 05.04.2022 and Compliance Verification Report dtd. 10.06.2024, Certificate in Form-26-G (duly Filled In) and other necessary papers & documents for renewal of licence in favour of the firm M/s. N.R.S. Medical College & Hospital Blood Centre , 138, A.J.C.Bose Road,Kolkata -700014.

Now, I, being the State Licensing Authority(HQ) & Controlling Authority have decided that the licence having No. DL-43-MB/SLA/CLAA/WB dtd.30.12.1996 may be renewed for the period 01.01.2022 to 31.12.2026 for collection, storage, processing and distribution of Whole Human Blood I.P. & its components under the said licence, if approved by the CLAA.

- Encl: 1. Application in Form 27-C dtd. 17.12.2021 & Revised application on 10.06.2024.
2. Joint Inspection Report dtd. 05.04.2022 and Compliance Verification Report dtd. 10.06.2024.
3. Certificate in Form-26-G (in triplicate).
4. List of products & CTS.
5. Layout Plan 2(Two) copies.

Sd/-
Deputy Director of Drugs Control
And
State Licensing Authority(HQ) & Controlling Authority

No. DCWB/GBB/NRSMCH-8-96/Pt-II /653/5(6)

Date: 01.07.2024

Copy forwarded for information to:-

1. The Dy. Drugs Controller (I), CDSCO (E.Z.), Nizam Palace, 7th. Floor, 234/4, AJC Bose Rd., Kol-20.
2. The Project Director, WBSAP & CS, Deptt. of H & FW, Swasthya Bhaban, Salt Lake City, Kolkata - 700091.
3. The Joint Director, WBSAP & CS, Deptt. of H & FW, Swasthya Bhaban, Salt Lake City, Kolkata - 700091.
4. Sri M. Ghosh, ADDC, Blood Centre Cell.
5. The Medical Superintendent cum Vice Principal, M/s. N.R.S. Medical College & Hospital Blood Centre, 138, A.J.C.Bose Road, Kolkata -700014.
6. DDC's Guard file

S. Pyne
28.06.2024
Deputy Director of Drugs Control
And
State Licensing Authority(HQ) & Controlling Authority

THE DRUGS & COSMETICS RULES, 1945

FORM 26-G

(See Rule 122-F)

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CERTIFICATE OF RENEWAL OF LICENCE TO OPERATE A BLOOD BANK FOR PROCESSING OF WHOLE HUMAN BLOOD AND / OR* FOR PREPARATION FOR SALE OR DISTRIBUTION OF ITS COMPONENTS.

1. Certified that licence number DL-43-MB/SLA/CLAA/WB granted on 30.12.1996 to M/s N.R.S Medical College & Hospital Blood Bank for the operation of a Blood Bank for processing of whole human blood and/or for preparation of its components at the premises situated at 138, A.J.C Bose Road, Kolkata - 700014, West Bengal is hereby renewed with effect from 01.01.2017 to 31.12.2021.

2. Name(s) of Items :
- (1) Whole Human Blood, I.P.
 - (2) Concentrated Human Red Blood Corpuscles I.P.
 - (3) Platelet Concentrate, I.P.
 - (4) Fresh Frozen Plasma, DG&HS Technical Manual 2003.
5. Cryoprecipitated Anti Hemophilic Factor, I.P.
6. Single Donor Platelet (Plateletpheresis), DG&HS Techn. Manual - 2003.
7. Aphaeresis Fresh Frozen Plasma (Plasmapheresis), DG&HS Technical Manual 2003.
3. Name(s) of Competent Technical Staff :
- (1)
 - (2)
 - (3)
 - (4)
 - (5)
 - (6)

List Enclosed

Signature Sri Swapan Kumar Mondal 12.4.18

Name and Designation Director of Drugs Control
Govt. of West Bengal

Dated : Licensing Authority.

Dr. S. ESWARA REDDY
Drugs Controller General (India)

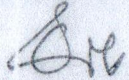
Central Licence Approving Authority.
Ministry of Health and Family Welfare
FDA Bhawan, Kofa Road, I.T.O.
New Delhi-110002

* delete, whichever is not applicable.

LIST OF ITEMS

1. License No. DL-43-MB/SLA/CLAA/WB Dated: 30.12.1996
2. Name of Blood Bank: N.R.S. Medical College & Hospital Blood Bank.
3. Address of the Blood Bank: 138, A.J.C Bose Road, Kolkata-700014, West Bengal.
4. Name of the Items: Whole Human Blood & Blood Components as stated below are renewed for the period from 01.01.2017 to 31.12.2021.

Sl. No.	Items	Standard	Reference	Container	Volume	Storage	Expiry Date	Quality Control	Frequency of QC
1.	Whole Human Blood	I.P	I.P 2014 & DGHS Technical Manual 2003	Bag	350/450ml± 10% excluding anticoagulant. Anticoagulant Preservative: 49/63ml	2 - 6°C	35 days with CPDA-1	As per IP2014 & DGHS Technical Manual 2003	As per DGHS Technical Manual 2003
2.	Concentrated Human Red Blood Corpuscles	I.P.	I.P 2014 & DGHS Technical Manual 2003	Bag	310ml±20ml (with SAGM) For 350ml of whole blood 230ml±20ml (without SAGM) for 350ml of whole blood	2 - 6°C	42 days with SAGM 35 days without SAGM	As per IP2014 & DGHS Technical Manual 2003	As per DGHS Technical Manual 2003
3.	Platelet Concentrate	I.P.	I.P 2014 & DGHS Technical Manual 2003	Bag	40-70 ml (For 350ml of Whole Blood) 50-70ml (For 450ml of Whole Blood)	22°-24°C with agitation	3-5 days depending on the type of plastic bag used	As per IP2014 & DGHS Technical Manual 2003	As per DGHS Technical Manual 2003
4.	Fresh Frozen Plasma	DGHS Technical Manual 2003	DGHS Technical Manual 2003	Bag	150-160 Plasma (For 350ml of Whole Blood) 200-220ml Plasma (For 450ml of Whole Blood)	-30°C or below	1 Year	As per DGHS Technical Manual 2003	As per DGHS Technical Manual 2003


 Dr. S. E. ...
 Drugs Controller General and
 Dir. General of Health Services
 Ministry of Health and Family Welfare
 Government of West Bengal
 Howrah-721102

5.	Cryoprecipitated Anti Hemophilic Factor	I.P.	I.P 2014 & DGHS Technical Manual 2003	Bag	10-20ml	-30°C or below	1 Year	As per IP2014 & DGHS Technical Manual 2003	As per DGHS Technical Manual 2003
6.	Single Donor Platelet(Plateletpheresis)	DGHS Technical Manual 2003	DGHS Technical Manual 2003	Bag	200-300ml	22°-24°C with agitation	3-5 days depending on the type of plastic bag used	As per DGHS Technical Manual 2003	As per DGHS Technical Manual 2003
7.	Aphaeresis Fresh Frozen Plasma(Plasmapheresis)	DGHS Technical Manual 2003	DGHS Technical Manual 2003	Bag	400-500ml	-30°C or below	1 Year	As per DGHS Technical Manual 2003	As per DGHS Technical Manual 2003

Name of the Competent Technical Staff:

1. Dr. Dilip Kr. Panda, MBBS, D.T.C.D, Medical Officer In-charge for Blood Bank & Aphaeresis Section(Already Approved).
2. Dr. Isita Bandyopadhyay, M.B.B.S, Medical Officer for Blood Bank & Component Section (Already Approved).
3. Dr. Abhijit Purkait, M.B.B.S, D.G.O, Medical Officer for Blood Bank & Aphaeresis Section(Already Approved).
4. Dr. Sibamay Das, M.B.B.S, Medical Officer(Already Approved).
5. Mr. Debapriya Sarkar, D.M.L.T, Technical Supervisor for Blood Component Section(Already Approved).
6. Mr. Kalyan Kumar Mukhopadhyay, D.M.L.T, Technician for Blood Bank & Aphaeresis section(Already Approved).
7. Mr. Somnath Deb, DMLT, Technician for Blood Bank & Aphaeresis section.
8. Mr. Souvik Chattopadhyay, D.M.L.T, Technician for Blood Bank & Aphaeresis section.
9. Mr. Subodh Roy, D.M.L.T, Blood Bank Technician(Already Approved).
10. Mrs. Mita Sarkar, DMLT, Blood bank technician.
11. Abhi Mondal, DMLT, Blood Bank technician.
12. Mrs. Dola Chatterjee, GNM, Registered Nurse for Blood bank & Aphaeresis section.
13. Mrs. Chandrima Saha, GNM, Registered Nurse, Aphaeresis Section(Already Approved).

Signature...

Name & Designation
Central License Approving Authority
Dr. S. ESWARA REDDY
Drugs Controller General (India)
Director, Central Licensing Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotta Road, I.T.O.
New Delhi-110002



Signature....

Name & Designation
Licensing Authority

Dr. SWAPAN KUMAR MONDAL
Director of Drugs Control
Govt. of West Bengal Page 2 of 2