

Regd.  
From

State Drug Controller-cum-Licensing Authority,  
Food and Drugs Administration, Haryana,  
S.C.O.No.94, Sector-5, Panchkula.

To

M/s. N.C. Medical College & Hospital  
(A Unit of Shanti Devi Charitable Trust Regd.)  
Panipat-Rohtak Road, Israna  
District Panipat-132107 (Haryana)

Memo. No. 63/297-1 Drug-1-2019/ 8736  
Dated Panchkula, the 27/11/19

Subject:

Regarding renewal of Blood Bank licence No. 729-B(H) w.e.f. 20.06.2019 to 19.06.2024 and grant of permission for preparation of Human Blood Components - M/s. N.C. Medical College & Hospital (A Unit of Shanti Devi Charitable Trust Regd.) Panipat-Rohtak Road, Israna District Panipat-132107 (Haryana).

Please refer to the subject cited above.

The license No. 729-B(H) granted to Blood Bank of M/s. N.C. Medical College & Hospital (A Unit of Shanti Devi Charitable Trust Regd.) for operation of a Blood Bank for processing of Whole Human Blood IP at the premises situated at Panipat-Rohtak Road, Israna District Panipat-132107 (Haryana) is hereby renewed with effect from 20.06.2019 to 19.06.2024 duly approved by Central Licensing Approving Authority to the following conditions:-

1. The Blood Bank shall not collect blood from professional paid donors.
2. The Blood Bank shall forward draft donor selection card with all particulars to this Directorate for further examination.
3. The Blood Bank shall prepare Standard Operating Procedures for collection of Blood, donor selection, testing and transportation of blood.
4. The Blood Bank shall validate the equipments used in the collection and process and testing. A report in this regard shall be maintained.
5. The Blood Bank shall carry out the test for unexpected antibodies on Whole Human Blood.
6. The Blood Bank shall carry out quality control test on blood grouping reagents and kits.
7. They shall store the blood samples of the donor's blood as well as recipient for a period of 7 days after transfusion.
8. The Blood Bank shall provide proper facilities for proper disposal of HIV, HCV and HBsAg infected blood.
9. Blood Bank refrigerator should be fitted with recording thermograph and alarm device, records of thermograph should be preserved in the Blood Bank.
10. The Blood Bank shall use only disposable sets including needles during the collection of blood.
11. The Blood Bank shall maintain all records and reports as per Drugs and Cosmetics Act and Rules.
12. The Blood Bank shall prepare their own Laboratory Manual describing the tests to be done in case of HTR.
13. The Blood Bank shall furnish the specimen labels containing all information as per Drugs and Cosmetics Rules.
14. The Blood Bank shall use only blood bags for collection of blood.
15. The Blood Bank is advised to carry out Du test for the confirmation of D negative blood.
16. The Blood Bank shall use approved test kits by this Dte. For testing of HIV, HCV and HBsAg.
17. The Blood Bank shall carry out patient pre-transfusion test.
18. In the case of Hospital based Blood Bank they shall constitute a Transfusion Committee to monitor the quality of blood and its components.
19. Cross Matching shall be carried by Saline, Albumin and Coomb Serum Method.
20. It is advised to carry out blood group testing by Cell/Serum technique.
21. The Blood Bank is directed to comply with all the suggestions mentioned by the inspection team at the time of inspection.
22. The Blood Bank is directed to comply with all the provisions prescribed under Schedule F Part-XII-B of the Drugs and Cosmetics Rules.
23. The Blood Bank is directed to comply with all the requirements as per the latest amendment pertaining to Blood bank vide GSR No. 245(E) dated 5.4.99 before operation.
24. The blood bank may be re-inspected periodically at least once in a year from the date of licensing.
25. The Whole human blood and blood components may be transferred, under prescribed storage conditions, to another blood bank which have facilities to store and monitor blood distribution.
26. The recipient blood bank shall not further transfer units obtained from another blood bank except to another blood storage centre or a patient.
27. The educational qualification and experience of all the technical staff endorsed under license is as per the requirements of Drugs & Cosmetics Rules 1945 and documents in support shall be submitted to DCG(I), New Delhi alongwith copy of plan of premises.
28. Precise address of blood bank which describes its operational area i.e. floor no./room no./block no./plot no. etc. alongwith license no. & its validity shall be communicated to DCG(I), New Delhi.

*N. K. Ahoja*  
(N. K. Ahoja) 26/11/19  
State Drug Controller-cum-Licensing Authority  
Food & Drugs Administration, Haryana

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Endst No. 63/297-1Drug-1-2019/

Dated:-

A copy is forwarded to Drugs Controller General (India), Directorate General of Health Services, Food & Drugs Administration Bhawan, Kotla Road, New Delhi w.r.t. their letter No. CLAA/B&BP/HAR/03/2014-D dated.18.11.2019 for information.

(N. K. Ahooja)  
State Drug Controller-cum-Controlling & Licensing Authority  
Food and Drugs Administration, Haryana

Endst No. 63/297-1Drug-1-2019/

Dated:-

A copy is forwarded to Deputy Drugs Controller (India), CDSCO, North Zone, C.G.O. Building No.1, Kamla Nehru Nagar, Hapur Road, Ghaziabad (U.P.) for information.

(N. K. Ahooja)  
State Drug Controller-cum-Controlling & Licensing Authority  
Food and Drugs Administration, Haryana

Endst No. 63/297-1Drug-1-2019/

Dated:-

A copy is forwarded to the following for information and necessary action:

1. Deputy Director (Blood Safety), C-15, Awas-Bhawan, Sector-6, Panchkula.
2. Senior Drugs Control Officer, Sonipat.

(N. K. Ahooja)  
State Drug Controller-cum-Controlling & Licensing Authority  
Food and Drugs Administration, Haryana

*[Faint handwritten notes and stamps at the bottom of the page]*



FORM 26-G  
(See Rule 122-F)

Certificate of renewal of License to operate a Blood Bank for Whole Human Blood and for preparation for sale or distribution of its components and apheresis.

1. Certified that License No. 729- B(H) granted to M/s. N.C. Medical College & Hospital (A Unit of Shanti Devi Charitable Trust Regd.) for operation of a Blood Bank for processing of Whole Human Blood at the premises, situated at Panipat-Rohtak Road, Israna District Panipat-132107 (Haryana), is hereby renewed with effect from 20.06.2019 to 19.06.2024.

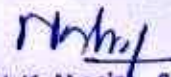
2. Name of items:

1. Whole Human Blood I.P.
2. Packed Red Blood Cells I.P
3. Platelet Concentrate I.P
4. Fresh Frozen Plasma B.P.
5. Cryoprecipitate AHF

3. Name(s) of competent Technical Staff:-

Sr. No.	Name	Qualifications	Designation	Expeirence
1.	Dr. Isha Gupta	MD (Pathology)	Medical Officer	already apporved
2.	Dr. Sachin Chauhan	MD (Pathology)	Medical Officer	already apporved
3.	Dr. Shikha Sharma	MD (Pathology)	Medical Officer	----
4.	Mr. Subhash Chander Rana	BTA Class-I	Technical Supervisor	Approved
5.	Ms. Krishna	DMLT	Technician	----
6.	Mr. Vivek	DMLT	Technician	03 months in component preparation
7.	Mr. Ashu	DMLT	Technician	----
8.	Mr. Ajay	DMLT	Technician	02 years 07 months
9.	Mr. Meharban Khan	DMLT	Technician	----
10.	Ms. Rekha	GNM	Staff Nurse	Approved

Dated:-

  
(N. K. Ahooja) 061119  
Signature State Drugs Controller-cum-Controlling &  
Name and Designation Licensing Authority  
Licensing Authority, Haryana

  
Dr. V. G. SOMANI  
Drugs Controller General (India)  
Central Licence Approving Authority  
Ministry of Health and Family Welfare  
FDA Bhawan, Kolar Road, I.T.O  
New Delhi-110002