

Regd.
From

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

Directed
BPS Medical College
10024
Date 06/01/2014
Khanpur
ADG (on leave)
06/01/2014

To

✓ Director,
M/s. Blood Bank of
Bhagat Phool Singh Medical College for Women,
Khanpur Kalan District Sonapat (Haryana)

Memo No. 63/296-2Drug-1-2013: 27
Dated Panchkula, the 03/01/14.

Subject :-

Grant of Licence to operate a blood bank for collection, storage and processing of Whole Human Blood, I.P. to be granted in favour of M/s. Blood Bank of Bhagat Phool Singh Medical College for Women, Khanpur Kalan District Sonapat (Haryana).

Reference your letter no PA/BPS/13-1423 dated 11.07.2013 on the subject noted above.

The license No. 722-B(H) on Form 28-C (Enclosed) valid up to 01-01-2019 is hereby granted to you to operate Blood Bank for Whole Human Blood I.P. and for manufacture of Blood Component and to carry out aphaeresis mentioned in the License, 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 advice 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 requirements as per the latest amendment pertaining to Blood bank vide GSR No. 245(E) dated 5.4.99 before operation.

Enclosure Blood Bank
Director
27/1/14

Director
BPS Govt. Medical College For Women
Khanpur Kalan, Sonapat (Haryana)

(Dr. G. L. Singhal)
State Drug Controller
(Central Licensing Authority)
Food & Drug Administration, Haryana

Endst No. 63/296-2Drug-1-2013/

Dated

A copy is forwarded to Drugs Controller General (India), Directorate General of Health Services, Central Drugs Standard Control Organization (HQ), FDA Bhawan, Kotla Road, New Delhi with the reference his letter No. CLAA/B&BP/HAR/27/2013-D dated 26.12.2013 for information. A copy of License no. 722-B(H) dated 02.01.2014 issued to the said blood Bank is also enclosed, as desired.

(Dr. G. L. Singal)

State Drug Controller
State Drugs Controller
Food and Drug Licensing Authority
Food & Drug Administration, Haryana

Endst No. 63/296-2Drug-1-2013/

Dated

A copy is forwarded to Deputy Drugs Controller (India), CDSCO, North Zone, Hapur Road, Kamla Nehru Nagar, Ghaziabad (U.P.) for information. He is requested to depute one Drug Inspector under his control after six month for carrying Joint Inspection of the said Blood Bank with Officer of State Drugs Control Authority.

(Dr. G. L. Singal)

State Drug Controller
State Drugs Controller
Food and Drug Licensing Authority
Food & Drug Administration, Haryana

Endst No. 63/296-2 Drug-1-2012/

Dated

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

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

(Dr. G. L. Singal)

State Drug Controller
State Drugs Controller
Food and Drug Licensing Authority
Food & Drug Administration, Haryana

BPS Govt. Medical College For Women
Khanpur Kaian, Sonapat (Haryana)

