

Regd.  
From

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

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 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 requirements as per the latest amendment pertaining to Blood bank vide GSR No. 245(E) dated 5.4.99 before operation.

Enclosure Blood Bank  
Dr. G. L. Singhal  
27/1/14

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

State Drug Controller-cum-Licensing Authority  
Food and Drugs 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(11) dated 02-01-2014 issued to the said blood Bank is also enclosed, as desired.

(Dr. G. L. Singal)

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

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

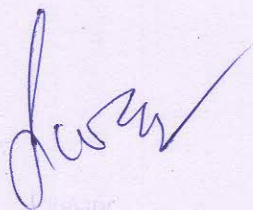
Dated

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



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



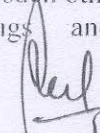
**FORM 28 C**  
**(See Rule 122-G)**

**LICENCE TO OPERATE BLOOD BANK FOR STORAGE AND PROCESSING OF WHOLE HUMAN BLOOD IP.**

1. Number of Licence. 722-BCH date of issue 02-01-2014 at the premises situated at **Khanpur Kalan District Sonapat (Haryana)**
2. **M/s. Blood Bank of Bhagat Phool Singh Government Medical College for Women** is hereby licensed to collect, store, process and distribute **Whole Human Blood IP.**
3. Name(s) of the item(s) :- **Whole Human Blood IP.**
4. Name of the competent Staff:

Sr. No.	Name	Qualifications	Designation
1.	Dr. Sanjay Verma	MD (Pathology)	Medical Officer
2.	Dr. Deepti Aggarwal	MD (Pathology)	Medical Officer
3.	Dr. Kulwant Singh	MD (Pathology)	Medical Officer
4.	Dr. Hemlata Kamra	MD (Pathology)	Medical Officer
5.	Dr. Parveen Rana	MD (Pathology)	Medical Officer
6.	Dr. Ruchi Aggarwal	MD (Pathology)	Medical Officer
7.	Sh. Ram Chander	DMLT	Laboratory Technician
8.	Sh. Bishan Dutt	DMLT	Laboratory Technician
9.	Sh. Dinesh	DMLT	Laboratory Technician
10.	Mrs. Rajesh	GNM	Staff Nurse

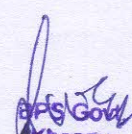
5. The license authorizes licensee to collect, store, distribute and processing of Whole Human Blood subject to the conditions applicable to this license.
6. The licence shall be in force from 02-01-2014 to 01-01-2019
7. The licence shall be subjected to the conditions stated below and to such other condition as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act, 1940.

  
**(Dr. G. L. Singal)**  
State Drugs Controller  
(Controlling & Licensing Authority)  
State Drugs Controller-cum-Licensing and  
Food & Drug Administration, Haryana  
Controlling Authority  
Food & Drugs Administration, Haryana

(Central License Approving Authority)

**Conditions of License**

1. The licensee shall neither collect blood from any professional donor or paid donor nor shall he prepare blood components from the blood collected from such a donor.
2. The license and any certificate of renewal in force shall be displayed on the approved premises and the original shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
3. Any change in the technical staff shall be forth with reported to the licensing Authority and Central License Approving Authority.
4. The License shall inform the Licensing Authority and Central Approving Authority in writing in the event of any change in the constitution of the firm operating under the license. Where any change in the constitution of the firm takes place, the current license shall be deemed to be valid for maximum period of the three months from the date on which the change has taken place unless, in the meantime, a fresh license has been taken from the Licensing Authority and Central License Approving Authority in the name of the firm with the change constitution.

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



Regd.

From

State Drugs Controller-cum-Licensing Authority,  
Food & Drugs Administration, Haryana,  
SCO-94, Sector-5, Panchkula.

To

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

Memo. No. 63/296-2 Drug-1-2015/ *July*  
Dated *16/07/2015*

Subject:- Grant of approval for processing of blood components as additional products to be granted in the license No. 722-B(H) dated 02.01.2014 valid upto 01.01.2019 issued in favour of Blood Bank M/s. Bhagat Phool Singh Govt. Medical College for Women, Khanpur Kalan District Sonapat (Haryana)

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

Under the approval of DCG(I), New Delhi vide their office letter no. CLAA/B&BP/HAR/22/2012-D dated 27.10.2014, you are hereby permitted to manufacture Plasmapheresis (using cell separator) and Plateletapheresis (using cell separator) at your licensed premises under your Blood Bank License No. 722-B(H) subject to the following conditions:-

1. The Blood bank shall adhere to all the conditions of license under the provisions of Drugs and Cosmetics Act 1940 and Rules thereunder including Part XII-B of Schedule F.
2. The Blood Bank shall carryout all tests on the blood components from time to time for all quality control parameters as laid down.

*N. S.*  
*16/7/15*  
(Raj Kumar)  
Deputy State Drugs Controller  
(Controlling & Licensing Authority)  
Food & Drugs Administration, Haryana

Endst No. 63/296-2 Drug-1-2015/

dated

A copy alongwith a copy of list of additional items approved by the undersigned & countersigned by the CLAA is forwarded to the following for information and necessary action:-

1. Deputy Drugs Controller (India), CDSCO, North Zone, Hapur Road, Kamla Nehru Nagar, Ghaziabad (U.P.)
2. Deputy Director (Blood Safety), C-15, Awaas Bhawan, Sector-6, Panchkula.
3. Senior Drugs Control Officer, Karnal (Haryana)

*Sg*  
(Raj Kumar)  
Deputy State Drugs Controller  
(Controlling & Licensing Authority)  
Food & Drugs Administration, Haryana

*[Signature]*

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



**M/s. Bhagat Phool Singh Govt. Medical College for Women, Khanpur Kalan**  
**District Sonapat (Haryana)**

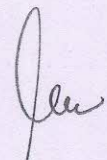
**Blood Bank License No. 722-B(H) Valid upto 01.01.2019**


**List of items :-**

1. Blood components-
  - i. Packed Red Blood Cells IP
  - ii. Fresh Frozen Plasma BP
  - iii. Cryoprecipitate
  - iv. Platelet Concentrate IP
2. Apheresis Procedure (Single Donor Platelet)

18-1  
08/6/15

(Raj Kumar)  
Deputy State Drugs Controller  
(Controlling & Licensing Authority)  
Food & Drugs Administration, Haryana

  
Dr. L. A. SINGH  
Drugs Controller General (India)  
Dto. General of Health Services  
Ministry of Health & Family Welfare  
FDA Bhawan, Kille Road, J.T.O.  
New Delhi-110002

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