



GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
(DIRECTORATE GENERAL OF HEALTH SERVICES)
CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
OFFICE OF THE ASSISTANT DRUGS CONTROLLER (INDIA)
SUB ZONE - BANGALORE

No. ADC/BSZ/KTK/06-172/2016/24

Date: 11/4/2016

To,
The Drugs Controller,
Karnataka, Bangalore.

Sub: Forwarding Joint inspection Report of M/s. Sapthagiri Hospital Blood Bank, No. 15,
Chikkasandra, Hesaraghatta Main Road, Bangalore-560090, Karnataka -reg.

Ref: DCD, Karnataka letter no. DCD/24/BBC/2015-16 dated 3.2.2016

Sir,

With reference to above, M/s. Sapthagiri Hospital Blood Bank, No. 15,
Chikkasandra, Hesaraghatta Main Road, Bangalore-560090, Karnataka was jointly inspected
by Sh. Mahesh N.A, Drugs Inspector of this office and Sh. Manohara. K.V, Drugs
Inspector, HQ, Bangalore, State DC Department, Karnataka on 6.4.2016 to consider the
Blood Bank's application for renewal of license for collection, storage and processing of
Whole Human Blood IP and Blood Components.

From the joint inspection report, it is observed that the Blood Bank has provided
adequate area, whole time competent technical staff, required equipments and reagents for
collection, storage and processing of Whole Human Blood and Blood Components as well as
SOPs, records, registers and labels are maintained as required under Part XII B, Schedule F
of Drugs and Cosmetics Rules. The inspection team has also made the following suggestions:

1. The blood bank should constitute Transfusion committee to monitor the quality of
blood processing.
2. The blood bank should provide temperature display to Refrigerator used for storing
diagnostic kits and reagents
3. The Blood Bank should provide Temperature indicator for Autoclave.
4. The blood bank should use dry rubber balancing material during preparation of blood
components.
5. The Blood bank should prepare SOP for "Maintenance, calibration & validation of
equipments and Pilot samples preservation for seven days after issue".

In view of the above, the application of M/s. Sapthagiri Hospital Blood
Bank, No. 15, Chikkasandra, Hesaraghatta Main Road, Bangalore-560090, Karnataka may
be considered for renewal of license in Form-26G for collection, storage and processing of
following products for the period 25.1.2016 to 24.1.2021 with a direction to comply the
above mentioned suggestions.

1. Whole Human Blood IP.
2. Concentrated Human Red Blood Corpuscles IP.
3. Fresh Frozen Plasma BP
4. Platelet Concentrate USP.
5. Cryoprecipitate USP

Yours faithfully,

Shanthy Gunasekaran

(Shanthy Gunasekaran)

Deputy Drugs Controller (India)

Encl: Joint Inspection Report

Copy to: i. The Drugs Controller General (India), FDA Bhawan, New Delhi.

✓ ii. M/s. Sapthagiri Hospital Blood Bank, No. 15, Chikkasandra, Hesaraghatta Main Road, Bangalore-560090, Karnataka

Form 26-G
(See Rule 122-F)

KTK/26G-01/2016-21

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 : KTK/28C-232/2011 granted on 25/01/2011 for M/S. SAPTHAGIRI HOSPITAL BLOOD BANK, for the operation of a Blood Bank for processing of Whole Human Blood I.P and its Components at the premises situated at SAPTHAGIRI HOSPITAL, NO:15, CHIKKASANDRA, HESARAGHATTA MAIN ROAD, BANGALORE- 560 090 is hereby renewed with effect from 25/01/2016 TO 24/01/2021.

2. Name(s) of the items(s)

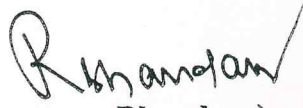
- WHOLE HUMAN BLOOD IP
- PLATELET CONCENTRATE IP
- CRYOPRECIPITATE
- FRESH FROZE PLASMA BP
- CONCENTRATED RBC IP

3. Name(s) of competent Technical Staff.

- | | | |
|---|---|----------------------|
| ➤ Dr. Jayalakshmi V.J MBBS,DCP | - | Medical Officer |
| ➤ Dr. Aparna Narasimha MBBS,MD(Path) | - | Medical Officer |
| ➤ Dr. Archana Shetty MBBS,MD(Path) | - | Medical Officer |
| ➤ Dr. Padma Priya Kasukurti MBBS,MD(Path) | - | Medical Officer |
| ➤ Smt. Vijaya Joseph | - | Technical Supervisor |
| ➤ Sri. Shridhara N | - | Lab Technician |
| ➤ Sri. Revanna | - | Lab Technician |
| ➤ Smt. Veena B.K | - | Lab Technician |
| ➤ Smt. Sunitha K | - | Lab Technician |
| ➤ Smt. Chandrakala G.S | - | Registered Nurse |

Date: 21/04/2016




(Ragurama Bhandary)
DRUGS CONTROLLER
& LICENSING AUTHORITY


Central Licence Approving Authority

* Delete, whichever is not applicable

Dr. G. N. SINGH
Drugs Controller General (India)
Dte General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, New Delhi, I.O.
New Delhi