## File No. CLAA/B&BP/MAHA/79/2010-D Government of India Directorate General of Health Services Central Drugs Standard Control Organization (Blood Centre División)

FDA Bhawan, Kotla Road, New Delhi-110002, Dated:-

To

The Joint Commissioner (Drug) (Gr. Mumbai) & Licensing Authority, Food and Drug Administration, M.S., 3rd Floor, Bandra Kurla Complex, Bandra (East), Mumbai - 400051.

0 7 JUN 2022

Subject: Renewal of Blood Centre Licence no. 954 granted on 28.10.1988 for the period of 01.01.2022 to 31.12.2026 for the processing of Whole Human Blood IP & its components including apheresis issued in favor of M/s. K. E. M. Hospital Blood Centre, Acharya Donde Marg, Parel, Mumbai - 400012 (Maharashtra State) -reg.

Ref. No. - 1. Your office letter no. N.B.Ren/248-22/Z-II dated 04.05.2022.

- 2. This office letter no. CLAA/B&BP/MAHA/79/2010-D dated 04.02.2022,
- 3. Your office letter no. KEM/BBK/Ren./05-2022/Z-2 dated 11.01.2022

Sir.

With reference to the letters cited above on the subject matter, CLAA hereby approves the renewal of Blood Centre Licence no. 954 granted on 28.10.1988 for the period of 01.01.2022 to 31.12.2026 for the processing of Whole Human Blood IP & its components including apheresis issued in favor of M/s. K. E. M. Hospital Blood Centre, Acharya Donde Marg, Parel, Mumbai - 400012 (Maharashtra State).

Two copies of the renewal certificates duly approved by the CLAA are enclosed herewith for further necessary action by your Administration.

> 1. The Blood Centre may be re-inspected periodically at least once in a year from the date of licensing by a team comprising of Drugs Inspectors of CDSCO and State Licensing Authority and if required with an expert. The report may be forwarded to this Directorate for information.

> 2. The Blood Centre should comply with all the provisions prescribed under

schedule F Part XII-B of the Drugs and Cosmetic Rules.

Enclosure: Renewal certificate in Duplicate as above.

Yours faithfully,

(Dr. V.G.SOMANI) CENTRAL LICENCE APPROVING AUTHORITY

Copy forwarded for information to:

- The Deputy Drugs Controller (I), CDSCO, West Zone , 4th floor , Zonal FDA Bhawan, GMSD Compound, Bellasis Rd, Mumbai Central, Mumbai-400008.
- M/s. K. E. M. Hospital Blood Centre, Acharya Donde Marg, Parel, Mumbai -400012 (Maharashtra State)

## Form 26- G

(See rule 122-F)

Certificate of renewal of licence to operate a blood centre for processing of Whole Human Blood and/or for preparation for sale or distribution of its components

- 1. Certified that license 28-C No. 954 granted on 28.10.1988 to M/s. K. E. M. Hospital Blood Centre for the operation of a Blood Centre for processing of whole human blood and/or for preparation of its components at the premises situated at Acharya Donde Marg, Parel, Mumbai-400012 renewed with effect from 01.01.2022 to 31.12.2026.
- 2. Name (s) of Items:
  - 1. Whole Human Blood I.P.
  - 2. Packed Red Blood Cells I.P. (Concentrated Human Red Blood Corpuscles)
  - 3. Platelet Concentrate I.P.
  - 4. Cryoprecipitated Anti-Haemophilic Factor I.P.
  - 5. Normal Human Plasma I.P.
  - 6. Fresh Frozen Plasma B.P.
  - 7. Cryo-poor Plasma
  - 8. Saline Washed Red Cells (Human Red Cells Saline Washed)
  - 9. Plateletpheresis (Single Donor Platelet) (Platelet Concentrate)
  - 10. Leucapheresis (Granulocyte Concentrate)
  - 11. Plasmapheresis
- 3. The Name(s) of competent Technical Staff:
  - A) Name(s) of Medical Officers
- 1) Dr. Jayashree Sharma, 2) Dr. Charusmita Modi,
- 3) Dr. Swarupa Bhagwat, 4) Dr. Darshan Adulkar,
- 5) Dr. Lalitkumar Sonawane
- B) Name(s) of Technical Supervisor
- 1) Ms. C. G. Sangle,
- 2) Smt. Chhaya Keny,
- 3) Shri. Amit Chalke,
- 4) Shri. Atul Gahine,

- C) Name(s) of Registered Nurse
- 1) Mrs. Asawari Patil
- D) Name(s) of Blood Bank Technician
- 1) Shri. V.V. Ghadigaonkar, 2) Smt. Riddhi Solanki,
- 3) Smt. Shreya Patil,
- 4) Smt. Suman Wadekar,
- 5) Smt. Milan Sonar,
- 6) Smt. Shrutika Kadam,
- 7) Smt. Pranjal Patil,
- 8) Smt. Vindee Govekar,
- 9) Smt. Swati Salgalgar,
- 10) Smt. Smita Avhad,

- 11) Smt. Rohinee Kokane,
- 12) Smt. Namrata Parab,

Smt. Pradnya Mistry

(G. B. Byale)

ploint Commissioner(Drug)(Greater Mumbai)

& Licensing Authority,

Food and Drug Administration, M.S., Mumbai

Central Licence Approving Authori

डॉ. वी. जी. सोमानी औषधि महानियंत्रक (भारत) रवारध्य रोवा महानिदेशालय रवारध्य एवं परिवार कल्याण मंत्रालय एक.डी.ए. भवन, कोटला रोड़, आई.टी.ओ. नई दिल्ली-110002