

File NO: CLAA/B&BP/Maha/221/2011-D
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation (HQ)
O/o DCG (I)

FDA Bhawan, Kotla Road
New Delhi -110002
Tel no : 011-23236975
Fax no : 011-23236973
Dated: 23.12.2011

To,

Joint Commissioner (Amt. Divn.)
FDA (M.S.) Amravati

Sub: Grant of Licence to operate a blood bank for collection, storage and processing of Whole Human Blood I.P., Blood Components and apheresis to be issued of M/s Managing Trustee of Ganediwal Charitable Trust for M/s ICON Blood Bank situated at Plot No. 8,9,-10 Sheet No. 64-C,1st Floor, ICON Hospital, Kedia Plots, Akola -Reg.

Ref. Your office letter no. D&C/Icon B.B./1156/2011/3 dated 05.12.2011

Sir,

CLAA hereby approves the licence in Form-28C to be issued of M/s Managing Trustee of Ganediwal Charitable Trust for M/s ICON Blood Bank, Akola. for the collection, storage and processing of Whole Human Blood I.P., Blood Components and apheresis.

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

1. The Blood Bank 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 Bank may be directed to comply with all the suggestions mentioned by the inspecting team at the time of inspection.
3. The Blood Bank should comply with all the provisions prescribed under schedule F Part XII-B of the Drugs and Cosmetic Rules.

please note that only approvable products with acceptable terminology are approved ✓

Yours faithfully

V.G.S.

(DR. V.G SOMANI)

CENTRAL LICENCE APPROVING AUTHORITY

Encl: - Certificates as stated above in duplicate

Copy to: The Deputy Drugs Controller (I), CDSCO, West Zone, Mumbai - 400 003

FORM 28-C

(See Rule 122-G)

License to Operate a Blood Bank for collection, storage and processing of whole human blood and/or its components for sale for distribution.

1. Number of Licence *AMD/BB/ 24 / 2011* Date of Issue at the premises situated at Plot No. 8,9,-10 Sheet No. 64-C, 1st Floor, *ICON Hospital, Kedia Plots, Akola*
2. *Managing Trustee of Ganediwal Charitable Trust for M/s. ICON Blood Bank Akola, is hereby licensed to collect, store, process and distribute whole blood I.P., Blood Components and Apheresis .*

3. Name(s) of the item(s)
 - 1 *Whole Human Blood I.P.*
 - ~~2. Concentrates Human Red Blood Cell I.P.~~
 3. *Platelet Concentrate U.S.P.*
 4. *Packed Red Cells I.P.*
 5. *Fresh Frozen Plasma B.P.*
 6. *Saline Washed Packed Red Cells*
 - ~~7. Apheresis Platelets~~ *SINGLE DONOR PLATELETS BY APHERESIS*

Dr. V. G. SOMANI
Drugs Controller General (India)
Dte. General of Health Services
Ministry of Health & Family Welfare
FDA Bhawan, Kotla Road, I.T.O.
New Delhi - 110 002

4. Name (s) of Competent Technical staff
Dr. Yogesh R. Bhatiwala (Blood Transfusion Officer)

- i Shri. Nitin S. Gabhe B.Sc. DMLT. (Tech. Supervisor)*
- ii. Ku. Snehal Sable B.Sc.PG DMLT. (Blood Bank Technician)*
- iii Ku. Monika Rokade B.Sc.PG DMLT.(Lab. Technician)*

- Regd. Nurse :-
 - i. Ku. Hima Das*
 - ii. Ku. Surya Sugathan*

- 5 The licence authorises licensee to collect, store, distribute, and processing of whole blood and /or blood components subject to the conditions applicable to this licence.
- 6 The Licence shall be in force from 05-12-2011 to 04.12.2016
- 7 The licence shall be subject to the conditions stated below and to such other conditions as may be specified from time to time in the Rules made under the Drugs and Cosmetics Act, 1940.



S.M. Dalal
(S.M. Dalal)

Joint Commissioner (Amravati Division)
and Licensing Authority
Food and Drug Administration M.S.
Amravati.

Date:- 5/12/11

Central Licence Approving Authority

CONDITIONS OF LICENCE

1. This licence and any certificate of renewal in force shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. Any change in the expert staff shall be forthwith reported to the Licensing Authority.
3. The Licensee shall be inform the Licensing Authority in writing in the event of any change in the firm operating under the licence. Where any change in the constitution of the firm take place, the current licence shall be deemed to be valid for maximum period of three months from the date on which the change takes place unless, in the meantime, a fresh licence has been taken from the Licensing Authority in the name of the firm with the changed constitution.
4. The Licensee shall inform the Licensing Authority and/or Central License Approving Authority in writing in the event of 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/or Central License Approving Authority in the name of the firm with the changed constitution.

Dr. V. G. SOMANI
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