

¹[FORM 28E

(See rule 122 G)

Licence to manufacture and store blood products for sale or distribution.

1. Number of licence date of issue.....at the premises situated at.....

2. M/s.....is hereby licensed to manufacture, store, sell or distribute the following blood products:-

3. Name(s) of the item(s) :

1.

2.

3.

4. Name(s) of the competent technical staff:

(a) responsible for manufacturing

(b) responsible for testing

1.

1.

2.

2.

3.

3.

5. The licence authorises licensee to manufacture, store, sell or distribute the blood products, subject to the conditions applicable to this licence.

6. The licence shall be in force from..... to.....

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 Drugs and Cosmetics Act, 1940.

Dated.:

Signature.....

.....

Name and Designation ..

.....

*Licensing Authority/ *Central Licence Approving Authority

* Delete whichever is not applicable

Conditions of License

1. The licensee shall not manufacture blood products from the blood drawn from any professional donor or paid donor.

2. The licence and any certificate of renewal in force shall be displayed on the approved premises and 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 forthwith reported to the Licensing Authority and/or Central Licence Approving Authority.

4. The licensee shall inform the Licensing Authority and/or Central Licence Approving Authority in writing any change in the constitution of the firm operating under the licence. In the event of any change in the constitution of the firm, the licence shall be deemed to be valid for a 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 and/or Central Licence Approving Authority in the name of the firm with the changed constitution.]