Annexure I
COPY VALID MANUFACTURING LICENSE

FORM-25

[See Rule 70]

Licence to manufacture for sale [or for distribution] of drugs other than those Specified in Schedules C, C (I) and X

Number of licence and date of issue 43/UA/2016 Date of issue 31-05-2016

1. M/s Lucent Biotech Ltd. Unit-II, is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C, C (I), and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at– Khasra No. 165/3, Nalhera Anantpur, Roorkee, Distt. Haridwar, (Uttarakhand) under the direction and supervision of the following competent technical staff:

(a) Competent Technical Staff (Names)

For Manufacturing- 1- Sh. Pawan Kumar Pandey (Tablets & Capsule)

For Analysis- 1- Sh. Prashant Tyagi, (Chemical, Instrumental & Microbiology)

(b) Name of Drugs- As per list enclosed.

2. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the licence, subject to the conditions applicable to licence for sale.
3. The licence shall be in force from 31-05-2016 to 30-05-2021.
4. The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Drugs and Cosmetics Act, 1940.

Date: 31-05-2016

Signature.....

Designation.....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act 1940.
2. Any change in the expert staff named in the licence shall be forthwith reported to the Licensing Authority
3. If the licensee wants to manufacture for sale additional items of drugs not included above he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 69 (5). The licence will be deemed to extend to the drugs so endorsed.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a 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
5. The Licensee, Who is Marketing or engaged in manufacture of drug containing psychotropic substance under the Drug License, shall have to register and shall file quarterly return with the Narcotics Commissioner for each of the substance in the form and manner as many be specified by the "Narcotic Commissioner" prior to initiating and activities mentioned therein under the license issued to them, Vide GSR 224(E) dt. 25-03-2015

Annexure I

FORM 28

[Rule 76]

LICENCE TO MANUFACTURE FOR SALE [2][OR FOR DISTRIBUTION] OF DRUGS SPECIFIED IN SCHEDULE C AND C (1) [3][EXCLUDING THOSE SPECIFIED IN SCHEDULE X]

Number of licence 45/UA/SC/P-2016 Date of issue 31-05-2016

1 M/s Lucent Biotech Ltd. Unit-II, is hereby licensed to manufacture at the premises situated at Khasra No. 165/3, Nalhera Anantpur, Roorkee, Distt. Haridwar, (Uttarakhand) the following drugs being drugs specified in Schedules C and C (1) [3][excluding those specified in Sch. X] to the Drugs and Cosmetics Rules, 1945.

Name of Drugs- As per list enclosed

2. Names approved [Competent Technical Staff]

For Manufacturing- 1- Sh. Pawan Kumar Pandey (Tablets & Capsule)

For Analysis- 1- Sh. Prashant Tyagi, (Chemical, Instrumental & Microbiology)

3. The licence authorizes the sale by way of wholesale dealing and storage for sale by the licenses of the drugs manufactured under the licence subject to the conditions applicable to licenses for sale

4. The licence will be in force form 31-05-2016 to 30-05-2021.

5. The licence is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs & Cosmetics Act, 1940

Date of Issue: 31-05-2016

Signature.....

Designation.....

Conditions of Licence

1. This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector appointed under the Drugs and Cosmetics Act, 1940.
2. If the licensee wishes to undertake during the currency of the licence the manufacture of any drug specified in Schedule C and (C(1)[2] [excluding those specified in Schedule X] not included above, he should apply to the Licensing Authority for the necessary endorsement as provided in Rule 75(3). This licence will be deemed to extend to the items so endorsed.
3. Any change in the [3][Competent Technical Staff] shall be forthwith reported to the Licensing Authority.
4. The licensee shall inform the Licensing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a 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.
5. The firm shall abide by any order passed under Drug (Prices Control) Order.
6. The Licensee, Who is Marketing or engaged in manufacture of drug containing psychotropic substance under the Drug License, shall have to register and shall file quarterly return with the Narcotics Commissioner for each of the substance in the form and manner as many be specified by the "Narcotic Commissioner" prior to initiating and activities mentioned therein under the license issued to them, Vide GSR 224(E) dt. 25-03-2015.