## ORIGINAL



# **FORM - 25**

[See Rule 70]

Licence to manufacture for sale (or for distribution) of drugs other than those specified in Schedules C, C(1) and X)

Number of licence and date of issue 20/EG/AP/2020/F/G Dt.31/03/2020

#### 1.M/s.KBK BIOTECH PRIVATE LIMITED

is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in [Schedules, C, C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at

D.No.3-56/2, Chyinnabrahmadevam (Village), Marripudi Post, Peddapuram (Mandal) East Godavari-Dist. - 533 105, Andhra Pradesh, INDIA under the direction and supervision of the following competent technical staff.

(a) Competent Technical Staff (Names):

1.Mr.Kollipara Suresh Babu

B.Sc

Manufacturing Chemist

2.Mr.Peramasetty Ganesh

**Analytical Chemist** 

- (b) Names of drugs (Each Item to be separately specified) LIST ENCLOSED
- 2. The licence authorises 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 31/03/2020 TO 30/03/2025

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: 3(103 2020

Signature Designation

(Licensing Authority)

DIRECTOR Drugs Control Administration lovernment of Andhra Pradesh Chuttugunta, Guntur-522 004

## 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 [competent technical 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). This licence will be deemed to extend to the categories 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.

Constitution of the Firm (Private Limited)

- 1 .Mr.Kundula Balarama Krishna
- 2 .Mrs.Kundula Ganga Bhavani
- 3 .Mr.Kundula Murali Krishna

4 .Mr.Kundula Suresh Kumar

Director

Director Director

Director

3/13/2020

DIRECTOR
Drugs Control Administration
Fovernment of Andhra Pradesh
Chuttugunta, Guntur-522 004

## GOVERNMENT OF ANDHRA PRADESH DRUGS CONTROL ADMINISTRATION

L.Dis.No.2011/Stores/2020 Dated: 3 -03-2020

From To

M.B.R. Prasad, M.Pharm, M.Phil, A.I.C. M/s. KBK Biotech Private Limited.

Director, D.No.3-56/2,

O/o. the Director General, Chinnabrahmadevam (V),

Drugs and Copyrights, Marripudi Post,
Drugs Control Administration, Peddapura, (M),

Chuttugunta, Guntur-522 004, East Godavari District – 533 437,

Andhra Pradesh, India.

Andhra Pradesh, India.

Sirs,

Sub:- Drugs and Cosmetics Act, 1940 and Rules made thereunder – Grant of License in

Form-25 - Regarding.

Ref:- Your Application dated: 30-03-2020.

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With reference to your application cited, I forward herewith the Drug Manufacturing License in Form-25 bearing No.20/EG/AP/2020/F/G, granted on 31-03-2020 for manufacture of the following product. The License is valid from 31-03-2020 to 30-03-2025.

## NAME OF THE PRODUCT (UNDER FORM-25)

1. HAND SANITIZER (25 ml, 50 ml, 90 ml, 100 ml, 180 ml, 250 ml, 375 ml, 500 ml, 1 ltrs, 5 ltrs, 20 ltrs, 50 ltrs and 200 ltrs)

Each 100 ml contains:

Ethanol IP 80% v/v
Hydrogen Peroxide IP 0.125% v/v
Glycerol IP 1.45% v/v
Fragrance O.S.

The above product is granted with the following conditions.

- 1. You are further informed that on failure to manufacture any of the drugs approved herewith without a reasonable cause during the licensing period the matter will be reviewed and such drugs are liable for deletion.
- 2. The provisions of Drugs Price Control Order, 2013 shall be complied with.
- 3. You should ensure that the drugs approved herewith shall not make any false/misleading/objectionable claims and should not be an imitation or resemble any other drug in respect of design, colour combination etc., and shall comply with all the provisions relating to the labelling of Drugs.



31/3/2010

L.Dis.No.2011/Stores/2020 Grant of Additional Product to M/s. KBK Biotech Private Limited, D.No.3-56/2, Chinnabrahmadevam (V), Marripudi Post, Peddapura, (M), East Godavari District – 533 437, Andhra Pradesh, India in Form-25 bearing No.20/EG/AP/2020/F/G, dated: 31-03-2020. The License is valid from 31-03-2020 to 30-03-2025.

In case of Narcotics/Psychotropic Drugs, you are also directed to approach TheNarcotic Commissioner of India, 19<sup>th</sup> The Mall Morar, Gwalior-6 so far as the revisions of the NDPS Act and the Rules are concerned in the matter.

You are advised to make clear separation area to avoid contamination with other area of bottling of beverages.

Further you are informed that non-compliance of any the conditions mentioned above the matter will be reviewed and the licenses/permissions issued herewith are liable for Suspension/Cancellation for which you may take this as a notice under Rule 85(2) of the Drugs and Cosmetics Rules. You are therefore requested to plan your production accordingly.

 $\underline{\text{Note:}}$  Drugs Inspector is directed to draw samples of the first batch manufactured by the firm.

DIRECTORATE OF ORDER WING TO STAND OF THE ST

Yours faithfully,

DRUGS CONTROL ADMINISTRATION