

Regd.

From

State Drugs Control-Cum-Licensing Authority,
Food and Drugs Administration, Haryana,
S.C.O. No.94, Sector-5, Panchkula

To

M/s Ebele Cosmeceuticals,
C/o M/s Voda Chemicals Pvt. Ltd.,
Plot No. 171, Sector - 53, Phase - V,
HSIDC, Industrial Estate, Kundli,
District - Sonapat (Haryana)

Memo No. 12/120-1Drug-1-2021/
Dated:

Subject: Grant of loan License on Form No. 25-A for the manufacture for sale or for distribution of drugs other those specified in Schedule C & C (1) and X of Drugs and Cosmetics Rules, 1945.

Reference your letter No. Nil dated 15.07.2021 on the subject cited above.

This license No. **657** -L-OSP(H) on Form No. 25-A for drugs other those specified in Schedule C & C (1) and X of Drugs and Cosmetics Rules, 1945 of the Drugs & Cosmetics Rules, 1945 framed under Drugs & Cosmetics Rules, 1940.

This license has been granted on the following conditions:-

1. That you will manufacture only those drugs which have been permitted to be manufacture under these licenses and no new item will be manufactured without obtaining permission from this office.
2. That the firm will manufacture drugs and maintain all the records as per the Schedule M and U as per "Good Manufacturing Practices" only.
3. That the products of the firms will not resemble with the name, packing, design and color of strips of the products of any other firm/firms in the country.
4. That the firm will test all the raw-material and finished products in its own testing laboratory. Only those tests will got done from the outside approved laboratories which require sophisticated instruments.
5. That firm shall make compliances of directions issued by DCG(I) from time to time. That firm shall conduct BA/BE studies for products falls under category II & IV of BA/BE and stability studies.
6. The products should not resemble in name, pack size and colour of strips and outer labeled, cartoons etc. of the products of other firms & manner of labeling& packing should not be in violation of section 18 read with section 17, 17-B. of Drugs & Cosmetics Act, 1940 read with Rule 94, 96, 104-A, 105, 105-A & 106 of Drugs & Cosmetics Rules 1945, non-compliance of which may warrant a legal action against you & your firm and permission of products given vide this letter shall also be cancelled/ withdrawn.
7. Before release of these products in the market the labels and labeled cartoons shall be got approved by you from Senior Drugs control officer of your zone/area and no banned drug will be manufactured.
8. You will not manufacture any banned drug.
9. That you will apply for Retention of your DML on or before **07/09/2026**

sd
(H. K. Ahooja)

State Drugs Controller-cum-controlling &
Licensing Authority
Food and Drugs Administration, Haryana
Food & Drugs Administration, Haryana

Endst. No. 12/120-1Drug-1-2021/ **10288-89** Dated: **08/09/21**

A copy is forwarded to the following for information and necessary action:-

1. Senior Drugs Control Officer, Sonapat.
2. M/s Voda Chemicals Pvt. Ltd., Plot No. 171, Sector - 53, Phase - V, HSIDC, Industrial Estate, Kundli, District - Sonapat (Host firm).

H. K. Ahooja
(H. K. Ahooja)
State Drugs Controller-cum-controlling &
Licensing Authority
Food and Drugs Administration, Haryana
Food & Drugs Administration, Haryana

FORM 25-A
(See rule 70A)

Loan I [license to manufacture for sale or for distribution of] drugs other than those specified in 2 [Schedules C and C (1) and X]

Number of license 657-L-OSP(H) Date of issue 08/09/21

1. M/s Ebele Cosmeceuticals, C/o M/s Voda Chemicals Pvt. Ltd., is hereby granted a loan license to manufacture the following drugs being drugs other than those specified in 58 [Schedules C, C(1) and X] to the Drugs and Cosmetics Rules, 1945, on the premises situated at Plot No. 171, Sector - 53, Phase - V, HSIIDC, Industrial Estate, Kundli, District - Sonapat (Haryana), under the direction and supervision of the following [competent technical staff]:

2. Name(s) of approved competent technical staff:

Approved Manufacturing Chemist

1. Mr. Shyam Singh S/o Sh. Kesar Singh, B.Sc.

Approved Analytical Chemist

1. Ms. Benna Kumari D/o Sh. Rajesh Kumar, B. Pharmacy

Quality Assurance Person

1. Mr. Sunil S/o Sh. Rampal Saini, B.Sc.

3. Names of drugs. (List Attached)


4. The license authorities the sale by way of wholesale dealing by the license and storage for sale by the license of the drugs manufactured under the license subject to the conditions applicable to licenses for sale.

5. "The License unless sooner suspend or cancelled shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of Drugs & Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach."

6. The license 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.

Note:- The firm shall deposit retention fee on or before 07/09/26

Date 08/09/21


(N. K. Ahooja)
State Drugs Controller-cum-controlling &
Designating Authority
Food & Drugs Administration, Haryana

CONDITIONS OF LICENCE

1. This license and any certificate of retention in force shall be kept on the approved premises under the Drugs and Cosmetics Act, 1940.
2. Any change in the [competent technical staff] 53 named in the license shall be forthwith reported to the Licensing Authority.
3. If the licensee wants to undertake during the currency of the license to the manufacture for of sale additional drugs he should apply to the Licensing Authority for the necessary endorsement to the license as provided in Rule 69-A. This license 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 license. Where any change in the constitution of the firm takes place, the current license 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 license has been taken from the Licensing Authority in the name of the firm with the changed constitution.