Regd.

From

State Licensing Authority,
Directorate of AYUSH Haryana,
Sector-3, Panchkula

To

M/s. Vokin Biotech Private Limited,
Plot No. 219, Sector-57, Phase-4,
Kundli, Distt. Sonepat

Memo No. 45/1350/Drug-1/AY/HR/2019/ 13658
Dated, Panchkula the 15-05-19

Subject:- **Grant of Manufacturing License No. 960-ISM (HR) for manufacturing and sale of Ayurveda/Unani/Siddha Medicines.**

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Reference your application no. **V/D/2** dated **05-04-2019** on the subject noted above.

Your manufacturing License No. **960-ISM (HR)** for manufacturing and sale of Ayurveda and Unani Medicines in **Form 25-D** valid from **14.05.2019 to 13.05.2024** is sent herewith subject to the full filing of following conditions:-

1. That the licensee shall maintain the proper records of manufacturing of drugs and their tests carried out by qualified person for the raw materials and finished products.
2. That the Licensee shall allow an Inspector appointed under the Drugs and Cosmetics Act and Rules to enter in premises where the manufacturing of drugs is carried on, to inspect the premises, to take sample of the raw material as well as the finished products, and to inspect the records maintained under these rules. The License and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an Inspector.
3. That the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.
4. That you should manufacture only those drugs of ISM which have already been approved in favour of your firm and no new item shall be manufactured by you without prior approval of the Licensing Authority.
5. That you have to ensure that your patent/proprietary products do not resemble with the name, packing, design, and colour or strips of the products of any other firm working in the country.
6. Any change in the technical staff named in the license shall be reported forthwith to the Licensing Authority.
7. The licensee shall inform the licensing authority in writing in the event of any change in the constitution of the firm operating under license.
8. That the licensee shall comply with all norms as prescribed in schedule 'T' of G.M.P. (See rule 157 of Drugs and Cosmetics Rules, 1945) and half yearly a compliance report of schedule 'T' shall be submitted to licensing Authority positively.
9. The licensee shall maintain the record of testing of finished drugs and raw materials as prescribed in Ayurvedic Pharmacopoeia . The necessary tests of raw materials and finished drug could be conducted by the firm in house laboratory or it may be got tested from Govt. approved laboratory.

State Licensing Authority
Directorate of AYUSH, Haryana

Endst No. 45/1350/Drug-1/AY/HR/2019/

From

State Licensing Authority
Directorate of AYUSH Haryana,
AYUSH Bhawan, Sector-3, Panchkula.

To

M/s. Vokin Biotech Private Limited,
Plot No. 219, Sector-57, Phase-4,
Kundli, Distt. Sonepat.

Memo No. 45/1350/Drug-1/AY/HR/2019/ 62
Dated, Panchkula, the 9-5-19

Subject:- **Regarding grant of ASU Drug Manufacturing License.**

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With reference to your letter no. **V/D/01** dated **05-04-2019** on the subject noted above.

The following shortcomings are found as per checklist:-

1. Ownership record of building where manufacturing unit is to be established.

You are hereby directed to submit the required documents within 15 days.

State Licensing Authority
Directorate of AYUSH Haryana

13.05.2019

Registered

From

State Licensing Authority
Directorate of AYUSH Haryana,
AYUSH Bhawan, Sector-3, Panchkula.

To

The District Ayurvedic Officer-cum-Drug Inspector,
Sonepat.

Memo No. 45/1350/Drug-1/AY/HR/2019/
Dated, Panchkula, the

Subject:- Regarding inspection of firm to grant ASU drug manufacturing license.

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Kindly refer to the subject cited above.

M/s. Vokin Biotech Private Limited, Plot No. 2019, Sector-57, Phase-4, Kundli, Distt. Sonepat has requested to grant ASU drug manufacturing license.

You are hereby directed to inspect the above said firm as per the norms of GMP/Schedule 'T' under Rule 157 of Drug and Cosmetic Act, 1945 and rules thereunder and the send the inspection report in prescribed format within 15 days. It should be mentioned clearly in the inspection report whether the firm is fully equipped with all facilities to grant new drug manufacturing license and GMP Certificate or not and the said certificates can be given to firm or not.

State Licensing Authority
Directorate of AYUSH Haryana

Endst. No. 45/1350/Drug-1/AY/HR/2019/ 61 Dated 9-5-19

A copy is forwarded to the M/s. Vokin Biotech Private Limited, Plot No. 2019, Sector-57, Phase-4, Kundli, Distt. Sonepat w.r.t. their letter dated 05.04.2019 and is hereby directed to contact with District Ayurvedic Officer-cum-Drug Inspector, Sonepat regarding inspection of firm.

State Licensing Authority
Directorate of AYUSH Haryana

Regd.

From

State Licensing Authority,
Directorate of AYUSH Haryana,
Sector-3, Panchkula

To

M/s. Vokin Biotech Private Limited,
Plot No. 219, Sector-57, Phase-4,
Kundli, Distt. Sonepat

Memo No. 45/1350/Drug-1/AY/HR/2019/ 13660
Dated, Panchkula the 15-05-19

Subject:- **Regarding G.M.P. Certificate.**

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With reference to the subject cited above.

The G.M.P. Certificate in **Form 26 E-I** is enclosed herewith.

Encl:- One Page

State Licensing Authority
Directorate of AYUSH Haryana

Endst.No. 45/1350/Drug-1 /AY/HR/2019/ Dated

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

1. District Ayurvedic Officer/Drug Inspector, Sonepat w.r.t. their office letter no. 13320 dated 13.05.2019.

State Licensing Authority
Directorate of AYUSH Haryana

FORM 26-E-I
(See rule 155-B & 157)

CERTIFICATE OF GOOD MANUFACTURING PRACTICES (GMP) TO MANUFACTURER OF AYURVEDAISIDDHA OR UNANI DRUGS.

Certified that Licensee Namely **M/s. Vokin Biotech Private Limited,** Plot No. 219, Sector-57, Phase-4, Kundli, Distt. Sonepat (Haryana) License No. **960-ISM (HR)** complies with the requirement of Good Manufacturing Practices of Ayurveda/Siddha/Unani Drugs as laid down in Schedule 'T' of the Drugs and Cosmetic Rules, 1945.

This certificate is valid for a period of five years from **14.05.2019 to 13.05.2024** and the Good Manufacturing Practices (GMP) is valid for the various dosage forms as follows:-

1. **Powder**
2. **Tablet**
3. **Capsule**
4. **Syrup**
5. **Oil**
6. **Ointment**

State Licensing Authority
Directorate of AYUSH, Haryana

FORM 25-D
(See Rule 154)

License to manufacture for sale of Ayurvedic (including Siddha) or Unani Drugs.

No. of License 960-ISM (HR)

M/s. Vokin Biotech Private Limited hereby licensed to manufacture the following Ayurvedic including Siddha or Unani Drugs on the premises situated at Plot No. 219, Sector-57, Phase-4, Kundli, Distt. Sonepat (Haryana).

Under the direction and supervision of the following Technical Staff:-

(a) **Technical Staff:-**

1. Dr. Kartar Singh, BAMS (Technical Person)
2. Sh. Jatin Batra, B.Sc. (Quality Control)

(b) **Name of Drugs** (each item to be separately specified)

Forty-Five (45) Classical Ayurvedic Formulations Approved.

The License shall be in force from **14-05-2019** to **13-05-2024**.

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 enforced under the Drugs and Cosmetics Act, 1940.

Date of Issue
14.05.2019

State Licensing Authority
Directorate of AYUSH, Haryana

CONDITIONS OF LICENCE

1. That the licensee shall maintain the proper records of manufacturing of drugs and their tests, carried out by him, or by any other qualified person on his behalf, for the raw materials and finished products.
2. That the Licensee shall allow an Inspector appointed under the Act to enter in premises where the manufacturing of drugs is carried on, to inspect the premises, to take sample of the raw material as well as the finished products, and to inspect the records maintained under these rules. The License 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.
3. That the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.
4. That you should manufacture only those drugs of ISM which have already been approved in favour of your firm and no new item shall be manufactured by you without prior approval of the Licensing Authority.
5. That you have to ensure that your patent/proprietary products do not resemble with the name, packing, design, and colour or strips of the products of any other firm working in the country.
6. Any change in the technical staff named in the license shall be reported forthwith to the Licensing Authority.
7. The licensee shall inform the licensing authority in writing in the event of any change in the