Regd. From

State Licensing Authority (ASU), Directorate of AYUSH Haryana,

Sector-3, Panchkula

To

M/s. Asli Ayurveda Wellness Pvt. Ltd, Nadana Road, Taraori, Distt. Karnal-132001

Memo No. 45/1457/Drug-1/AY/HR/2021/ 4 008 Dated, Panchkula the 05/09/2021

Subject:-

Grant of Manufacturing License No. 1061-ISM (HR) for manufacturing and sale of Ayurveda/Unani/Siddha Medicines.

Reference your letter no. Nil dated 16-12-2020 on the subject noted above.

Your manufacturing License No. 1061-ISM (HR) for manufacturing and sale of Ayurveda and Unani Medicines in Form 25-D valid from 08.01.2021 to 07.01.2026 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

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

6. Any change in the technical staff named in the license shall be reported firm working in the country. 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.

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

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 Dated

Endst.No. 45/1457/Drug-1/AY/HR/2021/

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

1. District Ayurvedic Officer/Drug Inspector, Karnal w.r.t. their letter no. 1219 dated 21.05.2020.

> 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 1061-ISM (HR)

M/s. Asli Ayurveda Wellness Pvt. Ltd hereby licensed to manufacture the following Ayurvedic including Siddha or Unani Drugs on the premises situated at Nadana Road, Taraori, Distt. Karnal-132116 (Haryana).

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

(a) Technical Staff:-

a. Dr. Rajni Sharma, BAMS

(Technical Person)

b. Sh. Mithlesh Kumar Singh, B.Sc.

(Quality Control)

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

Fourty-Six (46) Classical Ayurvedic Formulations Approved (as Attached).

The License shall be in force from 08.01.2021 to 07.01.2026.

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 08.01.2021

CONDITIONS OF LICENCE

- That the licensee shall mwaintain 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.
- That the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed.
- 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.
- 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.
- Any change in the technical staff named in the license shall be reported forthwith to the Licensing Authority.
- The licensee shall inform the licensing authority in writing in the event of any change in the
 constitution of the firm operating under license.
- 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 in-house laboratory or it may be got tested from Govt. approved laboratory.

FORM 26-E-1 (See rule 155-B & 157)

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

Certified that Licensee Namely M/s. Asli Ayurveda Wellness Pvt.

Ltd premises situated at Nadana Road, Taraori, Distt.Karnal-132001

(Haryana) License No. 1061-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 **08.01.2021** to **07.01.2026** and the Good Manufacturing Practices (GMP) is valid for the various dosage forms as follows:-

- a. Powder/Churan
- b. Capsule
- c. Syrup/Panak
- d. Oil/Taila (Medicated/Oil based formulations)
- e. Ointment/Gel/Lotion/Balm/Lepa Malhara

State Licensing Authority
State Licensing Authority
Directorate of AV USA MARKET

Sector-3, Panchkula

Regd. From

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

To

M/s. Asli Ayurveda Wellness Pvt. Ltd, Nadana Road, Taraori, Distt. Karnal-132001

Memo No. 45/1457/Drug-1/AY/HR/2020-21/4012 Dated, Panchkula the 05/02/2021

Subject:-

Regarding G.M.P. Certificate.

Reference your letter no. Nil dated 16-12-2020 on the subject cited above.

The G.M.P. Certificate is enclosed herewith as desired.

Encl:- One Page

State Licensing Authority Directorate of AYUSH Haryana

Endst. No. 45/1457/Drug-1/AY/HR/2020-21/

dated:-

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

1. District Ayurvedic Officer/Drug Inspector, Karnal w.r.t. their letter no. 1219 dated 21-05-2020.

State Licensing Authority Directorate of AYUSH Haryana