Regd.
From

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

To

M/s Tres Manos India Pvt. Ltd,
Khasra No 28/14/1, Village Dukheri
Ambala.

Memo No. 45/1632/Drug-1/AY/HR/2021/ 7074
Dated, Panchkula the 26/02/21

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

****

Reference your application No **254** dated **25-02-2021** 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. 45/1631/Drug-1/AY/HR/2021/ dated:-

A copy is forwarded to the District Ayurvedic Officer/Drug Inspector, Ambala w.r.t. their online inspection report on dated 25.02.2021 for information and necessary action.

State Licensing Authority
Directorate of AYUSH Haryana

Regd.

From

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

To

M/s Tres Manos India Pvt. Ltd,
Khasra No 28/14/1, Village Dukheri
Ambala.

Memo No. 45/1632/Drug-1/AY/HR/2021/ 7072
Dated, Panchkula the 26/02/21

Subject:- **Grant of Manufacturing License No. 1232-ISM (HR) for manufacturing and sale of Ayurveda/Unani/Siddha Medicines.**

****

Reference your application No. **254** dated **25-02-2021** on the subject noted above.

Your manufacturing License No. **1232-ISM (HR)** for manufacturing and sale of Ayurveda and Unani Medicines in **Form 25-D** valid from **26.02.2021 to 25.02.2026** 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 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 (ASU)
Directorate of AYUSH Haryana
Sector-3, Panchkula

State Licensing Authority
Directorate of AYUSH Haryana

Endst.No. 45/1632/Drug-1/AY/HR/2021/ Dated

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

1. District Ayurvedic Officer/Drug Inspector, Ambala w.r.t. their online inspection report on dated 26.02.2021.

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 1232-ISM (HR)

M/s Tres Manos India Pvt. Ltd. hereby licensed to manufacture the following Ayurvedic including Siddha or Unani Drugs on the premises situated at **Khasra No 28/14/1, Village Dukheri, Ambala.**

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

(a) **Technical Staff:-**

a. Dr. Hari Parsad, BAMS (Technical Person)
b. Arvendra, B.Sc (Quality Control)

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

Twenty Two (22) Classical Ayurvedic Formulations Approved (as Attached).

The License shall be in force from **26.02.2021 to 25.02.2026**.

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
26.02.2021

State Licensing Authority (ASU)
Directorate of AYUSH Haryana
Sector-6, Panchkula
State Licensing Authority
Directorate of AYUSH Haryana

CONDITIONS OF LICENCE

1. 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.
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 in-house laboratory or it may be got tested from Govt. approved laboratory.