Government of India
Ministry of Ayush
(Drug Policy Section)

NBCC Office Block-III (2nd Floor),
East Kidwai Nagar South Ex-I,
New Delhi-110023

To,

All ASU Manufacturers/ Industry and ASU Drugs Associations.

Subject: Compliance to Pharmacopoeial Standards of *Guduchi* (*Tinospora cordifolia*) -reg.

Sir/Madam,

Guduchi (*Tinospora cordifolia*) is a popularly known herb, familiar as *Giloy* and is being used in therapeutics since long in AYUSH systems. It has been widely used by Ayush industry stakeholders/ Drugs manufactures as a single drug or as a constituent of various Ayush medicines. Further, use of Guduchi as *Guduchighan vati* and *Guduchi + pippali* has also been recommended for prophylactic care and in the management of asymptomatic & mild Covid-19 positive cases in the **"National Clinical Management Protocol based on Ayurveda and Yoga for management of COVID-19"** released by Government of India.

2. Ministry of Ayush has also released advisories/ notification regarding the safety concerns on use of *Guduchi*. Vide Ministry's advisory **(Copy enclosed),** it was earlier conveyed that *Guduchi* (Tinospora cordifolia) is safe to use but some similar looking plants like Tinospora crispa may be harmful as it is observed that different species of Tinospora are available and using such similar looking species like Tinospora crispa may manifest adverse effects**.**

3. In this regard, attention is drawn to the provisions of Schedule-T of Drugs and Cosmetics Rules, 1945, which stipulates 'Good Manufacturing Practices for Ayurveda, Siddha and Unani medicines. The compliance of provisions of Schedule-T is mandatory for all ASU manufacturers.

4. As per the provisions of Schedule-T, all ASU drug manufactures/ industry stakeholders are requested to ensure strict compliance of the following while using

Guduchi as a single drug or as a constituent of various ASU medicines:-

i. Identification of raw material in accordance with pharmacopoeial standards. Containers used for raw material storage shall be properly identified with the label which indicated name of the raw material, source of supply and will also clearly states the status of raw material. All the raw material shall be sampled and got tested either by the in- house ASU expert or by the laboratory approved by the government and shall be used on approval of the verifying. Procedure of 'First in First out' should be adopted for raw materials wherever necessary. Finished goods transferred from the production area after proper packaging shall be stored in finished goods stores with an area marked Quarantine *(1.1(F)(A) of Schedule-T).*
ii. Manufacturers shall maintain Batch Manufacturing Record of each batch drug manufactured *(1.1(K) of Schedule-T)*.
iii. Markets Complaints record & Grievance redressal -Manufacturers shall maintain a register to record all reports of markets complaints received regarding the products sold in the market. Once in a period of six months, the manufactures shall submit the record of such complaints to the licensing authority. Report of any adverse reaction resulting from the use of ASU drug shall also be maintained separately by each manufacturer and investigate to find if adverse reaction is due to any defect in the product or it is of any new observation. *(1.1(M) of Schedule-T)*.
iv. Manufacturers shall ensure the quality control in accordance with pharmacopoeial standards. The experts of quality control section shall verify all the raw materials, monitor in process quality checks and control the quality of finished products being released to finished goods store/ ware house *(1.1(N) of Schedule-T)*.
v. Manufacturers may also consider to disseminate the scientific merits, Quality assurances etc. of their product among general public.

5. In view of above, all ASU drug manufactures/ industry stakeholders are requested to ensure strict compliance to the pharmacopoeial standards of ***Guduchi*** **(*Tinospora cordifolia*)** for manufacturing its single or compound formulations.

This has the approval of the Competent Authority.

Encl. – As above.

Signed by Dr. Chinta Srinivas Rao
Date: 24-02-2022 15:32:37
Reason: Approved

(Dr S.R.Chinta)
Deputy Adviser

Copy for information to all SLA.