

**Government of India  
Ministry of Ayush  
(Drug Policy Section)**

**NBCC Office Block-III (2<sup>nd</sup> 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.

(Dr S.R.Chinta)  
Deputy Adviser

Copy for information to all SLA.

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**ADVISORY**

**Subject: Use of *Guduchi* - Reg.**

Ministry of Ayush has recently noticed safety concerns on use of *Guduchi* (*Tinospora cordifolia*) that were published in social media and in some scientific journals.

This advisory is being issued to confirm that *Guduchi* (*Tinospora cordifolia*) is safe to use but some similar looking plants like *Tinospora crispa* may be harmful. *Guduchi* is a popularly known herb, familiar as *Giloy* and is being used in therapeutics since long in AYUSH systems.

There are good number of studies published in peer reviewed indexed Journals to substantiate safety and efficacy of *Guduchi* (*Tinospora cordifolia*). Its hepato-protective properties are also well established. *Guduchi* is known for its immense therapeutic applications and the practices are regulated in accordance with various applicable provisions.

It is observed that different species of *Tinospora* are available and only *Tinospora cordifolia* should be used in therapeutics, whereas similar looking species like *Tinospora crispa* may manifest adverse effects.

Below is the information about these plant species

<b>Plant part</b>	<b><i>Tinospora cordifolia</i></b>	<b><i>Tinospora crispa</i></b>
Stem	<ul style="list-style-type: none"><li>• Green in colour</li><li>• Not having small rounded projections</li><li>• No milky secretion</li></ul>	<ul style="list-style-type: none"><li>• Greenish grey in colour</li><li>• Having small rounded projections</li><li>• milky secretion</li></ul>
Leaves	<ul style="list-style-type: none"><li>• heart shaped with groovy notch at the base</li></ul>	<ul style="list-style-type: none"><li>• heart shaped with no groovy notch at the base</li></ul>

Petals	<ul style="list-style-type: none"> <li>• Six in number</li> </ul>	<ul style="list-style-type: none"> <li>• Three in number</li> </ul>
Drupes (Bunch of fruit)	<ul style="list-style-type: none"> <li>• Spherical or ball shaped</li> <li>• red in colour</li> </ul>	<ul style="list-style-type: none"> <li>• Ellipsoid or rugby ball like shaped</li> <li>• Orange in colour</li> </ul>
Photograph of the plant		

Thus, it is reiterated that *Guduchi* is a safe and effective Ayurveda medicine, however it is advisable to use it in consultation with a qualified, registered Ayush physician.

Ministry of Ayush has a well-established system of Pharmacovigilance (for reporting of suspected adverse drug reactions from Ayush medication), with its network spreading across all over India. If any suspected adverse event occurs after intake of Ayush medicine it may be reported to the nearby Pharmacovigilance centre through an Ayush physician. Further it is advised to take Ayush medicine and treatment under supervision and consultation of a registered Ayush physician only.