

L-11011/9/2021-DCC
Government of India
Ministry of AYUSH
(Drug Policy Section)

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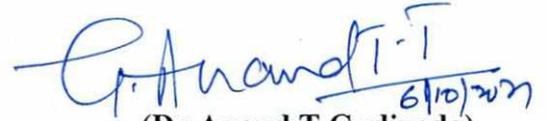
ADVISORY

Subject- Advisory for refrain from use of *Aswagandha (Withania somnifera)* leaves.

It has come to the notice of Ministry of AYUSH, that *Ashwagandha* leaves is being used by some manufacturers in their formulations. In this connection following are the view of this Ministry-

- *Withania somnifera (Aswagandha)* root is widely used drug in Ayurveda, Siddha and Unani (ASU) systems of medicine since ancient period.
- Ayurveda, Unani and Siddha systems refer the drug as *Aswagandha*, *Asgandh* and *Amukkura* respectively.
- Ayurvedic Pharmacopoeia of India defines that the *Aswagandha* consists of dried mature roots of *Withania somnifera* Dunal (API, Part I, Vol.I).
- All these systems use roots of the *Withania somnifera* as useful part in different single and compound classical formulations.
- As such, the use of leaves of *Withania somnifera* has not been reported in classical texts of ASU systems of medicine.
- However, some of the OTC formulations of *Withania somnifera* leaves are available in markets but neither their safety and efficacy is vividly studied nor reported in ASU classical texts.
- No substantial evidence and literature is available to endorse the efficacy of crude drug/ extract of *Withania somnifera* leaves.
- Considering this, it would not be appropriate to consider the *Withania somnifera* leaves as ASU medicine at this stage.
- Extensive studies are required to establish the safety and efficacy of leaves of *Withania somnifera* for different indications. Till then, the usage of leaves may not be considered for therapeutic purpose in ASU systems.

Considering the above and in the background of available textual/literature evidences, it is advised that the manufacturers of the crude drug/extracts, sellers, ASU drug manufacturing companies, ASU drug exporters not to use *Withania somnifera* leaves either in crude or extract or any other form for therapeutic purposes under the ambit of ASU drugs as per textual indications or as a food supplements in the name of ASU drugs.


(Dr Anand T Gudivada)
Adviser (Ay),

To,
All ASU Drugs Manufacturers Associations

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