

T-13020/4/2022-DCC-Part(2)

Government of India

Ministry of Ayush

(Drug Policy Section)

NBCC Office Block-III(2nd Floor)

East Kidwai Nagar, New Delhi

Date: 15th April, 2026

To,

All Ayush Drugs Manufacturers/ Associations.

Subject: Mandatory use of Ashwagandha (*Withania somnifera*) roots in Ayush products -reg.

Sir/Ma'am,

Ministry of Ayush vide letter no. L.11011/9/2021-DCC dated 06.10.2021 **(Copy enclosed)** had advised Ayush Drug Manufacturers, Exporters, Sellers not to use Ashwagandha leaves either in crude or extract or any other form in Ayush drugs/ products.

2. It has been brought to the notice of Ministry of Ayush that certain Ayush manufacturers are still using Ashwagandha leaves in their products. In this regard, it is pertinent to mention that –

- i. *Ashwagandha* (*Withania somnifera*) root is widely used herb in Ayush systems.
- ii. In the year 2024, Ministry through a multidisciplinary expert committee published updated Ashwagandha safety dossier and its report, which categorically recommended that Ashwagandha roots should be used for health benefits. (Available at https://ayush.gov.in/#!/quality_standard)
- iii. Available scientific studies reported possible safety concerns for Ashwagandha leaves due to higher concentrations of reactive withanolides, particularly Withaferin-A. (Details at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787217>, <https://pubmed.ncbi.nlm.nih.gov/22973447/>)

3. Keeping in view, all Ayush drug/ product manufacturers, exporters, sellers are hereby directed to:

- i. Use only Ashwagandha roots in crude or extract or any other form in single or as an ingredient in compound Ayush drugs/products.
- ii. The use of Ashwagandha leaves, in crude, extract, or any other form, in

Ayush drugs/products is strictly prohibited.

- iii. Ensure compliance with the provisions of Rule 161 of the Drugs Rules, 1945, which require that the plant parts used in the drugs/products be clearly mentioned on the label.
4. This issues with the approval of Competent Authority.

Yours faithfully,

Encl: As above.

(Shiela Tirkey)

Under Secretary to Government of India

Copy to:

1. All State/UT's Ayush Drug Licensing Authorities for information and further necessary action.
2. CEO, FSSAI, for information and further necessary action.