Writeups

AYUSH ADVISORY ON ASHWAGANDHA

WriteUps By Amritpal Singh

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The Drug Policy Section of Ministry of AYUSH has recently issued an advisory on parts of ashwagandha utilized in preparation of Ayurvedic formulations. The advisory (L-11011/9/2021-DCC) with the subject “Advisory for refrain from use of Aswagandha (*Withania somnjfera*) leaves has been released in July 2021. In Ayurveda, the dried roots are used in preparation of Ayurvedic formulations. The roots are available with herbal vendors and pharmacies at fluctuating rates. The recent advisory has objected to the use of leaves of Aswagandha in certain formulations manufactured and marketed in India.

Ashwagandha use is described primarily for its root in national pharmacopeias, such as the United States Pharmacopeia (USP),3 the British Pharmacopoeia, the Indian Pharmacopoeia, the Ayurvedic Pharmacopoeia, and reference works like the World Health Organization monograph.

Ayurvedic Pharmacopoeia of India defines that Aswagandha consists of dried mature roots of Withania *somnjfera* Dunal (API, Part I, Vol.1). All these systems use roots of the Withania *somnjfera* 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 somnfera* leaves are available in markets but neither their safety nor 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 somnfera* leaves.

As per advisory, extensive studies are required to establish the safety and efficacy of leaves of Withania *somnjfera* 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 *somnjfera* 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.

Ashwagandha churna, Ashwagandhadi churna, Ashwagandharishta are some of common Ayurvedic formulations present in the market at domestic and global level. Several proprietary medicines based on ashwagandha are part of doctor’s preion. Commercial extract of ashwagandha is also marketed by several companies for applied research.

Alkaloids and withanolides, two biologically active phytoconstituents besides minor are present in different parts of ashwagahdha. The alkaloidal content of the root varies between 0.13-0.31 percent. Alkaloids are present in the roots but withanolides have been reported from leaves and roots. Procedure for estimation of alkaloidal content has been developed. Similarly, Procedure for estimation of withanolide content has been developed. In

fact, the pharmacological activities of the roots have been ascribed to alkaloids.

Documentary standards on ashwagandha have been published by the American Herbal Pharmacopoeia, *Ayurvedic Pharmacopoeia of India*, *Siddha Pharmacopoeia of India*, *Unani Pharmacopoeia of India*, the World Health Organization (WHO) Monographs, as well as in the *British Pharmacopoeia*,16 *Indian Pharmacopoeia*,17 and *United States Pharmacopeia*.

These standards cover microscopic, macroscopic, high-performance thin-layer chromatography (HPTLC), and high-performance liquid chromatography (HPLC) methods for identification of ashwagandha roots and quantification of withanolides. Parts of *Withania somnifera* other than roots (e.g., stems, leaves) which have been used as adulterants, can be identified when present in crude powdered form using microscopic analysis

After the advisory was published on the official website of Ministry of AYUSH, the stakeholders and drug manufacturers sent several applications for allowing use of the leaves in finished formulations. Ministry of AYUSH has constituted a committee to look into the matter. However, the decision to be taken by the committee is awaited. Thus the advisory related to ashwagahdha is significant not only for drug manufacturers and clinical practice but for international business.

Drug standardization has swept the entire Ayurvedic drug industry and ashwagandha was one the herbal plant subjected to standardization and lot of literature has been published in this regard. Extracts standardized to alkaloids and withanolides are available in the market.

Much of the *W. somnifera* in the current market is being supplied to herbal products and dietary supplement manufacturers in the form of a dry extract. In most cases, the extract yield is approximately 10 times lower than the initial weight of raw material; i.e., 1 kg of dried root yields 100 g of *W. somnifera* root extract. The extract typically contains steroidal lactones called withanolides in concentrations between 1.5-5.0% (w/w) in the extract.

The therapeutic potential of ashwagandha is restricted if roots in finished formulations. The bark and berries contain a high proportion of free amino acids and tender shoots are rich in calcium and phosphorus and proteins.

Based on phytochemical profile and diversity of secondary metabolites, ashwagandha is significant from pharmaceutical and nutraceutical aspects. In fact, ashwagandha is a constant ingredient of nutraceutical and functional foods approved by FSSAI. FSSAI has recommended 3-6 G doe of the root powder and 0.5-1 g for the extract.

AYUSH formulations, food products (nutraceutical and functional foods), herbal extract and use by traditional healers, there are several forms of ashwagandha market. Ashwagandha in combination with shilajit is one of the best selling Ayurvedic OTC products.

Altoght the use of the lavesa is nor mentioned in Nighantu, Samhita and Ayurvedic Pharmacopoeia of India but keeping in the therapeutic potential of ashwagandha there is no harm in including the leaves as official part once efficacy and non-toxicity is established since potential withanolides are reported in the leaves as compared to other parts. This step may be taken as an initiative to revise the monograph of ashwagandha.

The root and total alkaloids present in the roots have diverse pharmacological actions. Ashwagandha is commercially addressed as “Indian Ginseng’ and ginsenosides are allied to withanolides. Ginseng on prolonged use is associated with ‘Ginseng abuse syndrome’. No such effect has been reported for ashwagandha.

Ashwagandha has been selected by The Central Council of Research in Ayurvedic Sciences (CCRAS) for conduction of a medically supervised clinical research study entitled ‘A clinical trial of Ashwagandha administration in participants vaccinated against COVID-19’. Tablet based on ashwagandha has been selected for the medically supervised clinical research study.

The ministry of AYUSH has also collaborated with United Kingdom’s London School of Hygiene and Tropical Medicine to conduct a study on Ashwagandha for promoting recovery from Covid-19. Ashwagandha was reported as a safer option to hydroxychloroquine in the chemoprophylaxis of COVID-19 but all based on results of interim analysis.

The Central Council for Research in Ayurveda and Siddha (CCRAS) under the Department of AYUSH has developed 'Quality of Life' (QOL), an herbal compound, aimed at supplementing cancer and AIDS treatment regimes with ashwagandha as one of the ingredient.

AYUSH and FSSAI must explore of including parts other than roots in official pharmacopoeias. Distribution of nutrients like free amino acids, proteins and minerals make ashwagandha a suitable target for developing novel formulations under ‘AYUSH foods’. Withaferin-A is proving a sound anticancer agents in animal studies expanding the therapeutic range for ashwagandga. Efficacy and toxicity studies should be undertaken for formulations extracts derived from parts under than roots. Time is ripe enough to market ashwagandha against ginseng and expanded therapeutics offers a good chance.

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