

BUREAU OF INDIAN STANDARDS**DRAFT FOR COMMENTS ONLY***(Not to be reproduced without permission of BIS or used as Standard)***भारतीय मानक मसौदा****होम्योपैथिक औषधियों में प्रयोग हेतु WITHANIA SOMNIFERA (L) DUNAL.****मदर टिचर - विशिष्टि****Draft Indian Standard****WITHANIA SOMNIFERA (L) DUNAL. MOTHER TINCTURE FOR USE IN
HOMEOPATHIC MEDICINE – SPECIFICATION**

Homoeopathy Sectional Committee, AYD 07

Last Date of Comments: 05-05-2024**FOREWORD**

Withania somnifera is an erect, evergreen, undershrub, stellate tomentose branched, 60-160 cm tall, of family Solanaceae. Roots stout, long, tuberous, fleshy and whitish-brown; leaves alternate, petioled, obtuse, ovate-oblong, and sometimes oblique at the base, 5–10 × 2.5-7 cm; inflorescence umbelliform cyme, flowers sub-sessile, greenish-lurid yellow, corolla campanulate, yellowish green, very small, covered by membranous closely-fitting calyx; fruit a berry, smooth, 0.6-0.8 cm, orange-red, globose; seeds numerous, yellowish-white, reniform, laterally compressed, 2-2.5 mm in diameter. It is native to India, found throughout the drier parts of subtropical region and upper Gangetic plains. It can be cultivated up to an altitude of 1000 m above msl. Plants grow well in red, sandy, black and loamy soil having pH 6.5 to 8.0 with good water drainage. Temperature between 20°C to 35°C is most suitable for its cultivation.

Withania somnifera is having synonyms/ common names as Winter cherry and sometimes called Indian Ginseng in reference to its rejuvenative and tonic effect on nervous system. Some of the regional names are *Punir*, *Asgandha*, *Asgandh*, *Rasbhari* (Hindi), *Ashvagandha*, *Handhpatri*, *Vajini* (Sanskrit), *Amukkuram*, *Pevette* (Malyalam), *Amkulang-kalang*, *Amukkara*, *Amukkilaachedi*, *Karappaan-thazhai* (Tamil), *Asvagandhi*, *Penerr*, *Penerru-hadda*, *Vajigandha* (Telgu), *Asandh*, *Askulong* (Marathi), *Asandha*, *Ghoda Aakun* (Gujarati), *Asvagandha* (Bengali), *Ashvagandhi* (Kannada).

The standard is one of the series of standards being brought out on ingredients used in formulations of Homeopathic medicine for the advantage of researchers, academicians, students, clinical practitioners and drug manufacturers.

In the formulation of this standard, significant assistance has been derived from Homeopathic Pharmacopoeia of India, Vol. X, 2013, Ayurvedic Pharmacopoeia of India Volume 1 Part 1 e-book. Inputs have also been derived from the information available in the public domain in print and electronic media including authoritative books.

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In formulating this standard, due consideration has been given to the provisions of the Drugs and Cosmetics Act 1940 and the Rules framed thereunder. However, this standard is subject to the restrictions imposed under these Rules and Regulations, wherever applicable.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2:2022 'Rules for rounding off numerical values (second revision).' The number of significant places retained in the rounded-off value shall be the same as that of the specified value in this standard.

BUREAU OF INDIAN STANDARDS**DRAFT FOR COMMENTS ONLY***(Not to be reproduced without permission of BIS or used as Standard)**Draft Indian Standard***WITHANIA SOMNIFERA (L.) DUNAL. MOTHER TINCTURE FOR USE IN
HOMEOPATHIC MEDICINE – SPECIFICATION****1 SCOPE**

This standard prescribes the methods of preparation and general specifications of *Withania somnifera* Mother Tincture (ϕ) for use in the Homeopathic system of medicine.

2 REFERENCES

The standards listed below contain provisions which, through reference in this text, constitute the provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards.

<i>IS No.</i>	<i>Title</i>
IS 1070: 1992	Reagent grade water — Specification (third revision)
IS 13145 : 2014	Spices and condiments — Methods of sampling (second revision)
IS 18098 : 2022	Ashvagandha [<i>Withania somnifera</i> (L.) Dunal.] Root for use in Traditional Medicine — Specifications

3 REQUIREMENTS**3.1 Withania somnifera root****3.1.1 Description**

Macroscopic, Microscopic, and Powder specifications of *Withania somnifera* root shall comply with the provisions as prescribed in IS 18098.

3.1.2 General Specifications

Withania somnifera root shall be free from extraneous/foreign matter and shall comply with the physical, chemical, and microbiological specifications as prescribed in IS 18098.

3.2 Withania Somnifera Mother Tincture (ϕ)**3.2.1 Method of preparation** (to prepare one thousand millilitres of Mother Tincture)

a) Drug strength	1/10
b) <i>Withania Somnifera</i> in coarse powder	100 g
c) Purified Water	250 mL
d) Strong Alcohol (95%)	800 mL

3.2.2 General Specifications of Mother Tincture (Finished product)

a) Appearance:	Dark brown liquid
b) Alcohol content:	72.0 - 76.0 percent v/v

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c) Wt. per mL:	Not less than 0.87 gm.
d) Total solids:	Not less than 1.2 percent w/v
e) pH at 25:	5.7 to 6.6
f) UV absorbance λ max:	205 & 274 nm

4 PACKING, MARKING AND STORAGE**4.1 Packing**

4.1.1 *Mother tincture* shall be packed in an amber-colored glass bottle (Type III) that prevents contamination, effects of light, and humidity, with a seal or security seal that guarantees the inviolability of the product. The packing material shall be free from any fungal or insect infestation and not impart any foreign smell. Each container shall be securely closed and sealed.

4.2 Marking

4.2.1 The following particulars shall be legibly and indelibly marked or labeled on each pack *Withania* mother tincture:

- Name and address of the manufacturer or packer including contact details;
- Name of the mother tincture;
- Net quantity;
- Date of Manufacturing;
- Date of packing (MM/YYYY);
- Best before date (MM/YYYY);
- Batch or code number;
- QR Code for Authentication (Optional); and
- Any other markings required under the *Legal Metrology (Packaged Commodities) Rules, 2011, and the Food Safety and Standards (Packaging and Labelling) Regulation, 2011* or its latest version as applicable.

4.3 Storage

4.3.1 *Mother tincture* shall be stored in an amber glass bottle (Type III) or SS316 that prevents contamination and effects of light and humidity, with a seal or security seal that guarantees the inviolability of the product.

4.4 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016, and the Rules and Regulations framed there under, and the product(s) may be marked with the Standard Mark.

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5 SAMPLING

5.1 Representative material samples shall be drawn and tested for conformity to this specification as prescribed in IS 13145.

5.2 The samples of *Withania* mother tincture shall be tested to ascertain the material's conformity to the requirements as per the specifications for finished product of clause 3.2.2.

6 QUALITY OF REAGENTS

6.1 Reagents, including pure chemicals used, shall be of analytical grade.

6.2 Reagent grade water for laboratory use shall be as per IS 1070.