

होम्योपैथी में उपयोग हेतु विथानिया
सोम्नीफेरा हाइड्रो-अल्कोहलिक
अर्क — विशिष्टि

***Withania somnifera* Hydro-alcoholic
Extract for Use in Homoeopathy —
Specification**

ICS 11.120.10

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भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDARDS

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Price Group 4

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards after the draft finalized by the Homoeopathy Sectional Committee had been approved by the Ayush Division Council.

Withania somnifera hydro-alcoholic extract is prepared from the plant *Ashwagandha* or *Withania somnifera*. In homoeopathy, this is synonymous with mother tincture (Ø) and is used as a starting material for homoeopathic dilutions or potencies. It is also used for the preparation of other dosage forms.

Withania somnifera is an erect, evergreen undershrub of the family Solanaceae. It is native to India and is found throughout the drier parts of the subtropical region and upper Gangetic plains. Commonly, it is known as Winter cherry or Indian Ginseng in reference to its rejuvenating and tonic effect on the nervous system. Some of the regional names are *Ashvagandha* (Hindi), *Vajini* (Sanskrit), *Amukkuram* (Malyalam), *Amkulang-kalang*, (Tamil), *Asvagandhi*, (Telgu), *Askulong* (Marathi), *GhodaAakun* (Gujarati), *Asvagandha* (Bengali), *Ashvagandhi* (Kannada). The specifications for the requirements and methods of testing for dried mature roots of *Withania somnifera* are prescribed in IS 18098.

The standard is one of the series of standards being brought out on specifications of homoeopathic Hydro-alcoholic extract for the use of researchers, academicians, students, clinical practitioners and drug manufacturers.

In the formulation of this standard, significant assistance has been derived from Homoeopathic Pharmacopoeia of India, Vol. X, 2013 and Ayurvedic Pharmacopoeia of India Volume 1 Part 1 published by the Ministry of Ayush, Government of India. Inputs have also been derived from the information available in the public domain in print and electronic media, including authoritative books.

Also, due consideration has been given to the provisions of the *Drug and Cosmetics Act*, 1940 and the Rules 1945, framed thereunder, including the latest amendments. In case of any disparity, this standard is subject to the restrictions imposed under these Rules and Regulations, wherever applicable.

The composition of the Committee responsible for the formulation of this standard is given in [Annex A](#).

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 or analysis, 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 should be the same as that of the specified value in this standard.

Indian Standard

***Withania somnifera* HYDRO-ALCOHOLIC EXTRACT
FOR USE IN HOMOEOPATHY — SPECIFICATION**

1 SCOPE

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of *Withania somnifera* prepared from the dried mature roots of *Withania somnifera* (L.) (Family-Solanaceae).

2 REFERENCES

The standards given 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 : 2023	Reagent grade water — Specification (fourth revision)
IS 2303 (Part 1)	Grading glass for alkalinity: Hydrolytic resistance of glass grains,
(Sec 1) : 2021/ ISO 719 : 2020	Determination and classification of hydrolytic resistance at 98 °C (third revision)
(Sec 2) : 2021/ ISO 720 : 2020	Determination and classification of hydrolytic resistance at 121 °C (third revision)
IS 6911 : 2017	Stainless steel plate, sheet and strip — Specifications (second revision)
IS 18098 : 2022	Ashvagandha [<i>Withania somnifera</i> (L.) Dunal.] Root for use in traditional medicine — Specifications
IS 18977 : 2024	Millefolium (<i>Achillea Millefolium</i> L.) Hydro-alcoholic extract for use in homoeopathy — Specification

3 REQUIREMENTS**3.1 Ashvagandha [*Withania somnifera* (L.) Dunal.] 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 3.2.2 of IS 18098.

3.2 Preparation of *Withania somnifera* Hydro-alcoholic Extract

3.2.1 To prepare one thousand milliliters of hydro-alcoholic extract with strength 1/10:

- | | |
|--|----------|
| a) <i>Withania Somnifera</i> in coarse powder | : 100 g |
| b) Purified water | : 250 ml |
| c) Strong alcohol (94.7 percent v/v to 95.2 percent v/v) | : 800 ml |

3.2.2 General Specifications of Hydro-alcoholic Extract (Finished Product)

- | | |
|-------------------------------|---------------------------------|
| a) <i>Appearance</i> | — Dark brown liquid |
| b) <i>Alcohol content</i> | — 72 percent to 76 percent v/v |
| c) <i>Wt. per ml</i> | — Not less than 0.87 g |
| d) <i>Total solids</i> | — Not less than 1.2 percent w/v |
| e) <i>UV absorbance λ max</i> | — 205 nm and 274 nm |

NOTE — Quality of reagent

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

To access Indian Standards click on the link below:

https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/knowyourstandards/Indian_standards/isdetails/

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

3 Pure chemicals shall mean chemicals that do not contain impurities that affect the analysis results.

4 PACKING, STORAGE AND MARKING

4.1 Packing

Withania somnifera hydro-alcoholic extract shall be packed in an amber-coloured bottle of hydrolytic resistance grain class HGA 2 (IS 2303/ ISO 720) or HGB 3 (IS 2303/ ISO 719) or better that prevents contamination, effects of light and humidity, with a 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 Storage

Withania somnifera hydro-alcoholic extract shall be stored in an amber-coloured bottle of hydrolytic resistance grain class HGA 2 or HGB 3 or in a stainless-steel container of SS316 type (IS 6911) that prevents contamination and effects of light and humidity, with a seal that guarantees the inviolability of the product.

4.3 Marking

4.3.1 The following particulars shall be legibly and indelibly marked or labeled on each pack of *Withania somnifera* hydro-alcoholic extract:

- a) Name of the hydro-alcoholic extract/mother tincture;

- b) Name and address of the manufacturer or packer, including contact details;
- c) Manufacturer's license no.;
- d) Batch number;
- e) Net quantity when packed;
- f) Date of manufacturing;
- g) Date of packing (MM/YYYY);
- h) Date of expiry (MM/YYYY);
- j) QR code for authentication (optional); and
- k) Any other information requested by the buyer.

5 SAMPLING

5.1 Representative material samples shall be drawn as prescribed in 5.1 of IS 18977.

5.2 The samples of *Withania somnifera* hydro-alcoholic extract shall be tested to ascertain the material's conformity to the requirements as per the specifications for the finished product of [3.2.2](#).

6 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.

ANNEX A

(Foreword)

COMMITTEE COMPOSITION

Homoeopathy Sectional Committee, AYD 07

<i>Organization</i>	<i>Representative(s)</i>
Govt of NCT, Directorate of Ayush, New Delhi	DR RAJ K. MANCHANDA (<i>Chairperson</i>)
Anchrom Enterprises Private Limited, Mumbai	SHRI AKSHAY CHAREGAONKAR SHRI VISHWAJIT PRAKASH KALE (<i>Alternate</i>)
ARP Industries, Meerut	SHRI RAVEENDRANATH ACHARYA
Bakson Drugs and Pharmaceuticals Private Limited, Greater Noida	DR MUDITA ARORA
Bhargava Phytolab Private Limited, Noida	SHRI RAJESHWAR SAHAI BHARGAVA SHRI KARAN BHARGAVA (<i>Alternate I</i>) MS NEHA VASHISHTHA (<i>Alternate II</i>)
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Central Council for Research in Homoeopathy, New Delhi	DR DIVYA TANEJA DR MANAS SARANGI (<i>Alternate</i>)
Central Drugs Standard Control Organization, New Delhi	SHRI SUSHANT SHARMA DR RACHNA PALIWAL (<i>Alternate</i>)
Centre of Medicinal Plants Research in Homoeopathy, The Nilgiris	DR J. SHASHIKANTH SHRIMATI ANAGH D. (<i>Alternate</i>)
Delhi Institute of Pharmaceutical Sciences and Research, New Delhi	PROF P. K. SAHOO DR BEAUTY BEHERA (<i>Alternate</i>)
Directorate of AYUSH (Homoeopathic Wing), Govt of NCT, New Delhi	DR LEENA V. CHHATRE
Dr Anjali Chatterjee Regional Research Institute for Homoeopathy, Kolkata	DR BIBASWAN BISWAS DR SURAIYA PARVEEN (<i>Alternate I</i>) SHRI G. V. NARASIMHA KUMAR (<i>Alternate II</i>)
Dr BR Sur Homoeopathic Medical College, Hospital and Research Centre, New Delhi	DR NEERAJ GUPTA DR AMAR BODHI (<i>Alternate</i>)
Dr DP Rastogi Central Research Institute for Homoeopathy, Noida	DR SWAPNIL A. KAMBLE DR BINIT DWIVEDI (<i>Alternate I</i>) DR ANAMIKA KOTIYA (<i>Alternate II</i>)
Dr Willmar Schwabe India Private Limited, Noida	SHRI SUNIL VISHWAKARMA DR R. VALAVAN (<i>Alternate I</i>) DR POORVA TIWARI (<i>Alternate II</i>)

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