**IS XXXXX : 2024**

***भारतीय मानक***

***Indian Standard***

**होम्योपैथी में प्रयोग हेतु अल्फाल्फा हाइड्रो-अल्कोहलिक अर्क** — **विशिष्टि**

**Alfalfa** **[*Medicago sativa* L] 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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**December 2024 Price Group 9**

Homoeopathy Sectional Committee, AYD 07

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.

Alfalfa is a perennial herb of Fabaceae Family, native to the Mediterranean, Central, and West Asia and is grown and cultivated throughout India. Alfalfa is known by its common names such as *Vilayti-gawuth, Lasunghas* (Hindi), *Vilayati-gavat* (Marathi), *Vilayti-ghas* (Gujarati), *Lusan* (Punjabi), *Vilayati – hullu* (Kannada).

The detailed specifications for the whole plant of Alfalfa are prescribed in IS 18978.

Alfalfa hydro-alcoholic extract or mother tincture (Ø) is prepared from *Medicago sativa* L whole plant excluding roots. In homoeopathy, it is used as a starting material for homoeopathic dilutions or potencies. It is also used for the preparation of other dosage forms.

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

In formulating this standard, significant assistance has been derived from Homoeopathic Pharmacopoeia of India, Vol. II, 1974, Vol. X, 2013, 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 other Pharmacopoeias and authoritative books.

In the formulation of this standard, due consideration has been given to the provisions of the Drugs and Cosmetics Act of 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*

ALFALFA [*Medicago sativa* L] HYDRO-ALCOHOLIC EXTRACT FOR USE IN HOMOEOPATHY — SPECIFICATION

**1 SCOPE**

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of Alfalfa, prepared from the whole plant excluding roots of *Medicago sativa* L (Family-Fabaceae).

**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.

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| --- | --- |
| *IS No.* | *Title* |
| IS 1070 : 2023 | Reagent grade water Specification (*fourth revision*) |
| IS 6911 : 2017 | Stainless steel plate, sheet, and strip ― specifications (*second revision*) |
| IS 18978 : 2024 | Alfalfa [*Medicago sativa* L] for use in traditional medicine — Specification |
| IS 18977 : 2024 | Millefolium (*Achillea millefolium* L.) hydro-alcoholic extract for use in homoeopathy — Specification |
| IS 19085 : 2024 | Glass Containers for Homoeopathic Pharmaceutical Preparations — Specification |

**3 REQUIREMENTS**

**3.1 Alfalfa whole plant excluding roots**

**3.1.1** *Description*

*Macroscopic, microscopic,* and *powder* specifications of *Alfalfa* [*Medicago sativa* L] whole plant excluding roots shall comply with the provisions as prescribed in **3.1** of IS 18978.

**3.1.2** *General Specifications*

*Alfalfa* [*Medicago sativa* L] whole plant, excluding roots, 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 18978.

**3.2 Preparation of Alfalfa Hydro-alcoholic Extract**

**3.2.1** *To prepare one thousand milliliters with strength* 1/10

1. Alfalfa, in coarse moist magma containing solids 100g and moisture appx. 233 ml 333 g
2. Purified water 117 ml
3. Strong alcohol (94.7 to 95.2 percent v/v) 680 ml

**3.2.2** *General Specifications (Finished product)*

1. Appearance  Greenish brown hydro-alcoholic liquid
2. Alcohol content 64.0 to 68.0 percent v/v
3. Wt. per ml 0.870 g to 0.910 g
4. Total solids Not less than 1.10 percent w/v
5. TLC Should comply as prescribed in Table 1 (Sl. No. vii) of IS 18978.
6. UV absorbance λ max270 nm and 320 nm
   * 1. *Identification*

**3.2.3.1** *Shinoda test*

Take 2 ml of the hydro-alcoholic extract. Heat the hydro-alcoholic extract in a water bath to remove the solvent. Then, add 2 ml of strong alcohol to the residue. Transfer the ethanolic solution to a test tube.  Add a piece of shining magnesium ribbon. Then, add 2 ml of concentrated hydrochloric acid to this solution. Note the colour change of the aforesaid solution. The formation of orange pink coloration of the solution indicates the presence of flavonoids.

**3.2.3.2** *Foam test*

Take 2 ml to 5 ml of hydro-alcoholic extract in the test tube, add 10 ml of water and shake, and observe for the formation of froth, which is stable for about 15 minutes. A positive test indicates saponins.

**3.2.3.3** *Ninhydrin test*

Add few drops of ninhydrin reagent to the TLC plate. Then dry it. Add few drops of hydro-alcoholic extract to the same place where ninhydrin reagent was added. Heat the TLC plate in an oven at 105 oC for five minutes. Note the colour change of the plate. Pink-violet colour formation indicates the presence of amino acids.

NOTE — Quality of reagents

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

**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 SAMPLING**

**4.1** Representative material samples shall be drawn and tested for conformity to this specification as prescribed in Annex B of IS 18977.

**4.2** The samples of *Alfalfa* hydro-alcoholic extract shall be tested to ascertain the material's conformity to the requirements as per the specifications for the finished product in **3.2.2** and **3.2.3**.

**5 PACKING, STORAGE AND MARKING**

**5.1 Packing**

*Alfalfa* hydro-alcoholic extract shall be packed in an amber coloured bottle of type 3 glass or better [IS 19085] 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.

**5.2 Storage**

*Alfalfa* hydro-alcoholic extract shall be stored in an amber-coloured bottle of type 3 glass or better [IS 19085] or in a stainless steel container of SS316 type (IS 6911) that prevents contamination and effects of light and humidity, with a seal or security seal that guarantees the inviolability of the product.

**5.3 Marking**

The following particulars shall be legibly and indelibly marked or labelled on each pack of *Alfalfa* hydro-alcoholic extract:

1. Name of the hydro-alcoholic extract/mother tincture;
2. Name and address of the manufacturer or packer, including contact details;
3. Manufacturer’s license no.;
4. Batch number;
5. Net quantity when packed;
6. Date of manufacturing;
7. Date of packing (MM/YYYY);
8. Date of expiry (MM/YYYY);
9. QR Code for authentication (optional); and
10. Any other information requested by the buyer.

**5.4 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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**ANNEX A**

(*Foreword*)

**COMMITTEE COMPOSITION**

Homoeopathy Sectional Committee, AYD 07

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| *Organization* | *Representative(s)* |
| Govt of NCT, Directorate of Ayush, New Delhi | Dr Raj K. Manchanda **(*Chairperson*)** |
| Anchrom Enterprises Private Limited, Mumbai | Shri Akshay Charegaonkar  Shri Vishwajit Prakash Kale (*Alternate*) |
| 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 (*Alternate* I)  Ms Neha Vashishtha (*Alternate* II) |
| Biosimilia Private Limited, Mumbai | Dr Rajesh Shah  Shrimati Gitanjali Talele (*Alternate*) |
| B Jain Pharmaceuticals Private Limited, Noida | Shri Nishant Jain  Dr Priyanka Motwani (*Alternate*) |
| Botanical Survey of India, Kolkata | Dr D. K. Agrawala  Dr Umeshkumar L. Tiwari (*Alternate*) |
| Central Council for Research in Homoeopathy, New Delhi | Dr Divya Taneja  Dr Manas Sarangi (*Alternate*) |
| Central Drugs Standard Control Organization, New Delhi | Shri Sushant Sharma  Dr Rachna Paliwal (*Alternate*) |
| Centre of Medicinal Plants Research in Homoeopathy, The Nilgiris | Dr J. Shashikanth  Shrimati Anagh D (*Alternate*) |
| Delhi Institute of Pharmaceutical Sciences and Research, New Delhi | Prof P. K. Sahoo  Dr Beauty Behera (*Alternate*) |
| 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 Suraia Parveen (*Alternate* I)  Shri G. V. Narasimha Kumar (*Alternate* II) |
| Dr BR Sur Homoeopathic Medical College, Hospital and Research Centre, New Delhi | Dr Neeraj Gupta  Dr Amar Bodhi (*Alternate*) |
| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | Dr Swapnil A. Kamble  Dr Binit Dwivedi (*Alternate* I)  Dr Anamika Kotiya (*Alternate* II) |
| Dr Willmar Schwabe India Private Limited, Noida | Shri Sunil Vishwakarma  Dr R. Valavan (*Alternate* I)  Dr Poorva Tiwari (*Alternate* II) |
| Hahnemann Publishing Company Private Limited, Kolkata | Dr Durga Sankar Bhar  Dr Kaushik Bhar (*Alternate*) |
| Indian Institute of Technology Bombay, Mumbai | Prof Jayesh Bellare  Prof Venkatesh V. Kareenhalli (*Alternate* I)  Dr Swapnil Rohidas Shinde (*Alternate* II) |
| Indian Pharmacopoeia Commission, Ghaziabad | Shrimati Ritu Tiwari |
| King George's Medical University, Lucknow | Dr Shailendra K. Saxena |
| Medisynth Chemicals Private Limited, Navi Mumbai | Dr Prakash V. Joshi  Shri Nihar J. Vaknalli (*Alternate* I)  Dr Dhara R. Bhatt (*Alternate* II) |
| Mind Technologies Private Limited, Mumbai | Dr Jawahar Shah  Shri Parag Shah (*Alternate* I)  Dr Tarana Malick (*Alternate* II) |
| Ministry of Ayush, New Delhi | Dr Sangeeta A. Duggal  Dr Abhijit Dutta (*Alternate*) |
| National Commission for Homoeopathy (NCH), New Delhi | Dr Mangesh R. Jatkar  Dr Laxmi Mahto (*Alternate*) |
| National Homoeopathy Research Institute in Mental Health, Kottayam | Dr K C Muraleedharan  Dr Dastagiri P (*Alternate* I)  Dr Arun Krishnan P (*Alternate* II) |
| National Institute of Homoeopathy, Kolkata | Dr Subhas Singh  Dr Raja Manoharan (*Alternate*) |
| Nehru Homoeopathic Medical College and Hospital, New Delhi | Dr Seema Rai  Dr Vandana Chopra (*Alternate*) |
| Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ghaziabad | Shrimati Devki Pant  Shri Lalit Tiwari (*Alternate* I)  Shri Kuldeep Singh (*Alternate* II) |
| The Kerala State Homoeopathic Co-operative Pharmacy Limited (HOMCO), Alappuzha | Dr Sobha Chandran R.  Dr Suresh S. (*Alternate* I)  Dr Vineetha L. (*Alternate* II) |
| BIS Directorate General | Shri S K Kanojia, Scientist ‘F’/Head (Ayush) [Representing Director General (*Ex –officio*)] |

*Member Secretary*

Dr Kumar Vivekanand

Scientist ‘D’/Joint Director

(Ayush), BIS

Working Group for Single Herbs and Mother tincture, AYD 07/WG 01

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| *Organization* | *Representative(s)* |
| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | Dr Binit Dwivedi **(*Convener*)** |
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| Botanical Survey of India, Kolkata | Dr D K Agrawala |
| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | Dr Satish Patel  Dr Rajat Rashmi |
| Dr Willmar Schwabe India Private Limited, Noida | Poorva Tiwari |
| Homoeopathic Pharmaceutical Association of India | Dr Geeta Arora |
| Medisynth Chemicals Private Limited, Navi Mumbai | Dr Prakash V. Joshi |
| Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ghaziabad | Dr Lalit Tiwari |