

BUREAU OF INDIAN STANDARDS

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*(Not to be reproduced without permission of BIS or used as an Indian Standard)***भारतीय मानक मसौदा****होम्योपैथी में प्रयोग हेतु अल्फाल्फा मदर टिंचर - विशिष्टि****Draft Indian Standard****ALFALFA MOTHER TINCTURE FOR USE IN HOMOEOPATHY – SPECIFICATION**

Homoeopathy Sectional Committee, AYD 07

Last Date of Comments: 12 Oct. 2024**FOREWORD***(Formal clauses would be added later)*

Homoeopathic mother tincture of Alfalfa is clinically used in the management of disorders such as neurasthenia, splanchnic blues, nervousness, sleeplessness, and nervous indigestion that are mostly within its therapeutic spectrum. Produces fat and eliminates tissue waste and inadequate nursing. It has a positive impact on nutrition, as shown by "toning up" the appetite and digestion, which leads to increased physical and mental energy, weight growth, increases the amount and quality of milk that breastfeeding moms produce. Because of its strong urine activity, it may be useful in treating phosphaturia and diabetes insipidus. It is also said to relieve the vesical irritation associated with prostatic hypertrophy. It appears that it is particularly effective in treating rheumatic diathesis.

It is prepared from *Medicago sativa* L whole plant excluding roots (Family-Fabaceae), a perennial herb native to the Mediterranean, Central, and West Asia and is grown and cultivated throughout India. It is known by regional names are *Vilayti-gawuth*, *Lasunghas* (Hindi), *Vilayati-gavat* (Marathi), *Vilayti-ghas* (Gujarati), *Lusan* (Punjabi), *Vilayati – hullu* (Kannada).

The standard is one of the series of standards being brought out on specifications of homoeopathic mother tincture 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. 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* framed thereunder. However, this standard is subject to the restrictions imposed under these Rules and Regulations, wherever applicable.

To decide whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the test result 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 an Indian Standard)**Draft Indian Standard***ALFALFA MOTHER TINCTURE FOR USE IN HOMOEOPATHY– SPECIFICATION****1 SCOPE**

This standard prescribes the methods of preparation and general specifications of Alfalfa [*Medicago sativa* L] mother tincture (ϕ) prepared from the whole plant excluding roots of *Medicago sativa* L.; Synonym: *Medica sativa* lam. (Family-Fabaceae) for use in Homoeopathy.

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 1070:2023	Reagent Grade Water Specification (<i>fourth revision</i>)
IS 4905:2015	Random sampling and randomization procedure (<i>first revision</i>)
IS 6911:2017	Stainless steel plate, sheet, and strip — specifications (<i>second revision</i>)
IS AYD 07 (24934)	Alfalfa [<i>Medicago sativa</i> L] for use in traditional medicine — Specifications
IS/ISO 11418-3: 2016	Containers and Accessories for Pharmaceutical Preparations Part 3 Screw-Neck Glass Bottles (Veral) for Solid and Liquid Dosage Forms

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 IS AYD 07 (24934).

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 clause 3.2.3 of IS AYD 07 (24934).

3.2 Preparation of Alfalfa Mother Tincture (ϕ)**3.2.1 To prepare one thousand milliliters of the mother tincture (ϕ) with Alfalfa strength 1/10:**

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

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3.2.2 General Specifications of mother tincture (Finished product)

- 3.2.2.1 Appearance of MT** : Greenish brown hydro-alcoholic liquid
3.2.2.2 Alcohol content : 64.0 to 68.0 percent v/v
3.2.2.3 Wt. per ml : 0.870 g to 0.910 g
3.2.2.4 Total solids : Not less than 1.10 percent w/v
3.2.2.5 TLC : Should comply as prescribed in Table 1 (Sl. No. vii) of IS AYD 07 (24934).
3.2.2.6 UV absorbance λ max : 270 nm and 320 nm

3.2.3 Identification

- a) Shinoda test: Take 2 ml of the mother tincture. Heat the mother tincture 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.
- b) Foam test: Take 2 ml to 5 ml of mother tincture 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.

Note-Quality of reagent

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 PACKING, STORAGE AND MARKING**4.1 Packing**

Alfalfa mother tincture shall be packed in an amber coloured borosilicate bottle of hydrolytic resistance grain class HGB 3 or HGA 2 (see clause 5.1 of IS/ISO 11418-3) 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 Storage

Alfalfa mother tincture shall be stored in an amber coloured borosilicate bottle of hydrolytic resistance grain class HGB 3 or HGA 2 (see clause 5.1 of IS/ISO 11418-3) or a Stainless-Steel container made from materials as prescribed in IS 6911 that prevents contamination and effects of light and humidity, with a seal or security seal that guarantees the inviolability of the product.

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4.3 Marking

The following particulars shall be legibly and indelibly marked or labelled on each pack *Alfalfa* mother tincture:

- a) Name of the 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);
- i) QR Code for Authentication (Optional); and
- j) Any other information requested by the buyer.

5 SAMPLING

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

5.2 The samples of *Alfalfa* mother tincture shall be tested to ascertain the material's conformity to the requirements as per the specifications for the finished product of clauses 3.2.2 and 3.2.3.

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.

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Annex A

(Clause 5.1)

SAMPLING OF ALFALFA MOTHER TINCTURE FOR USE IN HOMOEOPATHY

A-1 Lot - The quantity of packed mother tincture belonging to the same batch of manufacture packed in a day shall constitute a lot. The entire quantity of Mother Tincture manufactured and stored just prior to bottling shall constitute a batch.

A-1.1 To ascertain the conformity of the material to the requirements of the relevant specification, samples shall be tested from each lot separately.

A-1.2 The number of Mother tincture bottles to be selected from a lot shall depend on the size of the lot and shall be according to Table 1. The Mother tincture bottles selected for net volume according to column 3 of Table 1 shall be, in addition, those selected according to column 2 of Table 1.

Table -1 Scale of Sampling

No. of mother tincture bottles in the lot	Sample Size	
	Requirements other than Net Volume	Net Volume
(1)	(2)	(3)
Up to 5000	9	36
5001 – 10000	12	36
10001 – 15000	12	72
15001 – above	21	108

These Mother tincture bottles shall be chosen at random from the lot. In order to ensure the randomness of selection, procedures given in IS 4905 may be followed.

A-1.3 Initially, the number of cartons equal to the number of Mother tincture bottles to be taken from the lot in one set (see **A-1.7**) shall be chosen randomly. These cartons thus selected shall be opened, and the mother tincture bottles in these cartons examined visually for the condition of packing, the external appearance, and the fill. The lot shall be considered satisfactory for inspection of other characteristics given in the specification if all the mother tincture bottles in the cartons opened are found to meet the requirements for these characteristics.

A-1.4 In case any defective bottle is found according to **A-1.3**, twice the number of cartons shall be opened, and the mother tincture bottles examined for similar characteristics. If no defective bottle is found, the lot shall be considered satisfactory for inspection of other characteristics given in the specification.

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A-1.5 From each of the cartons opened according to **A-1.3**, three Mother tincture bottles shall be taken from their different layers so as to obtain the required number of Mother tincture bottles in the sample (see columns 2 and 3 of Table 1).

A-1.6 In case the number of cartons to be opened is according to **A-1.4**, the number of cartons equal to the number of Mother tincture bottles in a set (see **A-1.7**) shall be taken at random from these cartons and then the required number of Mother tincture bottles picked up according to **A-1.5**.

A-1.7 The sample Mother tincture bottles selected as in **A-1.5** or **A-1.6** shall be divided randomly into three equal sets and labeled with all the particulars of sampling. One of these sets of sample Mother tincture bottles shall be for the purchaser, another for the vendor, and the third for the referee. The sample Mother tincture bottles to be tested for net volume shall be kept separately.

A-2 Number of tests

Tests for identification and general specifications of mother tincture shall be carried out on the individual sample bottles selected according to column 2 of Table 1. The net volume of each of the individual bottles selected in each set (see **A-1.7**) shall be tested.

A-3 Criteria for conformity

The lot shall be declared as conforming to the requirements of the relevant specification if **A-3.1**, **A-3.2** are satisfied.

A-3.1 For those characteristics tested on the sample, all the test results shall satisfy the corresponding specification requirements.

A-3.2 The lot shall be deemed to have satisfied the requirement of net volume if each individual set of sample bottle (See **A-1.7**) bottle shall satisfy the requirement of net volume indicated on the bottle.