भारतीय मानक

Indian Standard

IS 18977 : 2024

होम्योपैथी में प्रयोग हेतु *मिलीफोलियम* (*अचिलिया मिलेफोलियम* एल.) हाइड्रो-अल्कोहलिक अर्क — विशिष्टि

Millefolium (*Achillea millefolium* L.) Hydro-alcoholic Extract for Use in Homoeopathy — Specification

ICS 11.120.10

भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

November 2024 **Price Group 5**

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.

Millefolium hydro-alcoholic extract is prepared from the plant *Achillea millefolium* L. 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.

Millefolium is an erect, pubescent, perennial herb of the Asteraceae family. It is distributed throughout the Northern Hemisphere including Europe, Asia and North America. In India, it is primarily found in the Himalayan region of Jammu and Kashmir, Himachal Pradesh and Uttarakhand where it thrives in hot, dry conditions and full sun.

Millefolium is known by its common names such as *Common Yarrow, Blood Wart, Thousand Leaves Yarrow and milfolia.* Some of the regional names are *Gandane* (Hindi), *Brinjosipha* (Sanskrit), *Rajmaari* (Marathi), *Achilliya* (Tamil), *Rajmari* (Konkani).

The detailed specifications for the whole plant of *Millefolium* are prescribed in IS 18975.

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 the Homoeopathic Pharmacopoeia of India, Vol. IV, 1983, 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 C.

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

MILLEFOLIUM (*Achillea millefolium* L.) HYDRO-ALCOHOLIC EXTRACT FOR USE IN HOMOEOPATHY — SPECIFICATION

1 SCOPE

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of *Millefolium* [*Achillea millefolium* L.] prepared from the whole plant of *Achillea millefolium* L. (Family Asteraceae).

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 edition of these standards:

IS No.	*Title*
IS 1070 : 2023	Reagent grade water — Specification (*fourth revision*)
IS 2303	Grading glass for alkalinity:
(Part 1)	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 4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedure (*first revision*)
IS 6911 : 2017	Stainless steel plate, sheet and strip — Specifications (*second revision*)
IS 18975 : 2024	*Millefolium* (*Achillea millefolium* L.) for use in traditional medicine — Specification

3 REQUIREMENTS

3.1 Millefolium Whole Plant

3.1.1 *Description*

Macroscopic, *microscopic* and *powder* specifications of *Millefolium* [*Achillea millefolium* L.] whole plant shall comply with the provisions as prescribed in **3.1** of IS 18975.

3.1.2 *General Specifications*

Millefolium [*Achillea millefolium* L.] whole plant 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 18975.

3.2 Preparation of Millefolium Hydro-alcoholic Extract

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

a) *Millefolium*, moist magma containing Solids 100 g, plant moisture 200 ml : 300 g

b) Purified water : 200 ml

c) Strong alcohol (94.7 to 95.2 percent *v/v*) : 635 ml

3.2.2 *General Specifications of Hydro-Alcoholic Extract* (*Finished Product*):

a) *Appearance of MT* — Greenish brown to yellowish brown liquid

b) *Alcohol content* — 56.0 percent v/v to 60.0 percent v/v

c) *Wt. per ml* — 0.900 g to 0.920 g

d) *Total solids* — Not less than 1.0 percent w/v

e) *TLC* — Should comply as prescribed in Table 1 (Sl no. vii) of IS 18975

f) *Assay* (*total flavonoids*) — Not less than 0.05 percent w/w (Annex A)

g) *UV absorbance λ max* — 272 nm and 327 nm

3.2.3 *Identification*

To 1 ml of the Hydro-alcoholic extract in a test tube, add 0.3 ml of dilute sodium hydroxide solution. A yellow colour is produced. Warm on water bath. The colour of moistened red litmus paper placed over the mouth of the test tube changes to blue.

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 PACKING, STORAGE AND MARKING

4.1 Packing

Millefolium 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

Millefolium 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

The following particulars shall be legibly and indelibly marked or labeled on each pack of *Millefolium* 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 Annex B.

5.2 The samples of *Millefolium* 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**.

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

(*Clause* 3.2.2.6)

ESTIMATION OF TOTAL FLAVONOIDS

A-1 ASSAY

The hydro alcoholic extract should contain not less than 0.05 percent w/w total flavonoids, expressed as luteolin-3′,7-di-o-glucoside ($C_{27}H_{30}O_{16}$; M.W. 610 g/mol).

A-2 METHOD FOR ESTIMATION OF ASSAY

A-2.1 Stock solution

In a 100 ml volumetric flask, introduce 10 g of extract and complete to 100 ml with ethanol R (60 percent *v/v*)

A-2.2 Test Solution

In a 25 ml volumetric flask, introduce 2 ml of stock solution, 2 ml of a 20 g/l solution of aluminium chloride R in methanol R and dilute to 25 ml with methanol R.

A-2.3 Compensation Liquid

In a 25 ml volumetric flask, introduce 2 ml of stock solution and dilute to 25 ml with methanol R.

Twenty-five minutes after the last addition of the reagent, measure the absorbance of the test solution at 390 nm, comparison with the compensation liquid.

A-2.4 Calculation

Calculate the percentage content m/m of total flavonoids, expressed as luteolin-3’,7-di-O-glucoside, from the expression:

$$\frac{A \times 1250}{196 \times m}$$

That is taking the specific absorbance to be 196 nm.

A = absorbance of the test solution at 390 nm; and

m = mass, of the sample in grams.

ANNEX B

(*Clause* 5.1)

SAMPLING OF HYDRO-ALCOHOLIC EXTRACT

B-1 LOT

The quantity of packed hydro-alcoholic extract (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.

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

B-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 col (3) of Table 1 shall be, in addition, those selected according to col (2) of Table 1.

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.

B-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* **B-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.

B-1.4 In case any defective bottle is found according to **B-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.

B-1.5 From each of the cartons opened according to **B-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* col (2) and col (3) of Table 1].

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

B-1.7 The sample mother tincture bottles selected as in **B-1.5** or **B-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.

B-2 NUMBER OF TESTS

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

B-3 CRITERIA FOR CONFORMITY

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

B-3.1 All test results shall satisfy the corresponding specification requirements for those characteristics tested on the sample.

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

Table 1 Scale of Sampling

(*Clause* B-1.2, B-1.5 *and* B-2)

Sl No.	No. of Mother Tincture Bottles in the Lot	Sample Size	
		Requirements other than Net Volume	Net Volume
(1)	(2)	(3)	(4)
i)	Up to 5 000	9	36
ii)	5 001 to 10 000	12	36
iii)	10 001 to 15 000	12	72
iv)	15 001 to above	21	108

ANNEX C

(*Foreword*)

COMMITTEE COMPOSITION

Homoeopathy Sectional Committee, AYD 07

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*)
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Member Secretary
DR KUMAR VIVEKANAND
SCIENTIST 'D'/JOINT DIRECTOR
(AYUSH), BIS

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

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 DP Rastogi Central Research Institute for Homoeopathy, Noida	DR RAJAT RASHMI
Dr Willmar Schwabe India Private Limited, Noida	DR POORVA TIWARI
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Medisynth Chemicals Private Limited, Navi Mumbai	DR PRAKASH V. JOSHI
Pharmacopoeia Commission for Indian Medicine & Homoeopathy, Ghaziabad	DR LALIT TIWARI

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BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

Regional Offices:		*Telephones*
Central	: 601/A, Konnectus Tower -1, 6th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002	2323 7617
Eastern	: 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091	2367 0012 2320 9474
Northern	: Plot No. 4-A, Sector 27-B, Madhya Marg, Chandigarh 160019	265 9930
Southern	: C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113	2254 1442 2254 1216
Western	: 5th Floor/MTNL CETTM, Technology Street, Hiranandani Gardens, Powai Mumbai 400076	25700030 25702715

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