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भारतीय मानक मसौदा

होम्योपैथी में प्रयोग हेतु हाइड्रोकोटाइल एशियाटिका मदर टिंचर -विशिष्टि

Draft Indian Standard

HYDROCOTYLE ASIATICA MOTHER TINCTURE FOR USE IN HOMOEOPATHY – SPECIFICATION

Homoeopathic Sectional Committee, AYD 07 **Last Date of Comments: 02 July 2024**

FOREWORD

(Formal clauses would be added later)

Homoeopathic mother tincture of Hydrocotyle is clinically used in the management of disorders of the liver, nerves, mucous membranes, and the female generative organs. Skin affections like leprosy, acne, eczema, pemphigus, lupus, etc., can be managed with it. It is also used as an ingredient for several formulations in homoeopathy and for the preparation of homoeopathic dilutions or potencies.

It is prepared from the *Centella asiatica* L. (Urb), a perennial herbaceous creeper distributed in tropical and subtropical regions throughout India, growing in moist places up to an altitude of 1800m. It is also found in Pakistan, Sri Lanka, Madagascar, South Africa, and South Pacific and Eastern Europe. Commonly, it is known as *Brahami, Mundukparni* (Hindi), Thick-leaved pennywort (English); *Hydrocotyle* (French); *Wassernable* (German), *Mandukaparnika* (Sanskrit), *Kodagam* (Malayalam), *Babassa* (Tamil), *Babasa* (Telgu), *Brahamanduki* (Bengali).

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 the formulation of this standard, significant assistance has been derived from Homoeopathic Pharmacopoeia of India, Vol. 1, 1971; Vol. 10, 2013; Ayurvedic Pharmacopoeia of India, Part 1, Vol 4, 2004; and Ayurvedic Pharmacopoeia of India, Part 1, Vol 8, 2011 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.

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.

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1 SCOPE

This standard prescribes the methods of preparation and general specifications of *Hydrocotyle asiatica* mother tincture (ϕ) prepared from the dried whole plant of *Centella asiatica* L. (Urb) syn. Hydrocotyle asiatica L. (Family Apiaceae) for use in Homeopathy.

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.

IS No.	***Title***
IS 1070: 1992	Reagent grade water — Specification (third revision)
IS 4905:2015	Random sampling and randomization procedure (first revision)
IS 6911:2017	Stainless steel plate, sheet, and strip ― specifications (second revision)
IS 18186:2023	Mandukaparni [Centella asiatica (L.) Urban.] Whole Plant for use in Traditional Medicine — Specification
IS AYD/07/23564	Glass Containers and Closures for Packaging and Dispensing of Homoeopathic Medicine — Specification

3 REQUIREMENTS

3.1 Mandukaparni whole plant

3.1.1 *Description*

Macroscopic, Microscopic, and Powder Specifications of Mandukaparni [Centella asiatica (L.) Urban.] dried whole plant shall comply with the provisions as prescribed in IS 18186:2023.

3.1.2 *General Specifications*

Mandukaparni [Centella asiatica (L.) Urban.] dried whole plant shall be free from extraneous/foreign matter and shall comply with the physical, chemical, and microbiological specifications as prescribed in clause 3.2.2 of IS 18186:2023.

3.2 Preparation of Hydrocotyle asiatica Mother Tincture (φ)

3.2.1 To prepare one thousand milliliters of the mother tincture (ϕ) with drug strength 1/10:

Hydrocotyle Asiatica in moderately coarse powder	**:**	100 g
Purified Water	**:**	300 mL
Strong Alcohol	**:**	730 mL

3.2.2 *General Specifications of Mother Tincture (Finished Product)*

3.2.2.1	**Appearance of MT**	**:**	Clear liquid
3.2.2.2	**Alcohol content**	**:**	66 to 70 percent v/v
3.2.2.3	**Wt. per mL**	**:**	0.850 g to 0.920 g
3.2.2.4	**Total solids**	**:**	Not less than 0.50 percent w/v
3.2.2.5	**UV absorbance λ max**	**:**	322 nm

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, MARKING AND STORAGE

4.1 Packing

Hydrocotyle asiatica mother tincture shall be packed in an amber-colored glass bottle (Type I or III) prescribed in IS AYD/07/23564 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

Hydrocotyle asiatica mother tincture shall be stored in an amber glass bottle (Type I or III) as prescribed in IS AYD/07/23564 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

4.3 Marking

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

a) Name of the mother tincture;

b) Name and address of the manufacturer or packer, including contact details;
c) Net quantity when packed;
d) Manufacturer's license no.;
e) Date of Manufacturing;
f) Date of packing (MM/YYYY);
g) Best before date (MM/YYYY);
h) Batch or code number;
i) QR Code for Authentication (Optional); and
j) 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.

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 *Hydrocotyle asiatica* mother tincture shall be tested to ascertain the material's conformity to the requirements as per the specifications for the finished product of clause 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 5.1)

SAMPLING OF HYDROCOTYLE ASIATICA MOTHER TINCTURE

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 the 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.

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 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** and **A-3.2** are satisfied.

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

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