**IS XXXXX : 2024**

***भारतीय मानक***

***Indian Standard***

**होम्योपैथी में प्रयोग हेतु**

***हाइड्रोकोटाइल एशियाटिका* हाइड्रो-अल्कोहोलिक अर्क — विशिष्टि**

***Hydrocotyle Asiatica* 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.

Hydrocotyle asiatica hydro-alcoholic extract or mother tincture (Ø) is prepared from the *Centella asiatica* (L.) Urban. In homoeopathy, this is used as a starting material for homoeopathic dilutions or potencies. It is also used for the preparation of other dosage forms.

Hydrocotyle asiatica is a perennial herbaceous creeper distributed in tropical and subtropical regions throughout India, growing in moist places up to an altitude of 1 800 m. 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); *Wassernabel* (German), *Mandukaparnika* (Sanskrit), *Kodagam* (Malayalam), *Babassa*, *Vallerai* (Tamil), *Bokkudu* (Telgu), *Brahamanduki* (Bengali), *Barmi* (Gujrati) *Kutakam* (Malyalam) and *Vondelaga* (Kannad).

The detailed specifications for the whole plant of Alfalfa are prescribed in IS 18186.

The standard is one of the series of standards being brought out on specifications of 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. 1, 1971 and Vol. 10, 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 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*

*Hydrocotyle asiatica* HYDRO-ALCOHOLIC EXTRACT FOR USE IN HOMOEOPATHY — SPECIFICATION

**1 SCOPE**

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of *Hydrocotyle asiatica* prepared from the dried whole plant of *Centella asiatica* (L.) Urban, syn. *Hydrocotyle asiatica* L. (Family Apiaceae/Umbelliferae).

**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 18186 : 2023 | Mandukaparni [*Centella asiatica* (L.) Urban.] Whole Plant 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 Hydrocotyle asiatica** **whole plant**

**3.1.1** *Description*

*Macroscopic, microscopic,* and *powder* specifications of *Hydrocotyle asiatica* [*Centella asiatica* (L.)Urban*.*]dried whole plant shall comply with the provisions as prescribed in **3.1** IS 18186.

**3.1.2** *General Specifications*

*Hydrocotyle asiatica [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 **3.2.2** of IS 18186.

**3.2 Preparation of *Hydrocotyle asiatica*** **hydro-alcoholic extract**

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

1. *Hydrocotyle Asiatica* in moderately coarse powder 100 g
2. Purified Water 300 ml
3. Strong Alcohol (94.7 to 95.2 percent *v/v*) 730 ml

**3.2.2** *General Specifications of hydro-alcoholic extract (Finished Product)*

1. Appearance Greenish brown
2. Alcohol content 66 to 70 percent *v/v*
3. Wt. per ml 0.850 g to 0.920 g
4. Total solids Not less than 0.50 percent w/v
5. TLC Should comply as prescribed in Table 1 (Sl. No. vii) of IS 18186
6. UV absorbance λ max 299 nm and 322 nm

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 as prescribed in Annex B of IS 18977.

**4.2** The samples of *Hydrocotyle asiatica* 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**.

**5 PACKING, STORAGE AND MARKING**

**5.1 Packing**

*Hydrocotyle asiatica* 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**

*Hydrocotyle asiatica* 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 labeled on each pack of *Hydrocotyle asiatica* 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.

**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 BhargavaShri Karan Bhargava (*Alternate* I)Ms Neha Vashishtha (*Alternate* II) |
| Biosimilia Private Limited, Mumbai  | Dr Rajesh ShahShrimati Gitanjali Talele (*Alternate*) |
| B Jain Pharmaceuticals Private Limited, Noida | Shri Nishant JainDr 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 TanejaDr Manas Sarangi (*Alternate*) |
| Central Drugs Standard Control Organization, New Delhi | Shri Sushant SharmaDr 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 GuptaDr 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 VishwakarmaDr R. Valavan (*Alternate* I)Dr Poorva Tiwari (*Alternate* II) |
| Hahnemann Publishing Company Private Limited, Kolkata  | Dr Durga Sankar BharDr 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 ShahShri Parag Shah (*Alternate* I)Dr Tarana Malick (*Alternate* II) |
| Ministry of Ayush, New Delhi | Dr Sangeeta A. DuggalDr Abhijit Dutta (*Alternate* ) |
| National Commission for Homoeopathy (NCH), New Delhi | Dr Mangesh R. JatkarDr 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 SinghDr Raja Manoharan (*Alternate*) |
| Nehru Homoeopathic Medical College and Hospital, New Delhi | Dr Seema RaiDr 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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| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | Dr Satish PatelDr 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 |