**IS XXXXX : 2024**

***भारतीय मानक***

***Indian Standard***

**होम्योपैथी में प्रयोग हेतु**

***जिमनेमा सिल्वेस्ट्रर* हाइड्रो-अल्कोहोलिक अर्क — विशिष्टि**

**Gymnema Sylvestre 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.

*Gymnema sylvestre* hydro-alcoholic extract or mother tincture (Ø) is prepared from the leaves of *Gymnema sylvestre* (Retz.) R.Br. ex Sm*.* In homoeopathy, this is used as a starting material forhomoeopathic dilutions or potencies. It is also used for the preparation of other dosage forms.

*Gymnema sylvestre* (Retz.) R.Br. ex Sm. is a large, more or less pubescent, climbing shrub that is native to tropical forests of central and southern India, also found in Malaysia, Srilanka, Australia, Indonesia, Japan, Vietnam, Tropical Africa, and the Southwestern region of the People`s Republic of China. Commonly, it is known as *Gurmar, Gudmar, Meshashringi* (Hindi), *Madhunashine*, (Sanskrit), *Cakkarakolli* (Malayalam), *Shirukurunja* (Tamil), *Podapatro* (Telgu), *Kaavalee*, (Marathi), *Dhuleti* (Gujarati), *Kadhasige* (Kannada), *Medhasingi* (Bengali).

The detailed specifications for the leaves of *Gymnema sylvestre* (Retz.) R.Br. ex Sm. are prescribed in IS 18193.

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. 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 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*

*Gymnema sylvestre* HYDRO-ALCOHOLIC EXTRACT FOR USE IN HOMOEOPATHY — SPECIFICATION

**1 SCOPE**

This standard prescribes the preparation and general specifications of hydro-alcoholic extract of *Gymnema sylvestre* prepared from the dried leaves of *Gymnema sylvestre* (Retz.) R.Br. ex Sm. (Family Asclepiadaceae /Apocynaceae).

**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 18193: 2023 | Meshashringi (*Gymnema sylvestre* R.Br.) Leaf 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** **Gymnema sylvestre leaves**

**3.1.1** *Description*

*Macroscopic, microscopic, and powder* specifications of *Gymnema sylvestre* leaves shall comply with the provisions as prescribed in **3.1** of IS 18193.

**3.1.2** *General Specifications*

*Gymnema sylvestre* leaves 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 18193.

**3.2 Preparation of *Gymnema sylvestre* hydro-alcoholic extract**

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

1. *Gymnema sylvestre* leaves in moderately coarse powder 100g
2. Purified water 200 ml
3. Strong alcohol (94.7 to 95.2 percent v/v) in sufficient quantity.

**3.2.2** *General Specifications (Finished Product)*

1. Appearance Yellowish brown hydro-alcoholic liquid
2. Alcohol content 76 to 80 percent *v/v*
3. Wt. per ml 0.869 g to 0.882 g
4. Total solids Not less than 1.20 percent w/v
5. TLC Should comply as prescribed in Table 1 (Sl No. vii) of

 IS 18193.

1. UV absorbance λ max 265 nm and 325 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 *Gymnema sylvestre* hydro-alcoholic extract 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**.

**5 PACKING, STORAGE AND MARKING**

**5.1 Packing**

*Gymnema sylvestre* 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**

*Gymnema sylvestre* hydro-alcoholic extract shall be stored in an amber-coloured bottle type 3 glass or better [IS 19085] or 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 *Gymnema sylvestre* 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 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 |