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भारतीय मानक मसौदा

होम्योपैथी में प्रयोग हेतु जिमनेमा सिल्वेस्ट्र मदर टिंचर -विशिष्टि

Draft Indian Standard

**GYMNEMA SYLVESTREMOTHER TINCTURE FOR USE IN HOMOEOPATHY –
SPECIFICATION**

Homeopathic Sectional Committee, AYD 07

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FOREWORD

(Formal clauses would be added later)

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

Gymnema sylvestre mother tincture is clinically used in the management of blood sugar levels and is useful for poisonous snake bites and altered taste. It is also used as an ingredient for several formulations in homoeopathy and for the preparation of homoeopathic dilutions or potencies.

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, Vol.5 Part 1 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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**GYMNEMA SYLVESTREMOTHER TINCTURE FOR USE IN HOMOEOPATHY –
SPECIFICATION**

1 SCOPE

This standard prescribes the methods of preparation and general specifications of *Gymnema sylvestre* mother tincture (ϕ) prepared from the leaves of *Gymnema sylvestre* (Retz.) R.Br. ex Sm. syn. *Asclepias geminate* Roxb., *Cynanchum lanceolatum* Poir (Family Asclepiadaceae /Apocynaceae) 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: 1992	Reagent grade water — Specification (<i>third 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 18193: 2023	Meshashringi (<i>Gymnema sylvestre</i> R.Br.) Leaf for use in Traditional Medicine Specification
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 *Gymnema sylvestre* leaves

3.1.1 Description

Macroscopic, Microscopic, and Powder Specifications of *Gymnema sylvestre* leaves shall comply with the provisions as prescribed in 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 clause 3.2.2 of IS 18193.

3.2 Preparation of *Gymnema sylvestre* Mother Tincture (ϕ)

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

Gymnema Sylvestre in moderately coarse powder : 100g
Purified Water : 200 mL
Strong Alcohol (94.7 to 95.2 percent v/v) in sufficient quantity.

3.2.2 General Specifications of Mother Tincture (Finished Product)

3.2.2.1 Appearance of Mother Tincture : Yellowish brown hydro-alcoholic liquid
3.2.2.2 Alcohol content : 76 to 80 percent v/v
3.2.2.3 pH : 6.1 to 6.8
3.2.2.4 Wt. per mL : 0.869 g to 0.882 g

- 3.2.2.5 Total solids** : Not less than 1.20 percent w/v
- 3.2.2.6 TLC** : Should comply as prescribed in Table 1 (SI No. vii) of IS 18193.
- 3.2.2.7 UV absorbance λ max** : 265 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 PACKING, MARKING AND STORAGE

4.1 Packing

Gymnema sylvestre 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

Gymnema sylvestre 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 closure 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 *Gymnema sylvestre* 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 *Gymnema sylvestre* 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 GYMNEMA SYLVESTRE 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 Sample Size

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**) shall satisfy the requirement of net volume indicated on the bottle.

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