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भारतीय मानक मसौदा

पारंपरिक चिकित्सा में उपयोग के लिए वनस्पति - परीक्षण पद्धति

Draft Indian Standard

Herbal Raw Materials for use in Traditional Medicine - Methods of Test

ICS 67.220.10

Ayurveda Sectional Committee, AYD 01

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FOREWORD

(Formal Clause would be added later)

In the Indian system of medicine, plant-based raw materials are integral to therapeutic practices, where whole plants or their specific parts such as roots, stems, leaves, seeds, fruits, and barks are utilized either singly or in combination to develop compound formulations. As the global demand for herbal medicine continues to rise, having well-defined standards will be crucial for supporting its growth on the global stage.

Given the diverse and complex nature of these herbal raw materials, it becomes important to establish standardized test methods that can accurately assess their quality. This standard document on test methods for herbal materials is a significant step towards ensuring the repeatability and reproducibility of tests and analyses conducted on these plant-based drugs.

In the formulation of this standard, significant assistance has been derived from the Ayurvedic Pharmacopoeia of India, Part II, Vol. IV, 2017 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.

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.

Draft Indian Standard

HERBAL RAW MATERIALS FOR USE IN TRADITIONAL MEDICINE - METHODS OF TEST

1 SCOPE

This standard prescribes physical and chemical methods of test for herbal raw materials used in traditional medicine.

2 REFERENCES

The following standards contain provisions which through reference in this text, constitute provisions 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 the standards indicated below:

<i>IS No.</i>	<i>Title</i>
IS 1070: 2023	Reagent grade water – Specification (<i>fourth revision</i>)
IS 460: 2020	Test sieves (part 1) – Specification: Wire Cloth Test Sieves (<i>Fourth revision</i>)

1 FOREIGN MATTER

The sample shall be free from visible signs of mould growth, sliminess, contamination by insects and other animal and animal products including animal excreta or any other noxious foreign matter. Foreign matter consists of any organism, part or product of an organism, other than that named in the definition of the product and mineral admixtures, such as soils, stones, sand and dust. It shall also include other than official parts of organism beyond their specified limits.

1.1 Apparatus

1.1.1 *Magnifying glass (6x or 10x)*

1.1.2 *Sieve (250 μm)*

1.1.3 *Weighing Balance*

1.2 Procedure

Take 100 g of sample (unless otherwise specified) and spread in a thin layer on a suitable platform. Examine in daylight with unaided eye or using magnifying glass and separate the foreign matter. Appropriate sieve can also be used to separate the foreign matter [*see IS 460 (part 4)*]. Dust regarded as mineral admixture is separated by sifting the sample through a sieve. Weigh the sorted foreign matter and calculate the foreign matter content in per cent with reference to sample.

2 TOTAL ASH

2.1 Apparatus

2.1.1 *Weighing Balance*

2.1.2 *Tared Dish (Made up of platinum or silica).*

2.1.3 *Muffle furnace*

2.1.3 *Desiccator*

2.1.4 *Filter Paper (Ashless).*

2.2 Procedure

Incinerate about 2 to 3 g, accurately weighed material in a tared platinum or silica dish at a temperature not exceeding 600 °C until free from carbon, cool in a desiccator for 30 min and weigh without delay. If carbon free ash cannot be obtained in this way, exhaust the charred mass with hot water, collect the residue on an ashless filter paper, incinerate the residue and filter paper, add the filtrate, evaporate to dryness, and ignite at a temperature not exceeding 600 °C. Calculate the percentage of ash with reference to the air-dried material.

3 ACID INSOLUBLE ASH

3.1 Apparatus

3.1.1 *Weighing Balance*

3.1.2 *Hot Plate*

3.1.3 *Desiccator*

3.1.4 *Filter Paper, (Whatman no 41).*

3.2 Reagent

3.2.1 *Dilute Hydrochloric Acid*

3.3 Procedure

To the crucible containing total ash, add 25 ml of dilute hydrochloric acid. Collect the insoluble matter on an ashless filter paper and wash with hot water until the filtrate is neutral. Transfer the filter paper containing the insoluble matter to the original crucible, dry on a hot-plate and ignite to constant weight. Allow the residue to cool in a suitable desiccator for 30 min and weigh without delay. Calculate the content of acid-insoluble ash with reference to the air-dried material.

4 ALCOHOL SOLUBLE EXTRACT

4.1 Apparatus

4.1.1 Weighing Balance

4.1.2 Closed Flask

4.1.3 Dish, (tared, flat bottomed, shallow)

4.2 Reagent

4.2.1 Alcohol/Methanol

4.3 Procedure

Macerate 5 g of the coarsely powdered, air-dried material with 100 ml of alcohol of specified strength in a closed flask for 24 h, shaking frequently during 6 h and allowing to stand for 18 h. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish and dry at 105 °C, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried material. For determination of methanol soluble extractive, use methanol in place of alcohol.

5 WATER SOLUBLE EXTRACT

Proceed as directed for the determination of Alcohol-soluble extract, using chloroform water (2.5 ml chloroform in purified water to produce 1000 ml) instead of ethanol.

6 ETHER SOLUBLE EXTRACT (FIXED OIL CONTENT)

6.1 Apparatus

6.1.1 Weighing Balance

6.1.2 Soxhlet Extractor

6.1.3 Tared Evaporating Dish

6.2 Reagent

6.2.1 Solvent Ether (or Petroleum ether, b.p. 40 °C to 60 °C)

6.3 Procedure

Transfer a suitably weighed quantity (depending on the fixed oil content) of the air-dried, crushed material to an extraction thimble, extract with solvent ether (or petroleum ether) in a continuous extraction apparatus for 6 h. Filter the extract quantitatively into a tared evaporating dish and evaporate off the solvent on a water bath. Dry the residue at 105 °C to constant weight. Calculate the percentage of ether-soluble extractive with reference to the air-dried material.

7 MOISTURE CONTENT (LOSS ON DRYING)

7.1 Apparatus

7.1.1 Weighing Balance

7.1.2 Tared Evaporating Dish

7.1.3 Oven

7.2 Procedure

Dry the evaporating dish for 30 min under the same conditions to be employed in the determination. Place about 5 to 10 g of powder/material in a tared evaporating dish. By gentle, sidewise shaking, distribute the test specimen as evenly as practicable to a depth of about 5 mm generally, and not more than 10 mm in the case of bulky materials. Place the loaded bottle in the drying chamber. Dry the test specimen at 105 °C for 3 h and weigh. Continue the drying and weighing at half an hour interval until difference between two successive weighing corresponds to, not more than 0.25 per cent.

NOTE- For unpowdered material, prepare about 10 g of the sample by cutting, shredding so that the parts are about 3 mm in thickness. Seeds and fruits, smaller than 3 mm should be cracked. Avoid the use of high speed mills in preparing the samples, and exercise care that no appreciable amount of moisture is lost during preparation and that the portion taken is representative of the official sample.

8 VOLATILE OIL

The determination of volatile oil in herbal material is made by distilling the material with a mixture of water and glycerin, collecting the distillate in a graduated tube in which the aqueous portion of the distillate is automatically separated and returned to the distilling flask and measuring the volume of the oil. The content of the volatile oil is expressed as a percentage v/w.

8.1 Apparatus for volatile oil determination

The apparatus consists of the different parts as shown in Fig.1. The apparatus described below is recommended but any similar apparatus may be used provided that it permits complete distillation of the volatile oil. All glass parts of the apparatus shall be made of good quality resistance glass. The whole of the apparatus is effectively screened from draught. The apparatus is cleaned before each distillation by washing successively with acetone and water, then inverting it, filling it with chromic sulphuric acid mixture, after closing the open end at G, and allowing to stand and finally rinsing with water.

8.1.1 Distilling Flask

A spherical flask, 1,000 ml capacity with ground neck, taper of ground socket 1 in 10, internal diameter of larger end shall be 34.35 to 34.65 mm.

8.2.2 Still Head

Graduated measuring tube and return flow tube made in one piece, in accordance with the following specifications. External diameter of the smaller end shall be 31.0 to 31.2 mm. Minimum length of the ground zone shall be 34 mm.

8.2.2.1 Parts with specifications

Parts	Specification
Tube AC	Length: 220 to 240 mm Internal Diameter: 13 to 15 mm
Bulb CD	Length: 100 to 110 mm Internal Diameter: 13 to 15 mm
Spiral Condenser	Ground joint accurately fitting in the ground neck of the tube EG, taper 1 in 10
Tube EG	Length: 80 to 90 mm Internal Diameter: 30 to 40 mm
Bulb B	Length: 20 to 22 mm Internal Diameter: 15 to 20 mm The distance between B and P is 120 to 125 mm. Junction P and the center of the bulb B shall be in the same horizontal plane.
Measuring tube JL	Length of the graduated portion: 144 to 155 mm Capacity: 2 milliliters Graduated into fifths and fiftieths of a milliliter
Tube PL	Return flow tube -Internal diameter: 7 to 8 mm Levelling tube I, length: 450 to 500 mm. Internal diameter 10 to 12 mm, tapering at the lower end with a wide top (20 to 25 mm diameter). Rubber tubing (a-b)- length 450 to 500 mm. Internal diameter: 5 to 8 mm.

8.2.3 Burner

A luminous Argand burner with chimney and sensitive regulative tap.

8.2.4 Stand

A retort stand with asbestos covered ring and clamp carrying a piece of metal tubing connected by a short length of rubber tubing with the water inlet tube of the condenser jacket.

8.3 Procedure

A suitable quantity of the coarsely powdered material together with 75 ml of glycerin and 175 ml of water in the one litre distilling flask and a few pieces of porous earthen ware and one filter paper 15 cm cut into small strips, 7 to 12 mm wide, are also put in the distilling flask, which is then connected to the still head. Before attaching the condenser, water is run into the graduated receiver, keeping the tap T open until the water overflows at P. Any air

bubbles in the rubber tubing a-b are carefully removed by pressing the tube. The tap is then closed and the condenser attached. The contents of the flask are now heated and stirred by frequent agitation until ebullition commences. The distillation is continued at a rate which keeps the lower end of the condenser cool. The flask is rotated occasionally to wash down any material that adheres to its sides. At the end of the specified time (3 to 4 h) heating is discontinued, the apparatus is allowed to cool for 10 min and the tap T is opened and the tube L1 lowered slowly; as soon as the layer of the oil completely enters into the graduated part of the receiver the tap is closed and the volume is read. The tube L1 is then raised till the level of water in it is above the level of B, when the tap T is slowly opened to return the oil to the bulb. The distillation is again continued for another hour and the volume of oil is again read, after cooling the apparatus as before. If necessary, the distillation is again continued until successive readings of the volatile oil do not differ. The measured yield of volatile oil is taken to be the content of volatile oil in the drug. The dimensions of the apparatus may be suitably modified in case of necessity.

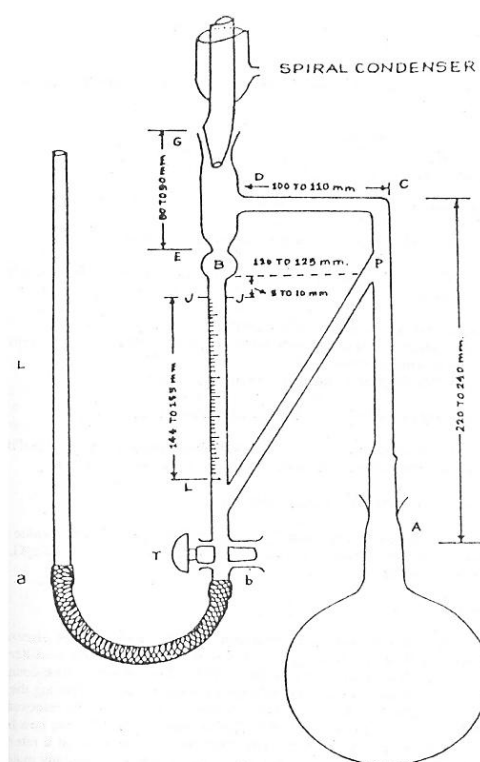


FIG.1 APPARATUS FOR VOLATILE OIL DETERMINATION