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BUREAU OF INDIAN STANDARDS

भारतीय मानक मसौदा

गैर औषधीय होम्योपैथिक टैबलेटस – विशिष्टि

Draft Indian Standard

Non-medicated Homoeopathic Tablets – Specification

Homoeopathy Sectional Committee, AYD 07 **Last Date of Comments: 09-03-2024**

FOREWORD

Non-medicated Tablets are the homoeopathic vehicles in which medicines are mixed and given for their internal administrations orally. These are comparatively inert and used as means of conveyance of homoeopathic medicine.

The standard is being brought out for the use of researchers, academicians, students, clinical practitioners, and drug manufacturers.

In the formulation of this standard, significant assistance has been derived from the Indian Standards published by the Government of India. Inputs have also been derived from the information available in the public domain in print and electronic media including authoritative books like Indian, U.S. and French Pharmacopoeias.

In the formulation of this standard due consideration has been given to the provisions of the *Drugs & Cosmetics Act*, 1940 and Rules framed thereunder. However, this standard is subject to the restrictions imposed under these rules and regulations, wherever applicable.

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 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.

BUREAU OF INDIAN STANDARDS

Draft Indian Standard

Non-medicated Homoeopathic Tablets – Specification

1 SCOPE

1.1 This standard prescribes the formulation, description, and test methods, including packing and storage for homoeopathic tablets used for dispensing Homeopathic medicines.

1.2 It does not include medicated tablets and only covers un-medicated ones that act as vehicles for the drug substance. These must be completely and rapidly soluble.

2 REFERENCES

The standards listed below 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 editions of the standards indicated below:

IS No.	***Title***
IS 1070 : 2023	Reagent grade water (Fourth Revision)
IS 10146: 1982	Polyethylene for its Safe Use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water.

3. TERMINOLOGY

For this document, tablets are the solid vehicles used in Homeopathy for the dispensing of medicines. They are made from pharma-grade sugar and lactose and are available in 100, 250 and 330 mg sizes.

Note: Trituration is not necessary for the manufacturing of these tablets.

4 METHOD OF PREPARATION

Non-medicated tablets are produced according to two approved compressed tablet methods.

4.1 Method 1

Compressed Tablets are defined as tablets formed by compression of a dry material and contain no special coating. They are compressed from powdered or crystalline solids and may contain binders, excipients, lubricants, and disintegrators.

Steps: Compressed Tablets are produced according to a six step process with appropriate modifications accepted. These steps include:

The **First** step is production of the necessary mixture according to techniques outlined in the Homoeopathic Pharmacopoeia of the United States.

Second, this preparation then is added to: a) the appropriate liquid attenuations and/or b) the appropriate liquid media (purified water, Ethanol, etc.) to such an extent that the lactose is thoroughly moistened. If binders are necessary (the generally accepted ratio for the binding solution is one (1) part to fifteen (15) parts of triturate material with accepted variations). Binding solutions are composed of a binder, i.e., gum arabic, microcrystalline cellulose, a preservative if necessary, an inert lubricant, and purified water);

The **Third** step is the granulation of the moistened material with the appropriate mesh screen.

Fourth, the wet granulation then is introduced into a dehumidified area and the relative humidity of that area is reduced 35-40% with respect to ambient humidity at room temperature. Drying is accomplished at 70º-110ºF. (210-430C).

Fifth, the dried granulation then is re-granulated through the appropriate mesh screen and the necessary lubricants are added. Lubricants such as mineral oil, talc, calcium stearate, corn starch, etc., as approved by the United States Pharmacopoeia, are acceptable.

Sixth, the mixture then is compressed in a rotary tablet compressor or any other similar apparatus to the desired tablet size. Compressed air or vacuum may be necessary to remove any untableted material from the compressed tablets prior to sale or use.

4.2 Method 2

Formulation:

Component	Quantity	Function
Calcium (hydrogen phosphate) dihydrate	94.00 g	Thinner Ph. Eur.
Corn starch	5.00 g	Disintegrating agent Ph. Eur.
Magnesium (stearate)	1.00 g	Lubricant Ph. Eur.

Methods: Grind the three components until a homogeneous powder is obtained, compress with flat or concave punches of appropriate dimensions. French pharmacopoeia is using it as a placebo.

5 TEST METHODS

5.1 Description

The tablets shall be uncoated, unscored, and flat or rounded having uniform size and bright white in appearance. They may have the manufacturer's logo engraved.

5.2 Weight variation

Weigh 20 tablets and find out average weight. When weighed singly, not more than two of the tablets should deviate from the average weight by 10 percent.

5.3 Identification test

5.3.1 For Non-medicated Lactose Tablets

A. To 5 ml of a saturated solution add 5 ml of 1 M sodium hydroxide and gently warm the mixture; the liquid becomes yellow and then brownish-red. Cool to room temperature and add 0.2 ml of potassium cupri-tartrate solution' a red precipitate is formed.

B. Heat 5 ml of a 5 per cent w/v solution with 5 ml of 10 M ammonia in a water-bath at 80° for 10 minutes; a red colour develops.

C. **Thin-Layer Chromatographic Identification Test** (Ref. USP)

Diluent: Methanol and water (3:2)

Standard solution A: 0.5 mg/mL of Lactose Monohydrate RS in Diluent.

Standard solution B: 0.5 mg/mL each of Dextrose RS, Lactose Monohydrate RS, Fructose RS and Sucrose RS in Diluent

Sample solution: 0.5 mg/mL of Lactose Monohydrate in Diluent

Adsorbent: 0.25 mm layer of chromatographic silica gel

Mobile phase: Ethylene dichloride, glacial acetic acid, methanol, and water (10:5:3:2 v/v/v/v)

Spray reagent: 5 mg/mL of thymol in a mixture of alcohol and sulphuric acid (19:1 v/v)

Analysis:

Allow the spots to dry, and develop the plate in a paper-lined chromatographic chamber equilibrated with developing solvent system for about 1 h prior to use.

Allow the chromatogram to develop until the solvent front has moved about three-quarters of the length of the plate.

Remove the plate from the chamber, dry in a current of warm air, and redevelop the plate in fresh developing solvent system. Remove the plate from the chamber, mark the solvent front, and dry the plate in a current of warm air. Spray the plate evenly with Spray reagent. Heat the plate at 130° for 10 min.

System suitability: The test is not valid unless the chromatogram of Standard solution B shows four clearly discernible spots, disregarding any spots at the origin.

Acceptance criteria: The principal spot from the Sample solution corresponds in appearance and Rf value to that from Standard solution A.

5.3.2 For Non-medicated Sucrose (Pharma grade sugar) Tablets

Dissolve 150.0 g in sufficient carbon dioxide-free water prepared from distilled water to produce 300 ml (Solution A).

Dilute 1ml of Solution A to 100 ml with water. To 5 ml of the solution add 2 ml of freshly prepared 2 M sodium hydroxide and 0.15 ml of a freshly prepared copper sulphate solution, the solution is clear and blue and remains so on boiling. To the hot solution add 4 ml of 2 M hydrochloric acid, heat to boiling and add 4 ml of 2 M sodium hydroxide, an orange precipitate is produced immediately.

5.3.3 For tablet made from Calcium (Hydrogen phosphate) dihydrate (as per FP)

A. Suspend 100 mg of powdered tablet in a mixture of 5 mL of dilute nitric acid R and 5 mL of water R. Filter. The solution gives the reactions of the phosphates.

B. 5 mg of powder gives reaction of calcium.

5.4 Test for Impurities

1. Test for Starch: Should be negative for Starch-Iodide test , except used as binder in formulation
2. Test for Talc: Should be Negative for Magnesium Silicate
3. Test for Kaolin: Should be Negative for Aluminum
4. Test for Chalk: Should be negative for carbonates and calcium except in tablets having calcium as one of the component.

5.5 Sulphated Ash Value

For Handmade tablets (Tablet Triturates) – not exceeding 0.1% w/w

For Compressed tablets – not exceeding 0.5% w/w

5.6 Assay

5.6.1 Lactose Content in Non medicated lactose Tablets: It should not be less than 94% (w/w) by HPTLC.

5.6.2 Sugar content in Non-medicated sucrose Tablets: It should not be less than 99% of the claimed amount.

5.7 Insoluble Matter

It should not be more than 5% w/w as per the Solubility method in IP.

5.8 Binder and Lubricants

Binder and Lubricants both should be not more than 3% w/w.

5.9 Friability

Friability should be not more than 1% w/w as per the test methods for friability prescribed in IP Vol -1.

5.10 Hardness

Hardness should be not more than 4 kg.

5.11 Disintegration

Disintegration time should not be more than 3 min, as per the testing method mentioned in IP (Disintegration 2.5.1).

5.12 Uniformity of dispersion

Place 2 tablets in 100 ml water and stir gently until completely dispersed. A smooth dispersion is obtained which passes through a sieve screen with a nominal mesh aperture of 710 μm (sieve number 22).

5.13 Microbiological Test

Should have values as per the method prescribed in Indian Pharmacopoeia (2.2.9 Microbial contamination in Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use).

6. Shelf Life

A shelf Life of 3 years is recommended, subject to data as per in-house stability studies.

7. Packing and Marking

7.1 Packing

The material shall be packed in clean, sound and dry container made of metal, glass, and food grade polymers. The container shall be free from any fungal or insect infestation and should not impart any foreign smell. Each container shall be securely closed and sealed. They can also be packed in airtight plastic bags in secondary packaging of Cartons as per IS 10146: Polyethylene for its Safe Use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water. A leaflet containing instructions for use shall be enclosed with each packing.

7.2 Marking

The packaging shall be securely closed and marked with the following particulars, legibly and indelibly:

a) Size of tablets
b) Number of Tablets
c) Name and address of the manufacturer or packer including contact details;
d) Name of the material;
e) Net quantity;
f) Date of Manufacturing;

g) Date of packing;
h) Best before date;
i) Batch or code number;
j) QR Code for Authentication (Optional);
k) Trade-name or brand name, if any; and
l) 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.

7.3 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 thereunder, and the products may be marked with the Standard Mark.

8. Sampling

Representative samples of the material shall be drawn, and their conformity to this standard shall be determined.

9. Quality of Reagents

Unless specified otherwise, pure chemicals/analytical grade reagents and distilled water (see IS 1070) shall be used in tests.

Note: ‘Pure chemicals’ shall mean chemicals that do not contain impurities that affect the result of analysis.

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