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भारतीय मानक मसौदा

होम्योपैथी में प्रयोग हेतु शुगर ऑफ़ मिल्क — विशिष्टि

Draft Indian Standard

Sugar of Milk for use in Homoeopathy — Specification

Homoeopathy Sectional Committee, AYD 07 **Last Date of Comments: 16-02-2025**

Foreword

(Formal clauses would be added later)

In homoeopathy, lactose (often referred to as sugar of milk) is primarily used as a vehicle or medium for preparing and administering homoeopathic remedies. It plays a key role in the preparation of both the homoeopathic biochemic tablets and sometimes globules. It is the main ingredient for the process of trituration. It is essential as a neutral, inert carrier, ensuring the proper delivery and administration of homoeopathic remedies in a stable and palatable form. It plays a crucial role in making homoeopathic remedies accessible and effective for patients, particularly in the form of tablets and powdered doses, without having any direct medicinal effect itself.

Establishing standard parameters and specifications for sugar of milk used in homoeopathy is crucial to ensure its purity, consistency, and safety. By defining quality standards for sugar of milk, manufacturers can ensure that it serves as an inert and effective medium for homoeopathic remedies and does not interfere with the potency of the active substance, while also ensuring batch-to-batch consistency in the final product.

The standard is being brought out for the use of manufacturers and assurance to the researchers, practitioners, and patients that the quality of the drug dispensed is not compromised.

In formulating this standard, 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 Homoeopathic Pharmacopoeia of India and U.S., French, German, Indian, and other Pharmacopoeias.

Also, due consideration has been given to the provisions of the Drug 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 will be 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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Indian Standard

SUGAR OF MILK FOR USE IN HOMOEOPATHY — SPECIFICATION

1 SCOPE

This standard prescribes the requirements and the methods of test for sugar of milk used in Homoeopathic pharmacy.

2 REFERENCES

The standards listed in Annex A 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 these standards.

3 REQUIREMENT

3.1 Description

Sugar of milk is a disaccharide sugar present in milk, often referred to Lactose ($C_{12}H_{22}O_{11}.H_2O$, Mol Wt. 360.3). Milk is composed of proteins, fats, carbohydrates, mineral salts, and water, with lactose being a key solid component. It is obtained from the whey of milk of buffalo or cow or goat or sheep or camel or mixture thereof. Sugar of milk used in homoeopathy is derived from goat's milk. It is the most important solid vehicle in homoeopathy pharmacy.

3.2 Physical Characteristics

a. It shall be white or nearly white, crystalline powder, slightly sweet, nearly odourless, sandy or gritty on touch.
b. Insoluble in chloroform, and in ether.
c. Soluble in 5 parts of water, more soluble in hot water and very slightly soluble in alcohol (95 percent). Its solution in water shall not form a syrup.
d. Particle Size - The material shall pass 100 percent through a sieve size 250 µm and min 83 to 95 percent through a sieve size of 150 µm [see IS 460 (Part 1)].
e. Bulk and Tapped Density - To assess flow properties, measure and calculate the Hausner ratio according to Indian Pharmacopeia.

3.3 Hygiene Requirements – Sugar of milk shall be manufactured and handled under strict hygienic conditions as prescribed in IS 2491.

3.4 The material shall comply with the requirements given in Table 1 and Table 2.

Table 1 Requirements for Sugar of Milk

(*Clause* 3.4)

S.No.	Characteristic	Requirement	Method of Test (Reference)
(1)	(2)	(3)	(4)
i.	Sugar of milk (Lactose) (on dry basis), percent by mass, min.	99 percent (98 percent anhydrous base)	ISO 22662 or ISO 26462
ii.	Water content, percent by mass,	4.5 percent to 5.5 percent	ISO 12779
iii.	Sulphated ash (on dry basis), percent by mass	Not more than 0.1 percent.	Clause 10 of IS 15279
iv.	Optical rotation	Between 54.4 and 55.9	Annex B
v.	Nitrogen, % by mass	Maximum 0.05%	Clause 7 of IS 1479 (Part 2)
vi.	Arsenic (As), mg/kg	Not more than 1 ppm	IS 11124
vii.	Heavy metals	Not more than 5 µg/g	Annex C
	a. Lead (Pb), mg/kg	Not more than 1 ppm	IS 12074
viii	Loss on Drying	NMT 0.5%	Annex C
ix.	Acidity / Alkalinity	Not more than 0.4 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink to red.	Annex C
x.	Scorched particles, mg/25 g	15 (equivalent to Disc B)	IS 13500
xi.	TLC	Should Comply	IS 18108
xii.	Infrared Absorption Spectrophotometry	Should Comply	IS 12760
xiii.	Caramelization Test	The sample leaves a bulky, carbonaceous residue with a burnt sugar odor.	Annex C
xiv.	Copper Tartrate Test (Sodium or Potassium Cupri-Tartrate)	copious precipitate of cuprous oxide (Cu_2O)	Annex C
xv.	Ammoniacal Copper Test	red color should develop,	Annex C
xvi.	More Soluble Sugars Test:	residue Not more than 7 mg.	Annex C
xvii.	Protein and Light-Absorbing Impurities	Acceptable Absorbance Limits: • 400 nm (Test Solution a): Max 0.04. • 210-220 nm (Test Solution b): Max 0.25 for proteins. • 270-300 nm (Test Solution b): Max 0.07 for light-absorbing impurities.	Annex C
xviii.	Appearance of Solution (Purity Test)	The solution should be clear, colorless, and odorless, and it should match the reference BY7 for color intensity.	Annex D
	Impurities	absent	Annex E
xix	Starch		
xx	Alum		
xxi	Phosphate of Sodium		
xxii	Sodium Hydroxide		
xxiii	Sodium Chloride		
xxiv	Sulphuric Acid		
xxv	Copper		

Table 2 Microbiological Requirements for Sugar of Milk

(*Clause* 3.4)

Sl No.	Characteristic	Requirement				Method of test, Ref to
		Sampling Plan		Limit (cfu)		
		n	c	m	M	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
i.	Aerobic Plate Count	5	2	1 × 102 CFU/g	1 × 10^2 CFU/g	IS 5402 (Part 1)
ii.	Coliform Count	5	2	1/g	50/g	IS 5401 (Part 1)
iii.	*E. coli*	5	0	Absent/g	Absent	IS 5887 (Part 1)
iv.	*Staphylococcus aureus*	5	2	10/g	Absent	IS 5887 (Part 2)
v.	*Salmonella* sp.	5	0	Absent/ 25g	Absent	IS 5887 (Part 3)
vi.	*Bacillus cereus*	5	3	5 x 10^2/g	1 x 10^3 CFU/g	IS 5887 (Part 4)
vii.	Yeast and Mold Count	5	0	50/g	Absent	IS 5403
viii.	*Listeria monocytogenes*	5	0	Absent/g	Absent	14988 (Part 1)
ix.	Sulfite-Reducing *Clostridia*	5	3	50/g	1 x 10^2 CFU/g	ISO 15213

Note - Quality of Reagents

Unless specified otherwise, pure chemicals shall be employed in tests and distilled water (see IS 1070) shall be used where the use of water as reagent is intended.

'Pure chemicals' shall mean chemicals that do not contain impurities which affect the test results.

4 SHELF LIFE

A shelf life of 2 years is recommended, subject to data as per in-house stability studies.

5 SAMPLING

Representative samples of the product shall be drawn and tested for conformity to this standard as prescribed in IS 1000.

6 PACKING AND MARKING

6.1 Packing

6.1.1 *Retail Packing*

The product shall be packed in clean and sound metal containers (see IS 11078) or glass containers or inert plastic containers like PET and HDPE Jars (see IS 19084) or in a food grade flexible pack made from a film or combination of any of the substrates made of board, paper, polyethylene, polyester metalized film or aluminium foil in such a way so as to protect it from deterioration. In the case of the plastic material, only food grade plastic (see IS 10171) shall be used.

6.1.2 *Bulk Packing*

The product may be packed in quantities of 25 kg in bags of food grade polyethylene (see IS 10171) of minimum thickness 0.05 mm. The bags should be properly closed by sewing or heat

sealing and shall be subsequently encased in multi-walled kraft paper, such as crepe kraft paper bags of not less than 80 g/m2 (GSM) grade, appropriately lined and having two or more inner layers of plain kraft paper of not less than 80 g/m2 (GSM) grade.

6.2 Marking

6.2.1 The following information shall be marked legibly and indelibly on each container:

a) Name and address of the manufacturer or packer, including contact details;
b) Name of the material;
c) Net quantity;
d) Manufacturer's license no.;
e) Date of manufacturing;
f) Date of packing;
g) Direction for storage;
h) Best before ..... (month and year in capital letters);
   OR
   Best before ..... (months) from the date of packing/manufacture;
j) Batch or code number;
k) Trade name or brand name, if any; and
l) Any other information requested by the buyer.

7 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 product(s) may be marked with the Standard Mark.

Annex A
(Clause 2)

LIST OF REFERRED STANDARDS

IS No./ other standards	*Title*
IS 1070: 2023	Reagent grade water — Specification (*fourth revision*)
IS 2491 : 2024	Food Hygiene — General Principles — Code of Practice (fourth revision)
IS 460 (Part 1) : 2020	Test Sieves — Specification Part 1 Wire Cloth Test Sieves (fourth revision)
IS 12760 : 2012 /ISO 8070 : 2007	Milk and milk products - Determination of calcium, sodium, potassium and magnesium contents - Atomic absorption spectrometric method (First Revision)
IS 15279 : 2003	Sugar and sugar products — Methods of test
IS 1479 (Part 2): 1961	Methods of test for dairy industry: Part 2 Chemical analysis of milk
IS 11124 : 1984	Method for atomic absorption spectrophotometric determination of arsenic
IS 12074 : 1987	Method for Determination of lead by atomic Absorption spectrophotometer
IS 13500 : 1992	Spray dried milk powders scorched particles - Determination
IS 18108 : 2023/ ISO 14674 : 2005	Milk and Milk Powder — Determination of Aflatoxin M1 Content — Clean-Up by Immunoaffinity Chromatography and Determination by Thin-Layer Chromatography
IS 5402 (Part 1) : 2021/ISO 4833 - 1:2013	Microbiology of the food chain — Horizontal method for the enumeration of microorganisms: Part 1 Colony count at 30 °C by the pour plate technique (third revision)
IS 5401 (Part 1) 2012/ISO 4832 : 2006	Microbiology of food and animal feeding stuffs — Horizontal method for the detection and enumeration of coliforms: Part 1 Colony-count technique (second revision)
IS 5887	Methods for detection of bacteria responsible for food poisoning
(Part 1) : 1976	Isolation, identification and enumeration of Escherichia coli (first revision)
(Part 2) : 1976	Isolation, identification and enumeration of Staphylococcus aureus and faecal streptococci (first revision)

(Part 3) : 1999	General guidance on methods for the detection of Salmonella (second revision)
(Part 4) : 1999	Isolation and identification of clostridium perfringens (Clostridium Welchii) and clostridium botul inum and enumeration of clostridium perfringens (Second Revision)
IS 5403 : 1999/ISO 7954	Method for yeast and mould count of foodstuffs and animal feeds (first revision)
IS 14988 (Part 1) : 2020 /ISO 11290-1 : 2017	Microbiology of the food chain — Horizontal method for detection and enumeration of listeria monocytogenes and of listeria spp: Part 1 detection method (first revision)
IS 10171 : 1999	Guide on suitability of plastics for food packaging (Second Revision)
IS 1000 : 2021	Edible Lactose - Specification
IS 11078 : 2012	Round open top sanitary cans for milk powder -- Specification (Second Revision)
IS 19084 : 2024	Plastic Containers and Closure for Homoeopathic Pharmaceutical Preparations - Specification
ISO 12779 : 2011	Lactose — Determination of water content — Karl Fischer method
ISO 15213 : 2003	Microbiology of food and animal feeding stuffs — Horizontal method for the enumeration of sulfite reducing bacteria growing under anaerobic conditions
ISO 22662 : 2007	Milk and milk products — Determination of lactose content by high performance liquid chromatography (Reference method)
ISO 26462 : 2010	Milk – Determination of lactose content- Enzymatic method using difference in pH

Annex B

[Clause 3.4, Table 1, Sl No. (iv)]

DETERMINATION OF OPTICAL ROTATION

B-1 PROCEDURE

Accurately weigh 10.00 g of the sample and dissolve it in a beaker in about 60 ml water. Cover with a watch glass and boil for 15 min. Allow to cool, add a few drops of dilute ammonium hydroxide of specific gravity 0.96 and make up to 100 ml in a volumetric flask. Measure the optical rotation at 20 °C.

B-2 CALCULATION

B-2.1 Specific rotation, degree(s) = $100a/lc \times 100/w$

where

a = observed optical rotation, in degrees;

l = length of tube, in decimetres;

c = weight in g, of sample dissolved in 100 ml of water; and

w = percentage of Sugar of milk (lactose) in the material.

Annex C

(Clause 3.4, Table 1 Sl No. vii, viii, ix, xiii, xiv, xv, xvi, xvii)

HEAVY METALS, LOSS ON DRYING, ACIDITY OR ALKALITY AND IDENTIFICATION TEST

C-1 HEAVY METALS

E-1.1 Sample Solution: 4 g in 20 ml of warm water. Add 1 ml of 0.1 N Hydrochloric acid, and dilute with water to 25 ml.

C-1.2Acceptance criteria: NMT 5 µg/g

C-2 LOSS ON DRYING

C-2.1Analysis: Dry a sample at 80% for 2 h.

C-2.2Acceptance Criteria: NMT 0.5%

C- 3 ACIDITY OR ALKALITY

C-1 Sample solution: Dissolve 6 g by heating in 25 ml of carbon dioxide – free water, cool, and add 0.3 ml of phenolphthalein solution.

C-3.2 Acceptance criteria: Not more than 0.4 ml of 0.1 M sodium hydroxide is required to change the colour of the indicator to pink to red.

C-4 CARAMELIZATION TEST - When heated, it melts, swells and burns, evolving odour of burnt sugar and leaving bulky, carbonaceous residue.

C-5 COPPER TARTRATE TEST (Sodium or Potassium Cupri-Tartrate) - When heated with the sodium of potassium cupri – tartrate, a **copious precipitate** of **cuprous oxide (Cu_2O)** forms, indicating the presence of reducing sugars or substances that can reduce copper ions.

C-6 AMMONIACAL COPPER TEST - Dissolve 0.25 g in 5 ml water, add 5 ml ammonia, heat at 80 °C for 10 min. A red color should develop.

C-7 MORE SOLUBLE SUGARS – Shake 5.0 g with 20 ml of alcohol (90 percent) for ten minutes, filter, evaporate 10 ml of the filtrate to dryness and dry at 105°, the residue shall weigh not more than 7 mg.

C-7 PROTEIN AND LIGHT-ABSORBING IMPURITIES

a) ***Test solution (a)*** – Solution S.
b) ***Test solution (b)*** – Dilute 1.0 ml of test solution (a) to 10.0 ml with *water R*.
i) Spectral Range
- Test Solution (a) – 400 nm.

- Test Solution (b) – 210-300 nm for proteins and light-absorbing impurities.

ii) Acceptable Absorbance Limits

- 400 nm: Max 0.04 for test solution (a);
- 210-220 nm – Max 0.25 for solution b.
- 270-300 nm – Max 0.07 for solution b.

Annex D

(Clause 3.4 Table 1, Sl No. xviii)

Appearance of Solution (Purity Test)

D-1 Appearance of Solution

D-1.1 Solution S - Dissolve 3 g of sugar of milk in 10 ml boiling water.

D-1.2 Result - Solution S should be clear, colourless, odorless and match the reference BY_7 for colour intensity.

D-2 Visual method for color comparison

D-2.1 Purpose: To visually assess the color intensity of a liquid sample by comparing it to a reference standard.

D-2.2 Equipment:

- Identical glass tubes (15-25 mm internal diameter, flat base)
- Water R (purified water)
- Solvent used for sample preparation
- Reference solution (as table 2)
- White background

D-2.3 Procedure:

a. **Sample Preparation:**
   - Fill one tube with the liquid to be examined.
   - Fill another tube with either:
     - Water R (for a colorless reference)
     - The solvent used for sample preparation
     - The specified reference solution from the monograph

b. **Depth Adjustment:**
   - Ensure both tubes have a liquid depth of 40 mm.

c. **Visual Comparison:**
   - Place both tubes side-by-side against a white background under diffuse daylight.
   - View the tubes vertically, looking down their length.

- Visually compare the color intensity of the sample to the reference.

D-2.4 Interpretation:

- **Colorless:** The sample appears similar to water R or the solvent.
- **Colored:** The sample exhibits a color intensity comparable to the reference solution or a specific degree of color.

D-2.5 Standard and reference solution

Using the 3 primary solutions (YELLOW, RED, BLUE), prepare the BY standard solutions given table 3

Table 3 Standard Solution
(Clause D-2.5)

Standard Solution	Yellow Solution (ml)	Red Solution (ml)	Blue Solution (ml)	Hydrochloric Acid (10 g/L HCl) (ml)
BY (brownish-yellow)	2.4	1	0.4	6.2

D-2.6 Reference solutions for Method

Table 4 Reference Solutions BY
(Clause D-2.6)

Reference Solution	Volume of Standard Solution BY (ml)	Volume of 10 g/L HCl (ml)
BY_1	100	0
BY_2	75	25
BY_3	50	50
BY_4	25	75
BY_5	12.5	87.5
BY_6	5	95
BY_7	2.5	97.5

Annex E

(Clause 3.4 Table 1, Sl No. xix, xx, xxi, xxii, xxiii, xxv, xxvi)

TESTS FOR IMPURITIES

E-1 Starch Impurity:

i. Test: Add a solution of iodine to the aqueous solution of sugar of milk (lactose).
ii. Observation: If starch is present, the solution will turn blue.

E-2 Alum Impurity:

i. Test: Add a small amount of alkaline hydrate to the sugar of milk solution.
ii. Observation: The formation of a white precipitate indicates the presence of alum.

E-3 Phosphate of Sodium Impurity:

i. Test: Add silver ammonia nitrate solution to the sugar of milk solution.
ii. Observation: A yellow precipitate will form, which will dissolve when cold dilute nitric acid is added, indicating the presence of phosphate of sodium.

E-4 Reaction with Sodium Hydroxide:

i. Test: Heat a hot saturated aqueous solution of sugar of milk with an equal volume of sodium hydroxide.
ii. Observation: The solution will turn yellow and then brownish-red. On adding a few drops of cupric sulfate, copper is reduced, and a red precipitate of cuprous oxide forms, confirming the presence of reducing sugars.

E-5 Sodium Chloride Impurity:

i. Test: Add silver nitrate solution to the sugar of milk solution.
ii. Observation: The formation of a precipitate that is insoluble in nitric acid indicates the presence of sodium chloride.

E-6 Sulphuric Acid Impurity:

i. Test: Add barium nitrate or chloride solution to the sugar of milk solution.
ii. Observation: The formation of a precipitate confirms the presence of sulphuric acid.

E-7 Acidity Test:

i. Test: Dip blue litmus paper into an aqueous solution of sugar of milk.
ii. Observation: If the litmus paper turns red, it indicates the presence of acidity, which may suggest that the milk sugar was prepared from milk that had become sour.

E-8 Copper Impurity (from Copper Vessel):

i. Test: Add potassium ferrocyanide solution to the aqueous solution of sugar of milk.
ii. Observation: The formation of a reddish-brown precipitate indicates the presence of copper.