*भारतीय मानक*

***Indian Standard***

**IS 19085 : 2024**

# होम्योपैथिक औषधियों के लिए ग्लास कंटेनर — विशिष्टि

# Glass Containers for Homoeopathic Pharmaceutical Preparations — Specification

ICS 11.120.99



भारतीय मानक ब्यूरो
BUREAU OF INDIAN STANDARDS
मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI - 110002
www.bis.gov.in www.standardsbis.in

**November 2024** **Price Group 7**

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.

Homoeopathic drugs are traditionally prepared, stored and dispensed in glass containers. Over the years, the strength and chemical properties, including leaching and sterilization, are key considerations affecting the safety, identity, strength, quality, or purity of the glass used for packaging, storage and dispensing of homoeopathic medicines.

Given the present scenario of the globalization of homoeopathic products, there is a need for standards for glass containers that should be followed by the homoeopathic industry to ensure the quality, safe storage, transportation and dispensing of drugs.

This document stipulates the specifications for homoeopathic pharmaceutical glass containers for primary packaging and dispensing of different dosage forms, including mother tinctures, dilutions and tablets.

In the formulation of this standard, due weightage has been given to the international standards and practices prevailing in different countries in addition to the practices followed by the homoeopathic industry in India. Assistance has also been derived from the Indian and United States Pharmacopoeia, including print and electronic media, while preparing these standards. The relation with the corresponding class of glass defined in the Indian Standards and the type as defined in IP/USP is given in Annex E.

The composition of the Committee responsible for the formulation of this standard is given in Annex F.

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*

# GLASS CONTAINERS FOR HOMOEOPATHIC PHARMACEUTICAL PREPARATIONS — SPECIFICATION

## 1 SCOPE

This standard prescribes the materials, requirements and testing methods of glass bottles used for different dosage forms in homoeopathy.

This document applies to phials, drop-dispensing glass bottles and screw-neck glass bottles used in homoeopathic pharmacies. Together with the corresponding closure systems, they are used for packaging and dispensing of homoeopathic pharmaceutical preparations in solid and liquid dosage forms.

## 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 TERMINOLOGY

For this document, the following terms and definitions shall apply.

**3.1 Phials** — Small cylindrical glass container, usually with plastic closures, colourless and used for dispensing homoeopathic preparations in solid and liquid forms.

**3.2 Drop-Dispensing Glass Bottles** — Amber-coloured glass container with a dropper plug and plastic closure, generally used for storing and dispensing homoeopathic dilutions.

**3.3 Screw-Neck Glass Bottles for Liquid** — Amber-coloured glass container with a stopper or dropper plug and plastic or metal closure, generally used for storing and dispensing syrups, mother tincture and other liquid homoeopathic preparations.

**3.4 Screw-Neck Glass Bottles for Solid** — Broad-mouthed amber-coloured glass container with plastic or metal closure, generally used for storing dry homoeopathic tablets and other homoeopathic preparations.

## 4 REQUIREMENTS

### 4.1 Material

Containers shall be made of clear or amber-coloured neutral glass of Type III or better (*see* Annex E).

NOTE — The selection of containers should be based on the suitability of the glass type for pharmaceutical products.

### 4.2 Dimension, Capacity and Neck Finish

The dimensions, capacity and neck finish of the containers shall generally conform to Table 1 or as mutually agreed between the purchaser and the supplier.

**Table 1 Dimension, Capacity and Neck Finish for Glass Bottle**

(*Clause* 4.2)

| SI No. | Glass Bottle Type | Dimension and Capacity | Neck Finish |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Phials | **3.1** of IS/ISO 11418-7 | |
| ii) | Drop-dispensing glass bottles | **4.1** of IS/ISO 11418-1 | |
| iii) | Screw-neck glass bottles for liquid | **4.1** of IS/ISO 11418-2 | Annex A of IS/ISO 11418-2 |
| iv) | Screw-neck glass bottles for solid | **4.1** of IS/ISO 11418-3 | Annex A of IS/ISO 11418-3 |

### 4.3 Annealing

The container shall be well annealed and shall not reveal any strain beyond what is shown by strain disc No. 4, when tested as per the method prescribed in IS 9153.

### 4.4 Closures

The bottles shall be equipped with a pilfer-proof cap made from aluminum, suitable plastic (*see* AYD/07/23521), or a combination of plastic and metal (*see* IS 8932). These closures shall form a liquid-tight seal with the threaded neck of the bottle, ensuring product integrity. As needed, the cap shall include a screw cap with a dropper plug for easy dispensing, a standard screw cap and various stoppers, such as inner plugs, designed to enhance usability and prevent leakage or contamination, as agreed upon by the purchaser and the manufacturer.

### 4.5 General Requirements/Characteristics

a) Containers shall have a smooth surface without cracks, pinholes, or sharp edges;

b) The containers shall be free from cords, blisters and stones and, as far as possible, from loading marks;

c) The glass containers shall be manufactured in compliance with good manufacturing practices (GMP);

d) The containers shall be well-formed with a uniform distribution of glass all over the walls and the base, avoiding any wedge bottom;

e) When placed on a horizontal plane, the containers shall rest evenly; and

f) Containers shall be pre and final rinsed through demineralized water/purified water and then air-dried or vacuum-dried properly so that the strength of the medicine is not affected on filling.

## 5 TESTS

### 5.1 Hydrolytic Resistance of Glass Grains (Glass Grain Test)

When tested and classified as per the method prescribed in IS 2303 (Part 1/Sec 2)/ISO 720, the glass shall meet the requirements of class HGA 2 or better.

### 5.2 Hydrolytic Resistance of the Inner Surface of Glass Containers (Surface Test)

When tested and classified as per the method prescribed in IS 2303 (Part 2)/ISO 4802-1, the glass shall meet the requirements of class $HC_T$ 3 or better.

### 5.3 Etching Test

To determine whether the container has been surface treated, testing shall be done according to 5.2. When tested, the sample shall not show signs of surface treatment.

### 5.4 Functionality Test

**5.4.1** *Spectral Transmission for Coloured Glass Container* (*Amber-Coloured*)

Spectral transmission for coloured glass containers shall not exceed 10 percent at any wavelength in the range of 290 nm to 450 nm using a UV-Visible spectrophotometer as prescribed in Annex B. This is independent of the type and capacity of the glass container.

**5.4.2** *Vertical Load Resistance*

The resistance to vertical load shall be tested in accordance with IS 11539/ISO 8113. The value shall be as declared by the manufacturer.

**5.4.3** *Thermal Shock Test*

When tested by Method A (range) as per IS 11930/ISO 7459, the bottles shall pass the test, with the temperature difference range of 45 °C. The sample shall be considered to have satisfied the test requirements, if the bottles show no visible crack after the test.

**5.4.4** *Leaching*

When tested for leaching as per IS 9806, extractable elements lead and cadmium shall not be observed.

**5.4.5** *Weathering* (*Optional Test*)

The test shall be performed as per Annex C.

NOTE — Quality of reagents:

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

## 6 SAMPLING

Representative samples of the material shall be drawn and tested for conformity to this specification as prescribed in Annex D.

## 7 PACKING

**7.1** The containers shall be packed as agreed to between the purchaser and the supplier. It is also crucial to protect the bottles from external contaminants during transport and storage.

**7.2** The container shall be packed as per IS 6945 using a thermoform or an automatic packaging machine after being sterilized in the sterilization plant using ethylene oxide or gamma radiations (wherever required).

## 8 MARKING

**8.1** Each container, except those of a very small size, shall be permanently and legibly marked on its bottom with the manufacturer's name and registered trademark.

**8.2** The following particulars shall be marked legibly on the package:

a) Name and address of the manufacturer or packer, including contact details;

b) Manufacturer's license no.;

c) Name of the material type;

d) Nominal capacity of the container

e) Lot no. or year of manufacture;

f) Date of packing;

g) Batch or code number;

h) Trade name or brand name, if any; and

j) Any other information required by the purchaser or statutory regulations.

## 9 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* 2)

## LIST OF REFERRED STANDARDS

| *IS No.* | *Title* |
|---|---|
| IS 1070 : 2023 | Reagent grade water — Specification (*fourth revision*) |
| IS 2303 | Grading glass for alkalinity |
| (Part 1/Sec 2) : 2021/ISO 720 : 2020 | Hydrolytic resistance of glass grains, Section 2 Determination and classification of hydrolytic resistance at 121 °C (*third revision*) |
| (Part 2) : 2018/ ISO 4802-1 : 2016 | Hydrolytic resistance of glass containers — Determination by titration method and classification (*second revision*) |
| IS 6945 : 1973 | Code of practice for packaging glass and glassware |
| IS 8932 : 1978 | Specification for preformed metal screw caps for glass containers |
| IS 9153 : 2023 | Methods of polariscopic examination of glassware (*first revision*) |
| IS 9806 : 2001 | Methods of test for and permissible limits of toxic materials released from ceramicware, vitreous enamelware, glassware and glass-ceramicware in contact with food (*first revision*) |
| IS 11539 : 2018/ ISO 8113 : 2004 | Method of vertical load test for glass containers (*first revision*) |
| IS/ISO 11418-1 : 2016 | Containers and accessories for pharmaceutical preparations Part 1 Drop-dispensing glass |
| IS/ISO 11418-2 : 2016 | Containers and accessories for pharmaceutical preparations Part 2 Screw-neck glass bottles for syrups |
| IS/ISO 11418-3 : 2016 | Containers and accessories for pharmaceutical preparations Part 3 Screw-neck glass bottles (Veral) for solid and liquid dosage forms |
| IS/ISO 11418-7 : 2016 | Containers and accessories for pharmaceutical preparations Part 7 Screw-neck vials made of glass tubing for liquid dosage forms |
| IS 11930 : 2018/ ISO 7459 : 2004 | Glass containers — Thermal shock resistance and thermal shock endurance — Test methods (*first revision*) |
| AYD/07/23521 | Plastic containers and closures for homoeopathic pharmaceutical preparations — Specification |

## ANNEX B

(*Clause* 5.4.1)

## SPECTRAL TRANSMISSION FOR COLOURED GLASS CONTAINER

### B-1 APPARATUS

**B-1.1** A UV-Visible spectrophotometer is required. It should be equipped with either a photodiode detector or a photomultiplier tube coupled with an integrating sphere.

**B-1.2** Circular saw fitted with a wet abrasive wheel to shape the glass

**B-1.3** Opaque paper or tape if required

**B-1.4** Lens tissue to clean the glass

**B-1.5** Mounting wax

### B-2 PREPARATION

**B-2.1** Break and cut the glass using a circular saw and select sections that qualify to represent the correct thickness. Trim these selections to become suitable for mounting.

**B-2.2** Wash and dry the specimens and wipe them with lens tissue.

**B.2.3** Mount the specimen in a holder using wax; take the aid of opaque paper or tape if the specimen may be too small for the slit.

### B-3 METHOD

**B-3.1** Mount the specimen such that its cylindrical axis is parallel to the slit and the light beam falls perpendicularly to the surface of the section to keep losses to reflection at a minimum.

**B-3.2** Measure the transmission of the specimen with reference to air in the spectral region of 290 nm to 450 nm, continuously or at intervals of 20 nm.

### B-4 LIMIT

Observed spectral transmission for coloured glass containers for products intended for non-parenteral use does not exceed 10 percent at any wavelength in the range of 290 nm to 450 nm, irrespective of the type and capacity of the glass container.

## ANNEX C

(*Clause* 5.4.5)

## WEATHERING TEST

**C-1** The weathering test of glass is conducted to evaluate its durability and performance under prolonged exposure to environmental factors such as sunlight, moisture, temperature fluctuations and other weathering conditions simulating the real-world behaviour and lifespan of the glass in outdoor environments, helping to assess its resistance to degradation, fading and other forms of deterioration. The test evaluates the potential of a drug product to cause the formation of glass particles and delamination.

**C-2** A key phenomenon observed during weathering is the repeated hydration and dehydration of the gel layer, which leads to cracking and the generation of particles. This process worsens as the gel layer thickens and it is especially pronounced in glass exposed to ambient moisture, contributing to its degradation over time. At higher *p*H values, the mechanism of glass degradation changes from the leaching of alkali elements to the dissolution of the silicate network. Surface glass test (*see* 5.2) represents only a first step in quality control of surface durability and additional screening methods should be used to demonstrate the suitability of containers for a formulation from a particular source before formal stability studies begin. The analytical screening methods for evaluating the three key parameters are shown in Table 2.

**Table 2 Analytical Methods for Screening Studies**

(*Clause* C-3)

| SI No. | Parameter | Test Parameter | Analytical Method |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Glass Surface | Degree of surface pitting<br>Chemical composition as a function of depth | DIC Microscopy[a] or EM[b]<br>SIMS[c] |
| ii) | Extracted elements in solution | a) Conductivity/*p*H<br>b) Individual or total extractables:<br>1) $SiO_2$ concentration<br>2) $SiO_2/B_2O_3$ or Si/Al ratio | Conductivity/*p*H meter<br>IC-MS[d] or ICP-OES[e] |
| iii) | Visible and sub visible glass particles | Particle number and size<br>Particle morphology and composition | Particle size analyzer<br>SEM-EDX[f] |

The exposure conditions are too harsh and do not provide a direct link to the product itself. In these instances, accelerated conditions are still relevant, but they must link to the relevant conditions for the given product. For example, if a product will be stored at 5° and accelerated conditions are 30°, then testing should occur at 30°. Many products or formulations cannot withstand the elevated temperatures.

To assess the suitability of a glass container for a specific product under aggressive conditions, testing must be conducted at lower temperatures. As a result, the testing duration needs to be extended, typically ranging from weeks to months.

[a] Differential interference contrast microscopy.

[b] Electron microscopy.

[c] Secondary ion mass spectroscopy.

[d] Inductively coupled plasma-mass spectrometry.

[e] Inductively coupled plasma-optical emission spectrometry.

[f] Scanning electron microscopy-energy-dispersive X-ray spectroscopy.

## ANNEX D

(*Clause* 6)

## SAMPLING OF GLASS CONTAINERS

### D-1 SCALE OF SAMPLING

#### D-1.1 Lot

In any consignment, all the containers of the same type and nominal capacity belonging to the same batch of manufacturers shall be grouped together to constitute a lot.

**D-1.2** The samples shall be tested from each lot to ascertain the containers' conformity to the requirements of this specification (Table 3).

**D-1.3** In order to ensure the randomness of the selection, random number tables shall be used. If such tables are unavailable, the following procedure is recommended: Starting from any container in the lot, count them 1,2,3..... up to r and so on. Every $r^{th}$ container thus counted shall be chosen, r being an integral part of N/n, where N is the total number of containers in the lot and n is the number of containers to be selected.

**D-1.3.1** *Stage* 1

In the first stage take 30 sample containers at random. Each of these 30 containers shall be tested for these requirements. If the number of defectives is found to be equal to or exceeds the rejection number corresponding to the first stage in Table 3 (that is 4), reject the lot without further testing; otherwise, proceed to the second stage.

**D-1.3.2** *Stage* 2

In the second stage take another 30 containers at random from the sample containers. Test them for these requirements and add the number of defectives to those found previously. If the total number of defectives in the cumulative sample (30 of the first stage + 30 of the second stage, that is 60) is found to be equal to or less than the corresponding acceptance number given in Table 3 (which is three for the second stage), accept the lot; if it is equal to or greater than the corresponding rejection number given in Table 3 (which is seven for the second stage), reject the lot; if it is between the acceptance number and the rejection number, proceed to the third stage.

**D-1.3.3** *Stages* 3 *to* 5

The procedure for the third and subsequent stages, if any, shall be the same as for the second stage till the decision to accept or reject the lot is reached.

### D-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

**D-2.1** Take two of the sample containers and test them for hydrolytic resistance according to the method given in **5.1**, **5.2**, **5.3**. If one or both containers fail the test, the lot shall be rejected without further testing. If both the containers pass the test the remaining sample containers shall undergo further testing.

**D-2.2** From the remaining sample containers, 10 containers shall be selected and tested for spectral transmission for coloured glass containers (amber-coloured). If the number of containers failing the spectral test is two or more, the lot shall be rejected without further testing. If the number of containers failing the spectral test is one or nil, further tests shall be carried out on the remaining sample containers, including those that passed the Spectral test.

**Table 3 Criteria for Conformity at Different Stages in Testing for Requirements Other than Hydrolytic Resistance and Thermal Endurance Test**

(*Clause* D-1.2, D-1.3.1 *and* D-1.3.2)

| SI No. | Stage | Sample Size | Cumulative Sample | | |
|---|---|---|---|---|---|
| | | | Size | Acceptance Number | Rejection Number |
| (1) | (2) | (3) | (4) | (5) | (6) |
| i) | First | 30 | 30 | 0 | 4 |
| ii) | Second | 30 | 60 | 3 | 7 |
| iii) | Third | 30 | 90 | 6 | 9 |
| iv) | Fourth | 30 | 120 | 8 | 10 |
| v) | Fifth | 30 | 150 | 10 | 11 |

**D-2.3** From the remaining sample containers, 10 containers shall be selected and tested for vertical load resistance as per the methods prescribed in IS 11539/ISO 8113. If the number of containers failing the vertical load resistance test is two or more, the lot shall be rejected without further testing. If the number of containers failing the vertical load resistance test is one or nil, further tests shall be carried out on the remaining sample containers, including those that passed the vertical load resistance test.

**D-2.4** From the remaining sample containers, 10 containers shall be selected and tested for thermal endurance. If the number of containers failing the thermal endurance test is two or more, the lot shall be rejected without further testing. If the number of containers failing the thermal endurance test is one or nil, further tests shall be carried out on the remaining sample containers, including those that passed the thermal endurance test.

**D-2.5** From the remaining sample containers, 10 containers shall be selected and tested for Leaching of extractable elements lead and cadmium as per IS 9806.

**D-2.6** From the remaining sample containers, 10 containers shall be selected and tested for weathering test (if required) as per the methods prescribed in Annex C.

**D-2.7** Requirements other than the above Tests A sample container failing in one or more of these requirements shall be called defective.

## ANNEX E

(*Foreword* and *Clause* 4.1)

## GLASS TYPES AND THEIR CORRESPONDING HYDROLYTIC RESISTANCE CLASS

**Table 4 Glass Types and Their Corresponding Hydrolytic Resistance Class**

| SI No. | IP/USP Glass Type | Hydrolytic Resistance Grains Class (Autoclave Method) | Hydrolytic Resistance Container Class (Titration Method) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| i) | Type I | HGA 1 | $HC_T$ 1 |
| ii) | Type II | HGA 2 | $HC_T$ 2 |
| iii) | Type III | HGA 2 | $HC_T$ 3 |

## ANNEX F

(*Foreword*)

## COMMITTEE COMPOSITION

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(AYUSH), BIS

Working Group for Plastic and glass containers and closures, AYD 07/WG 05

| *Organization* | *Representative(s)* |
|---|---|
| Dr BR Sur Homoeopathic Medical College, Hospital and Research Centre, New Delhi | DR NEERAJ GUPTA **(*Convener*)** |
| Bakson Drugs and Pharmaceuticals Private Limited, Greater Noida | DR MUDITA ARORA |
| BJain Pharmaceuticals Private Limited, Noida | DR PRIYANKA MOTWANI |
| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | DR BINIT DWIVEDI |
| Dr DP Rastogi Central Research Institute for Homoeopathy, Noida | MS ANAMIKA KOTIYA |

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**BUREAU OF INDIAN STANDARDS**

**Headquarters:**

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
*Telephones*: 2323 0131, 2323 3375, 2323 9402 *Website*: www.bis.gov.in

| **Regional Offices:** | | *Telephones* |
|---|---|---|
| Central | : 601/A, Konnectus Tower -1, 6th Floor, DMRC Building, Bhavbhuti Marg, New Delhi 110002 | 2323 7617 |
| Eastern | : 8th Floor, Plot No 7/7 & 7/8, CP Block, Sector V, Salt Lake, Kolkata, West Bengal 700091 | 2367 0012<br>2320 9474 |
| Northern | : Plot No. 4-A, Sector 27-B, Madhya Marg, Chandigarh 160019 | 265 9930 |
| Southern | : C.I.T. Campus, IV Cross Road, Taramani, Chennai 600113 | 2254 1442<br>2254 1216 |
| Western | : 5th Floor/MTNL CETTM, Technology Street, Hiranandani Gardens, Powai Mumbai 400076 | 25700030<br>25702715 |

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