भारतीय मानक

Indian Standard

IS 4006 (Part 1) : 2024

होम्योपैथिक औषधियों के लिए प्लास्टिक कंटेनर और क्लोजर — विशिष्टि

Plastic Containers and Closures for Homoeopathic Pharmaceutical Preparations — Specification

ICS 11.120.99

भारतीय मानक ब्यूरो
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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.

Plastic containers are widely used for packing, dispensing and storing homoeopathic preparations. However, the physio-chemical properties of the packaging material, particularly the leaching properties, are key considerations for drug quality, particularly in terms of long-term storage and dispensing of drugs.

There is a high demand for standards of plastic containers and closures for pharmaceutical use in homoeopathy. This standard prescribes the required materials and testing of plastic containers together with the corresponding closure systems for the packaging and dispensing of homoeopathic pharmaceutical preparations in different dosage forms. However, this standard does not deal with the specifications of the types of resin. Therefore, if needed, the plastic materials specified in this standard may be tested as per the relevant monographs in the Indian pharmacopoeia and USP.

The international standards and practices prevailing in different countries, in addition to the practices followed by the homoeopathic industry in India, are duly consulted during its preparation. Inputs have also been derived from the information available in the public domain in print and electronic media, including Indian Pharmacopoeia and USP.

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

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

PLASTIC CONTAINERS AND CLOSURES FOR HOMOEOPATHIC PHARMACEUTICAL PREPARATIONS — SPECIFICATION

1 SCOPE

This standard prescribes the materials, requirements, sampling methods and testing of plastic containers (phials, bottles and jars) and closures (screw caps, droppers and stoppers) used for storing and dispensing different dosage forms in homoeopathy.

This document is applicable to Phials, Jars, Drop-dispensing and Screw-neck plastic bottles for liquid and solid preparations used in Homoeopathy. 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 standard, apart from definitions given in IS 2828 and IS 7019, the following terms and definitions shall apply.

3.1 Plastic Container — A receptacle that holds an intermediate compound, active pharmaceutical ingredient, excipient, or dosage form and is in direct contact with the article (for example, phials, bottles and jars).

3.2 Plastic Closure — A material that seals an otherwise open space of a container and provides protection for the contents. It also provides access to the contents of the container (for example, screw caps, droppers and stoppers).

3.3 Phial — A phial is a small cylindrical plastic container with plastic closure that is frequently used to hold and dispense homoeopathy preparations in solid and liquid forms.

3.4 Screw Neck Plastic Bottle — A semitransparent, opaque, milky, or amber-coloured plastic container with a stopper and plastic or metal closure, generally used for storing and dispensing syrups and other liquid homoeopathic preparations.

3.5 Drop-Dispensing Plastic Bottle — A semitransparent, opaque, milky, or amber-coloured plastic container with a dropper plug or tip plug and plastic closure, generally used for dispensing liquid homoeopathic preparations.

3.6 Wide-Mouth Plastic Bottles — A semitransparent, opaque, milky, amber-coloured plastic container with plastic or metal closure, generally used for dispensing biochemic tablets or other solid homoeopathic preparations.

3.7 Jar — A transparent, milky, or amber-coloured plastic container with plastic closure, generally used for storing solid homoeopathic preparations.

4 REQUIREMENTS

4.1 Material

The material used for plastic containers and closures shall be pharmaceutical grade polyethylene (PE), including subcategories, high-density polyethylene (HDPE) and low-density polyethylene (LDPE), conforming to IS 7328 (any constituents, if added shall conform to IS 16738) or polyethylene terephthalate (PET) conforming to IS 12252 or polypropylene (PP) conforming to IS 10951.

4.1.1 *Plastic Container*

Material used for the different types of plastic containers shall be as per Table 1.

4.1.2 *Plastic Closures*

The material used for the different types of plastic closures shall be as per Table 2.

4.2 Pigments and Colorants

In case pigments and colorants are used, they shall comply with IS 9833.

4.3 Capacity

4.3.1 The capacity of containers shall generally conform to Table 3 or as mutually agreed between the purchaser and the supplier.

4.3.2 The brimful capacity of the bottle shall exceed the normal capacity by a minimum of 5 percent. The brimful capacity shall be determined by the method prescribed in IS 2798.

Table 1 Materials for Plastic Containers

(*Clause* 4.1.1)

SI No.	Container Type	Material
(1)	(2)	(3)
i)	Phials	HDPE
ii)	Bottles (Screw neck/Drop-dispensing/Wide-mouth)	HDPE, PET, or PP
iii)	Jar	HDPE or PET

NOTE — Drop-dispensing plastic bottles shall be leak-proof self-sealing dropper bottles.

Table 2 Material for Plastic Closures

(*Clause* 4.1.2)

SI No.	Closure Type	Material
(1)	(2)	(3)
i)	Caps (Screw cap or cap with nozzle)	HDPE or PP
ii)	Stoppers	LDPE
iii)	Droppers	LDPE

NOTE — The stopper/dropper shall form a liquid-tight seal with the bottleneck. Dropper insert flow rates refer to the speed at which droplets are dispensed. The first drop dispensed shall take 2 s to 5 s and after that, it shall take 1 s to 3 s.

Table 3 Nominal Capacity of Homoeopathic Plastic Container

(*Clause* 4.3.1)

SI No.	Container Type	Nominal Capacities
(1)	(2)	(3)
i)	Phial	½ dram, 1 dram, 2 dram, 4 dram, 6 dram
ii)	Bottle:	
	1) Screw neck or Drop-dispensing plastic bottle; and	5 ml, 10 ml, 15 ml, 30 ml, 50 ml, 100 ml, 500 ml
	2) Wide-mouth plastic bottle.	½ ounce, 1 ounce, 2 ounce
iii)	Jar	500 ml, 1 000 ml, 2 000 ml, 5 000 ml

NOTE — 1 dram = 3.7 ml, 1 ounce = 29.57 ml.

4.4 Design, Shape and Dimension

The containers and closures shall be of a suitable design, shape and dimensions as mutually agreed to between the purchaser and the supplier.

4.5 Odour

Containers and closures shall be free from any odour.

4.6 Mass

The mass of the container shall be as agreed to between the purchaser and the supplier.

4.7 Overall Migration

Overall migration shall be NMT 60 mg/kg or 10 mg/dm^2. The overall migration of constituents of plastic material shall be determined as per IS 9845.

4.8 Wall Thickness

The wall thickness shall be declared by the manufacturer. The wall thickness, when measured in accordance with 4.5 of IS 2798, shall be within ± 2 percent of the declared value.

4.9 Workmanship and Finish

a) Containers and closures shall be manufactured by a suitable process adhering to Good Manufacturing Practice (GMP);

b) The body of the container shall be free from any visual defects like cavities, crevices, flaws, or stains;

c) The containers and closures be free from residual plastics burr or free particles generated during manufacturing;

d) Containers and closures shall be free from dirt, dust particles, etc; and

e) 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 PERFORMANCE TESTS

5.1 Environmental Stress – Crack Resistance

The containers shall pass the test when tested in accordance with Method I of IS 8747 and shall show no evidence of environmental stress-crack failure.

5.2 Leakage Test

The containers shall pass the test when tested in accordance with **6** of IS 2798.

5.3 Drop Impact Test

The containers shall pass the test when tested in accordance with **8** of IS 2798.

5.4 Collapsibility Test

A container shall, by collapsing inwards during use, yield at least 90 percent of its nominal contents at the required rate of flow at ambient temperature.

NOTE — This test is applicable when the containers are of squeeze-bottle type.

5.5 Compatibility Test

Method of test for compatibility of containers shall be as prescribed in **12** of IS 2798.

5.6 Container Material Test

These tests shall be performed only on material obtained from containers before filling as prescribed in **4.3** of IS 7803.

5.7 Verticality test

The variation in verticality, when tested according to the method given in **7** of IS 2798, shall not be more than ± 1.5 mm.

5.8 Transparency

The transparency of a container shall not be less than 85 percent in light transmittance, when tested in accordance with the method as prescribed in Annex A of IS 15410.

NOTE — This test is applicable for transparent bottles only.

5.9 Stack Load Test

The containers shall be of sound construction and shall not show any cracks or permanent buckling when subjected to testing according to the method given in **9** of IS 2798.

6 PACKING

6.1 The containers shall be packed in acceptable outer packages as agreed to between the purchaser and the supplier. Only containers of the same nominal capacity and bearing the same batch identification shall be packed together in one package. Additionally, it is crucial to ensure that the bottles remain protected from external contaminants during transport.

6.2 The phials/droppers/stoppers/caps shall be packed by using Thermoform or an automatic packaging machine after sterilizing (wherever required) in a sterilization plant using Ethylene oxide or Gamma radiations.

7 MARKING

7.1 Each container, except in case of very small size, shall be permanently and legibly marked with the following:

a) Name of material;

b) Nominal capacity; and

c) Recycling symbol, as per IS 14534.

7.2 The packing slip in each package shall be marked with the following:

a) Name and/or trademark of the manufacturer;

b) Nominal capacity;

c) Batch no.; and

d) Homoeopathy use only.

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

8 SAMPLING

The method of drawing a representative sample from a lot and the determination of criteria of conformity of a lot to requirements of this specification shall be as per Annex B.

ANNEX A

(*Clause* 2)

LIST OF REFERRED STANDARDS

IS No.	*Title*
IS 2798 : 1998	Methods of test for plastics containers (*first revision*)
IS 2828 : 2019/ ISO 472 : 2013	Plastics — Vocabulary (*second revision*)
IS 4905 : 2015/ ISO 24153 : 2009	Random sampling and randomization procedures (*first revision*)
IS 7019 : 1998	Glossary of terms in plastics and flexible packaging, excluding paper (*second revision*)
IS 7328 : 2020	Specification for polyethylene material for moulding and extrusion (*third revision*)
IS 7803 (Part 1) : 1975	Specification for plastic containers for pharmaceutical use: Part 1 Other than parenteral and ophthalmic preparations
IS 8747 : 1977	Methods of test for environmental stress-crack resistance of blow-moulded polyethylene containers
IS 9833 : 2018	List of colourants for use in plastics in contact with foodstuffs and pharmaceuticals (*second revision*)
IS 9845 : 1998	Determination of overall migration of constituents of plastics materials and articles intended to come in contact with foodstuffs — Method of analysis (*second revision*)
IS 10951 : 2020	Specification for polypropylene (PP) materials for moulding and extrusion (*second revision*)
IS 12252 : 2017	Polyalkylene terephthalates (PET and PBT), their copolymers and list of constituents in raw materials and end products for their safe use in contact with foodstuffs and pharmaceuticals (*first revision*)
IS 14534 : 2023	Plastics — Recovery and recycling of plastics waste — Guidelines (*second revision*)
IS 15410 : 2003	Containers for packaging of natural mineral water and packaged drinking water — Specification
IS 16738 : 2018	Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals

ANNEX B

(*Clause* 8)

SAMPLING

B-1 SCALE OF SAMPLING

B-1.1 Lot

In any consignment, all the bottles of the same material nominal capacity and drawn from a single batch of manufacture shall be grouped together to constitute a lot.

B-1.2 Scale of Sampling

For ascertaining the conformity of the lot to the requirement of this standard, test shall be carried out for each lot separately. The number of bottles to be sampled from a lot shall be in accordance with Table 4.

B-1.3 The bottle shall be selected at random from the lot. To ensure the randomness of selection, methods given in IS 4905 may be followed.

B-2 CRITERIA FOR CONFORMITY

B-2.1 Visual Examination

The sample bottles selected as per col (2) of Table 4 shall be examined for manufacturing conditions (*see* **4.9**). Any containers failing in one or more of the requirements shall be termed as defective. The lot shall be accepted under this head if the number of defective bottles in the sample does not exceed the acceptance number given in col (3) of Table 4.

B-2.2 Brimful Capacity, Bottle Mass

For the purpose of the above tests, five bottles for lot sizes up to 5 000 and 10 bottles for lot sizes above 5 000 shall be selected at random from the samples already drawn according to **B-1.3**. Each of the sample bottles shall be subjected to tests for brimful capacity and bottle mass. There shall be no failure if the lot is to be accepted under this clause.

B-2.3 Test for Transparency and Leakage Test

The number of sample bottles to be drawn shall be in accordance with col (4) of Table 4. Each of the sample bottle shall be subjected to closure leakage test. The number of failures shall not exceed the acceptance number given in col (5) of Table 4.

B-2.4 Drop Impact, Collapsibility and Compatibility, Stack Load Test

One set of sample bottles as given in the test methods (*see* **5.3**, **5.4**, **5.5**, **5.9**) shall be drawn from the lot and these shall be subjected to the respective tests. The sample shall pass the tests for acceptance of the lot in respect of drop impact, Collapsibility, Compatibility and stacking requirement.

B-2.5 The sub-sample of size given in col (8) of Table 4 shall be subjected to overall height and diameter, wall thickness and verticality. No failure shall occur for acceptance of the lot under this clause.

B-2.6 Container Material Test

The number of sample bottles to be drawn shall be in accordance with col (6) of Table 4. The number of failures shall not exceed the acceptance number given in col (7) of Table 4.

Table 4 Scale of Sampling and Acceptance Number

(*Clauses* B-1.2, B-2.1, B-2.3, B-2.5 *and* B-2.6)

SI No.	Lot size	Workmanship and Finish		For Transparency and Leakage Test		Container Material Test		For Overall Height, Diameter, Wall Thickness, Verticality, Drop Impact, Collapsibility, Compatibility and Stack Load Test
		Sample Size	Acceptance Number	Sample Size	Acceptance Number	Sample Size	Acceptance Number	No. of Sample
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
i)	Up to 500	13	1	5	0	3	0	2
ii)	501 to 1 000	20	2	8	0	5	0	2
iii)	1 001 to 3 000	32	3	13	0	8	0	2
iv)	3 001 to 5 000	50	5	20	1	13	0	3
v)	5 001 and above	80	7	32	2	20	0	5

ANNEX C

(*Foreword*)

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