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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

चिकित्सीय उपयोग के लिए इन्फ्यूजन उपकरण
भाग 6 इन्फ्यूजन बोतलों के लिए फ़्रीज़ ड्राइंग क्लोजर

Draft Indian Standard

Infusion Equipment for Medical Use
Part 6 Freeze Drying Closures for Infusion Bottles

ICS 11.040.20

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12	Last date for comments: **06 June 2024**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*

ISO 3302-1, Rubber — Tolerances for products — Part 1: Dimensional tolerances	IS 16752 : 2018/ISO 3302-1 : 2014, Rubber — Tolerances for Products — Dimensional Tolerances	Identical
ISO 48-4, Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)	IS 3400 (Part 2/Sec 4) : 2022/ISO 48-4 : 2018, Methods of Test for Rubber, Vulcanized or Thermoplastic Part 2 Determination of Hardness Section 4 Indentation Hardness by Durometer Method (Shore Hardness) (*Second Revision*)	Identical
ISO 8536-1, Infusion equipment for medical use — Part 1: Infusion glass bottles	IS/ISO 8536-1 : 2011, Infusion Equipment for Medical Use Part 1 Infusion Glass Bottles	Identical
ISO 8536-3, Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	MHD/12/25422, Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 3302-2	Rubber — Tolerances for products — Part 2: Geometrical tolerances
ISO 8871-1	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates
ISO 8871-4	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods

This standard includes modification of cross reference from ISO 7619-1 to ISO 48-4. Wherever reference to ISO 7619-1 occurs in the text, ISO 48-4 has to be substituted.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

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*)’.

NATIONAL ANNEX A
(National Foreword)

A-1 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.

Scope

This document specifies the shape, dimensions, material, performance requirements and labelling for the type of closure for infusion bottles, as described in ISO 8536-1, that is used in connection with the freeze-drying (or lyophilization) of drugs and biological materials.

The dimensional requirements are not applicable to barrier-coated closures.

Closures specified in this document are intended for single use only.

NOTE The potency, purity, stability and safety of a medicinal product during its manufacture and storage can strongly be affected by the nature and performance of the primary packaging.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to ISO 8536-6:2016 or kindly contact:

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