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*भारतीय मानक मसौदा*

**अंतःशिरा इंजेक्शन के लिए प्लास्टिक के कंटेनर**

*Draft Indian Standard*

**Plastic Containers for Intravenous Injections**

[ICS 11.040.20]

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Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12      Last date for comments: **XX October 2023**

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**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 terminologies and 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 places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 2768-1, General tolerances — Part 1: Tolerances for linear and angular dimensions without individual tolerance indications	IS 2102 (Part 1) : 1993 ISO 2768-1 : 1989 General tolerances: Part 1 tolerances for linear and angular dimensions without individual tolerance indications (Third Revision)	Identical

ISO 22081, Geometrical product specifications (GPS) — Geometrical tolerancing — General geometrical specifications and general size specifications.	IS 17894 : 2022/ISO 22081 : 2021, Geometrical product specifications GPS - Geometrical tolerancing - General geometrical specifications and general size specifications	Identical
ISO 8536-4, Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	IS/ISO 8536-4 : 2019 Infusion equipment for medical use Part 4: Infusion sets for single use gravity feed	Identical
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Identical
ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	IS/ISO 10993-5 : 2009 Biological evaluation of medical devices Part 5 Tests for in vitro cytotoxicity	Identical

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 same as that of the specified value in this standard.

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**Note:** The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 15747:2018 or kindly contact:

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## **Scope**

This document specifies requirements to the safe handling and the physical, chemical and biological testing of plastic containers for parenterals.

This document is applicable to plastic containers for parenterals having one or more chambers and having a total nominal capacity in the range of 50 ml to 5 000 ml such as film bags or blow-moulded plastic bottles for direct administration of infusion (injection) solutions.

**NOTE** In some countries, national or regional pharmacopoeias or other government regulations are legally binding and these requirements take precedence over this document.