

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
स्वास्थ्य देखभाल उत्पादों का कीटाणु-नाशक प्रसंस्करण
भाग 3 लियोफिलाइजेशन

Draft Indian Standard
Aseptic Processing of Health Care Products
Part 3 Lyophilization

ICS 11.080.01

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:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- 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 9001, Quality management systems — Requirements | IS/ISO 9001 : 2015, Quality Management Systems — Requirements (Fourth Revision) | Identical |
| ISO 13408-4, Aseptic processing of health care products — Part 4: Clean-in-place technologies | MHD/12/25436, Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies | Identical |
| ISO 13408-5, Aseptic processing of health care products — Part 5: Sterilization in place | MHD/12/25437, Aseptic Processing of Health Care Products Part 5 Sterilization in Place | 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:

| <i>International Standard</i> | <i>Title</i> |
|-------------------------------|---|
| ISO 13408-1 | Aseptic processing of health care products — Part 1: General requirements |

Scope

This part of ISO 13408 specifies requirements for, and offers guidance on, equipment, processes, programmes and procedures for the control and validation of lyophilization as an aseptic process. It does not address the physical/chemical objectives of a lyophilization process.

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 13408-3:2006 or kindly contact:

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