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भारतीय मानक मसौदा

दवा वितरण प्रणालियों में परिवर्तनों के आकलन और मूल्यांकन के लिए मार्गदर्शन

Draft Indian Standard

Guidance for assessment and evaluation of changes to drug delivery systems

[ICS 11.040.01]

Hospital Equipment and Surgical Disposable Products Sectional Committee, MHD 12

Last date for comments: **20 Nov 2023**

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.

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)'.

In reporting the result of a test or analysis made in accordance with this standard, is to be rounded off, it shall be done in accordance with IS 2 : 2022 'Rules for rounding off numerical values (Second Revision)'.

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 20069:2018 or kindly contact:

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Scope

This document provides guidance for assessment and evaluation of planned changes to drug delivery systems that are integral with, packaged with, or cross-labelled for use with a specified medicinal product. This document is applicable to the drug delivery system's lifecycle from registration clinical studies to end-of-life. This document is applicable to the assessment of changes within the following drug delivery systems:
— needle-based injection systems for medical use;
— aerosol drug delivery devices;
— needle-free injectors for medical use.

NOTE These are covered by the ISO 11608 series, ISO 20072 and ISO 21649, respectively.

This document might also be useful for assessing and evaluate changes to other drug delivery devices or systems.
Examples of changes that are within the scope of this document include but are not limited to the following:

- a) the same route of administration (e.g. change resulting in including a marketed prefilled syringe to an autoinjector);
- b) changes to the drug delivery system design (e.g. change in configuration or layout of electrical and mechanical components);
- c) changes to the medicinal product that affect the drug delivery system; including the primary container closure (e.g. viscosity, particle size);
- d) changes in production or handling of the drug delivery system (e.g. process scale, manual to automated assembly, glue bond to sonic weld, mould cavitation, sterilization, storage, transportation, work instructions or methods);
- e) changes in component materials or source of supply;
- f) changes in software, including changes related to cybersecurity, encryption and connectivity;
- g) changes in the user interface, including packaging;
- h) changes to labelling and/or instructions for use.

Revisions or additions of software are within the scope of this document. The software can either be integrated into the physical drug delivery system, separate, or both.
The applicability of this document to non-integrated software is relevant to the extent that those software changes can impact the drug delivery system and/or impact how users interact with it.

Depending on the nature of the change, there can be additional assessments and resulting activities, which can be outside the scope of this document.
This document does not provide guidance for defining the objective of the change, nor the various potential opportunities/options for fulfilling this objective.