International Standard

ISO 11608-3

Needle-based injection systems for medical use — Requirements and test methods —

Part 3: Containers and integrated fluid paths

AMENDMENT 1

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —

Partie 3: Conteneurs et chemins de fluide intégrés

AMENDEMENT 1

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Clause 2 Normative references

Replace “ISO 10555-1:2013” with “ISO 10555-1:2023”.

4.3.2 Soft cannulas

Replace “ISO 10555-1:2013, 4.6” with “ISO 10555-1:2023, 4.9”.

4.5.3.1 General

Replace the content of the subclause with the following:

The reservoir and/or integrated fluid path shall be assessed for sub-visible and visible particulate matter.

Applicable pharmacopeia establishes limits for the size and number of particulates allowed for the medicinal product. Manufacturers shall establish design specifications for particulate matter limits from the reservoir and/or fluid path based on risk assessment.

It is recommended that the manufacturer and its suppliers agree upon the test methods to be used and the size and number of sub-visible and visible particulates permissible for the NIS.

Particulates from the NIS which, due to their size, nature and/or quantity, interfere with the function of the NIS or have a negative impact to patient safety shall not be acceptable.

NOTE The impact of any particulates on the function of the NIS can be assessed through dose accuracy testing.

4.5.3.2 Sub-visible

Replace the content of the subclause with the following:

Unless otherwise justified, limits for the NIS shall be:

— Particles ≥10 µm: 600 max. per NIS;

— Particles ≥25 µm: 60 max. per NIS;

when tested in accordance with the method described in 5.3.

NOTE These above listed limits are taken from ISO 11040-4:2024 unless otherwise negotiated with the drug manufacturer and device manufacturer.