

ISO/TC 76

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Injection containers and accessories —
Part 1:
Injection vials made of glass tubing
AMENDMENT 1

iTeh STANDARD PREVIEW
Réipients et accessoires pour produits injectables —
Partie 1: Flacons en verre étiré
(standards.iteh.ai)
AMENDEMENT 1
ISO 8362-1:2003/FDAmd 1
<https://standards.iteh.ai/catalog/standards/sist/5cb6dcae-d0ff-4c1f-8cf2-fac6939e59a5/iso-8362-1-2003-fdamd-1>

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Reference number
ISO 8362-1:2003/FDAM 1:2008(E)

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Foreword

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Amendment 1 to ISO 8362-1:2003 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical and pharmaceutical use*.

The purpose of this Amendment is to develop further types of neck finishes for injection vials (model B and model C) in order to meet the market actualities.

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Injection containers and accessories —

Part 1: Injection vials made of glass tubing

AMENDMENT 1

Page 1, Dimensions

Replace the first paragraph by the following:

The dimensions of injection vials made of glass tubing shall meet the requirements of Figure 1 or Figure 2 or Figure 3 and Table 1; the overflow capacity and mass shall be as shown in Table 1.

Page 2, Figure 1

Replace the legend of Figure 1 by the following:

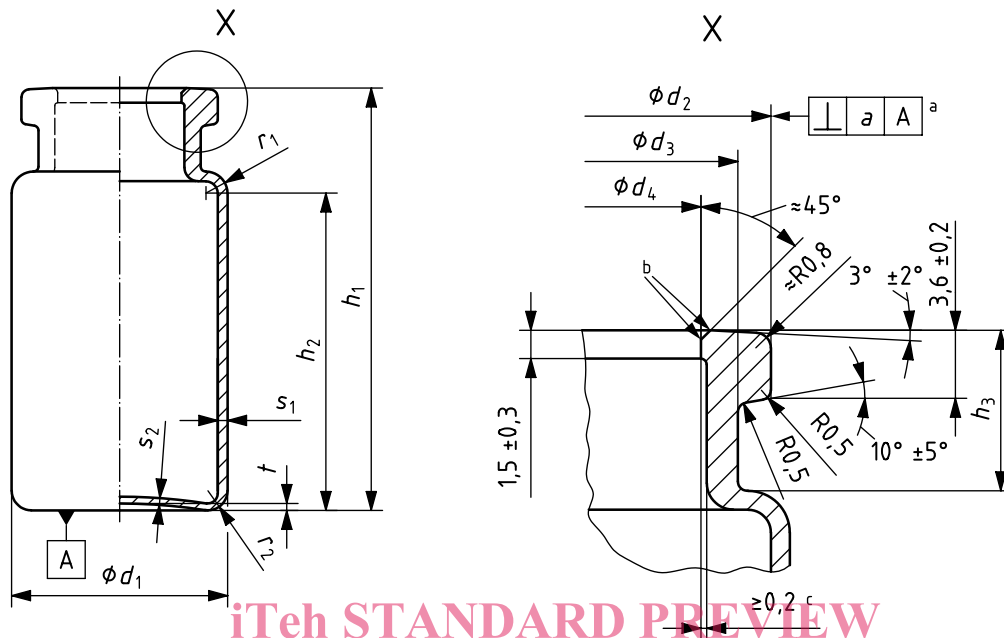
Figure 1 — Typical example of injection vial made of glass tubing containing a neck finish without blow back — Model A

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Add Figures 2 and 3 including the following NOTE:

NOTE The drawings illustrate ideal presentations. The transition to blow back is not sharp-edged but slightly rounded.

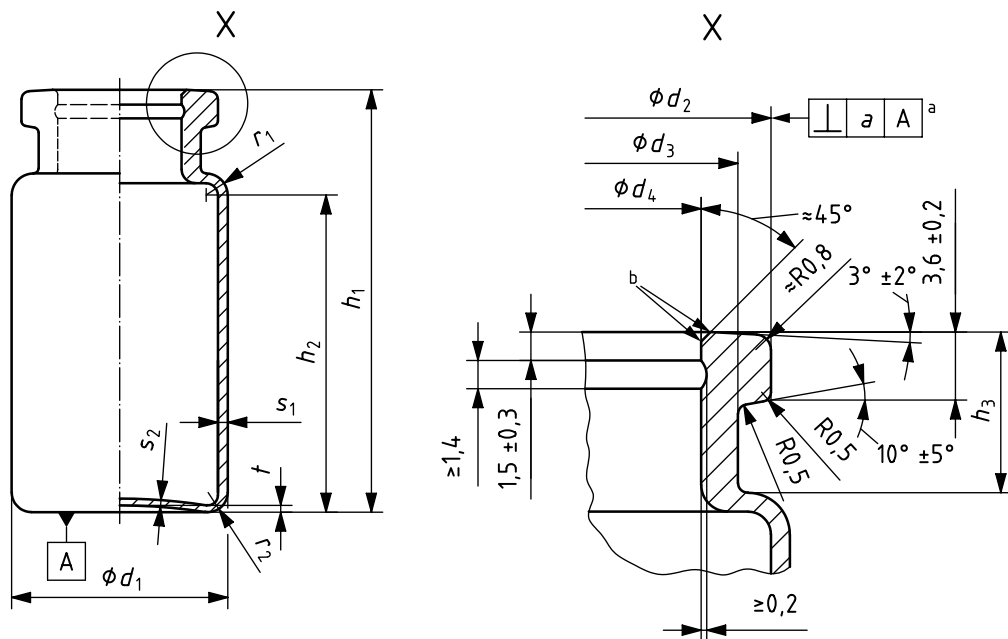
Dimensions in millimetres



- ^a The perpendicularity tolerance a (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the vial at the upper edge of the flange; it is measured at the brim.
- ^b Edges slightly rounded.
- ^c This value should not exceed 0,3 mm in order to avoid that the wall becomes too weak. This dimension has not been given as a requirement because it is not possible to measure it adequately.

Figure 2 — Typical example of injection vials made of glass tubing containing a neck finish with blow back (European style) — Model B

Dimensions in millimetres



^a The perpendicularity tolerance a (as defined in ISO 1101) is a limit for the deviation of the plumb-line through the centre of the bottom part and the axis of the vial at the upper edge of the flange; it is measured at the brim.

^b Edges slightly rounded.

Figure 3 — Typical example of injection vials made of glass tubing containing a neck finish with blow back (American style) — Model C

Page 3, Designation

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Replace the example by the following three examples:

EXAMPLE 1 An injection vial (model A), size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – A-10R – br – 1

EXAMPLE 2 An injection vial (model B), size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 – HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – B – 10R – br – 1

EXAMPLE 3 An injection vial (model C), size 15 (15R), made of colourless (cl) glass of hydrolytic resistance container class ISO 4802- HC 1 (1) complying with the requirements specified in this part of ISO 8362 is designated as follows:

Vial ISO 8362-1 – C – 15R – cl – 1

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