INTERNATIONAL STANDARD

ISO 11040-5

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Prefilled syringes —

Part 5:
Plungers for injectables

Seringues préremplies —

Partie 5: Bouchons-pistons pour produits injectables

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Contents

		Page
1	Scope	1
2	Normative references	1
3	Dimensions and designation	1
4	Requirements	2
5	Packaging and marking	3

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 11040-5 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use.*

ISO 11040 consists of the following parts, under the general title *Prefilled syringes*:

— *Part 1: Glass cylinders for dental local anaesthetic cartridges*

— *Part 2: Plungers and discs for dental local anaesthetic cartridges*

— *Part 3: Aluminium caps for dental local anaesthetic cartridges*

— *Part 4: Glass barrels for injectables*

— *Part 5: Plungers for injectables*

Introduction

For the parenteral use of liquid pharmaceutical products, ampoules and injection vials are mainly used at present. However, for the injection of the liquid pharmaceutical products contained in such vials, a hypodermic syringe combined with the appropriate injection needle is also needed. This means the liquid pharmaceutical product has to be transferred into the hypodermic syringe before its final use. This procedure is not only time-consuming, but also presents a great number of possibilities for contamination.

To ensure safe use of a liquid pharmaceutical product, prefilled syringes for single use are already on the market. Without doubt, such prefilled syringes permit immediate injection of the product contained after relatively simple handling.

Based on the diameter of the prefilled syringes, appropriate components, such as rubber plungers and aluminium caps, can also be standardized. The producers of filling machines can apply this part of ISO 11040 to achieve a degree of standardization in the equipment of the machines.

Prefilled syringes —

Part 5:
Plungers for injectables

1 Scope

This part of ISO 11040 applies to plungers for glass barrels (single-chamber design) for injection preparations in accordance with ISO 11040-4 and specifies materials, dimensions and performance details.

Plungers produced in accordance with this part of ISO 11040 are intended for single use only. In conjunction with the right sealing equipment, they offer a safe system for parenteral use.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 11040 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 48:1994, *Rubber, vulcanized on thermoplastic — Determination of hardness (hardness between 10 IRHD and 100 IRHD.*

ISO 3302:1990, *Rubber — Dimensional tolerances for use with products.*

ISO 8871:1990, *Elastomeric parts for aqueous parenteral preparations.*

ISO 11040-4:1996, *Prefilled syringes — Part 4: Glass barrels for injectables.*

3 Dimensions and designation

3.1 Dimensions

The dimensions of the plunger shall be as shown in figure 1 and as given in table 1. General dimensional tolerances shall be class M3 in accordance with ISO 3302.

3.2 Designation

The plunger designation shall comprise, in the following order, the descriptor "Plunger", a reference to this part of ISO 11040, the type of plunger [snap lip (PSL) or threaded (PT)], the volume of the barrel for which the plunger is intended, and the letters "lg" if the long version.

EXAMPLES

A plunger with snap lip for a glass barrel of 0,5 ml nominal volume complying with the requirements in this part of ISO 11040 is designated as follows:

Plunger ISO 11040-5 - PSL - 0,5

A threaded plunger for a glass barrel of 1 ml nominal volume, long version, complying with the requirements in this part of ISO 11040 is designated as follows:

Plunger ISO 11040-5 - PT - 1 - lg

Dimensions in millimetres

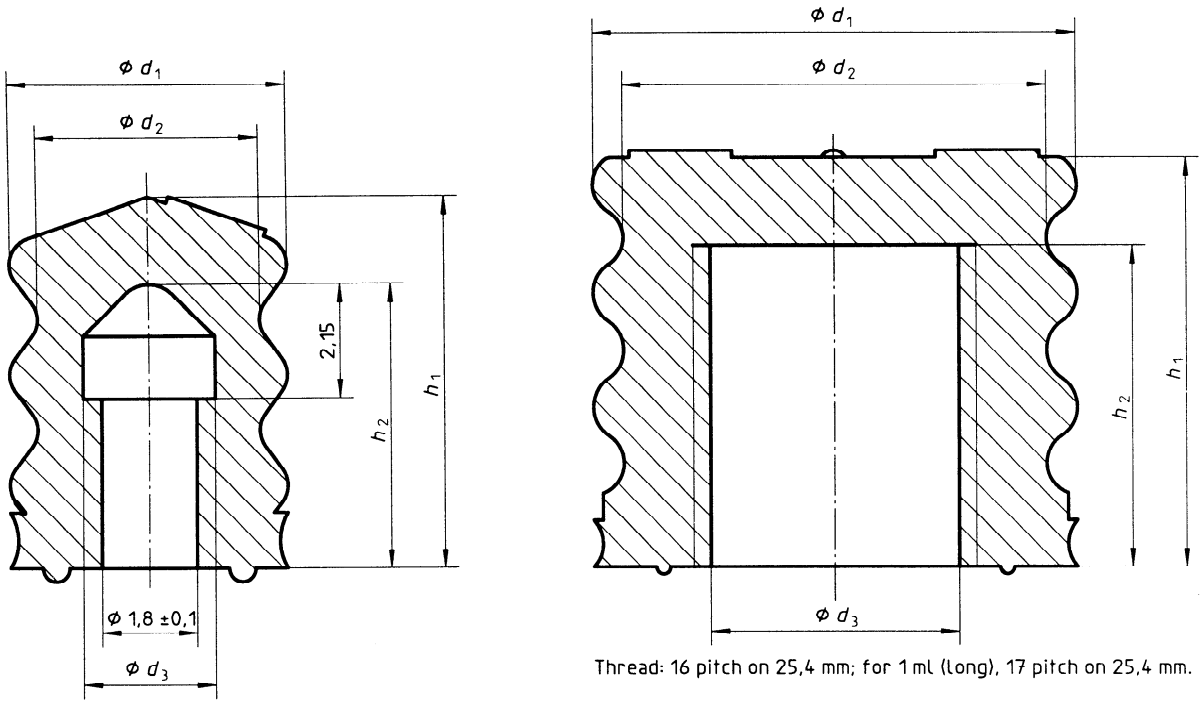

Figure 1 — Typical example of plunger for prefilled syringe

Table 1 — Plunger dimensions

Dimensions in millimetres

Nominal volume	Type	d_1		d_2		d_3		h_1		h_2	
ml		nom.	tol.	nom.	tol.	nom.	tol.	nom.	tol.	nom.	tol.
0,5	PSL	5,25	± 0,1	4,2	± 0,15	2,5	± 0,15	7	± 0,4	5,35	± 0,3
1 (long)	PT	6,9		6		2,6		7,85		4,5	
1		9,15		8		4,7		7,7		4	
2											
2,25											
3											
5		12,6		11,1		5,3				6	
10		15,2		13,7	± 0,2	7,4		8,5		6	
20		20	± 0,15	18,5	± 0,25	10,7	± 0,2	13,5		7	

4 Requirements

Elastomeric materials used for the manufacture of plungers shall be in accordance with the requirements specified in 5.1, 5.2 and 5.3.

4.1 Physical requirements

4.1.1 Sprues, if present, shall not protrude beyond the surface of the plunger.

4.1.2 The shore A hardness value of the plunger material shall be agreed between manufacturer and user. The hardness shall not differ from the nominal value by more than ± 5 IRHD when tested in accordance with ISO 48.

4.1.3 The performance and dimensions of the plunger thread shall be compatible with the plunger rod. The plunger shall not detach itself from the rod under normal use, e.g. aspiration.

4.2 Chemical composition requirements

The composition of the plunger material shall not exceed the limits specified in table 2.

4.3 Biological requirements

Biological requirements are not specified in this part of ISO 11040; biological tests are, however, required by most national pharmacopoeias or related health authority regulations and are mandatory for producers and users in countries where they exist. If this is not the case, reference shall be made to biological tests as described in e.g. the United States Pharmacopoeia, the European Pharmacopoeia or other pharmacopoeias.

5 Packaging and marking

In order to avoid adhesion of the plungers to each other when packaged, spacers such as interrupter rings or bridges shall be used. The height of the spacers shall not exceed 0,2 mm.

The design of the spacers should be agreed upon between manufacturer and cartridge assembler.

The packaged plungers shall be marked with a designation in accordance with 3.2.

Table 2 — Chemical composition limits for plungers

Characteristics	Limit[1)]	Test method in accordance with ISO 8871:1990
Reducing matter (oxidizables)	⩽ 7,0 ml of $c(KMnO_4)$ = 2 mmol/l per 20 ml	Annex C
Heavy metals (calculated as Pb^{2+})	⩽ 10 µg Pb^{2+}/10 ml	Annex D
Ammonia (calculated as NH_4^+)	⩽ 20 µg NH_4^+/10 ml	Annex E
Acidity/alkalinity	⩽ 1,0 ml of c(HCl) or c(NaOH) = 5 mmol/l per 20 ml	Annex G
Residue on evaporation (total solids)	⩽ 4 mg/100 ml	Annex H
Volatile sulfides (at pH ≈ 2)	Coloration of lead acetate paper ⩽ 50 µg Na_2S/20 cm^2 of rubber surface	Annex J
Zinc (calculated as Zn^{2+})	Zn^{2+} ⩽ 30 µg/10 ml	Annex K
Conductivity	⩽ 40 µS/cm	Annex L
Turbidity	Not exceeding the opalescence of suspension No.3	Annex M

1) The limit units are explained in the appropriate annex of ISO 8871.

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Descriptors: medical equipment, parenteral infusion equipment, anaesthetic equipment, dental equipment, disposable equipment, syringes, components, specifications, dimensions, tests, designation, marking.

Price based on 3 pages