
Prefilled syringes —
Part 5:
Plungers for injectables

Seringues préremplies —

Partie 5. Bouchons-pistons pour produits injectables
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this part of ISO 11040 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 11040-5:1996), which has been technically revised.

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

Liquid and solid pharmaceutical products for parenteral administration are at present mainly filled in containers such as ampoules and injection vials.

For the injection of the pharmaceutical product in its liquid form, a hypodermic syringe combined with an appropriate hypodermic needle is needed. The liquid product has to be transferred from the container to the hypodermic syringe before its final use, a procedure which involves several time-consuming handling steps and causes a certain amount of waste.

The use of prefilled syringes provides easier handling (and thereby reduced potential contamination risks), less waste and the possibility of immediate injection. Systems of prefilled syringes for single use are already on the market.

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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 for such plungers.

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.

This part of ISO 11040 does not apply to laminated or lacquered plungers.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11040. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11040 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 3302-1:1996, *Rubber — Tolerances for products — Part 1: Dimensional tolerances*

ISO 8871-1, *Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates*

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 3302-1:1996.

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.

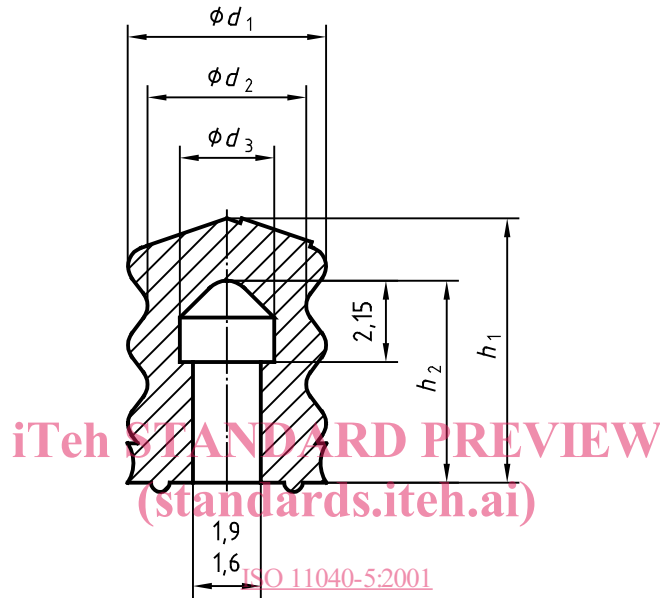
EXAMPLE 1 A plunger with snap lip for a glass barrel of 0,5 ml nominal volume complying with the requirements in this part of ISO 11040 is designated as follows:

Plunger ISO 11040-5 - PSL - 0,5

EXAMPLE 2 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:

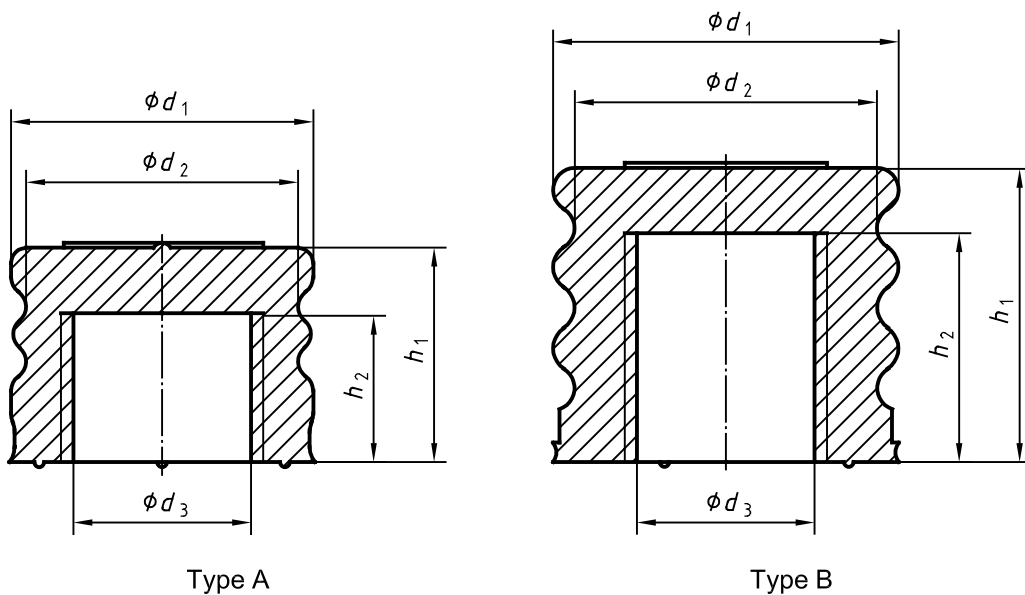
Plunger ISO 11040-5 - PT - 1 - lg

Dimensions in millimetres



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a) Plunger with snap lip (PSL)



Thread: 16 pitch on 25,4 mm; for 1 ml (long), 17 pitch on 25,4 mm

b) Plunger with thread (PT)

Figure 1 — Examples of typical plungers for a prefilled syringe

Table 1 — Plunger dimensions

Dimensions in millimetres

Nominal volume ml	Type	d_1^a		d_2^a		d_3^a		h_1^a		h_2^a		
		nom.	tol.	nom.	tol.	nom.	tol.	nom.	tol.	nom.	tol.	
0,5	PSL	5,2 to 5,3		4,1 to 4,2		2,5		6,85 to 7,0		5,3	$\pm 0,35$	
1 (long)	PT	6,8 to 7	$\pm 0,1$	5,9 to 6	$\pm 0,15$	2,6	$\pm 0,2$	7,65 to 7,85	$\pm 0,4$	4,5	$\pm 0,3$	
1		9,05 to 9,25		7,6 to 8		4,7		7,7 to 7,85		4		
2												
2,25		12,5 to 12,7		10,5 to 11,15		5,2 to 5,6		8,5		6,0		
3												
5		15 to 15,3		13,5 to 13,75		7,4 to 7,6		$\pm 0,25$		8,5 to 10		6 to 6,2
10												
20		19,9 to 20,1		$\pm 0,15$		18,4 to 18,6		10,7		13,45 to 13,5		7

^a The nominal diameter shall be agreed upon between manufacturer and user within the given range.

4 Requirements for plunger elastomeric materials

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 requirements

The aqueous extractables of the plunger material shall not exceed the limits specified for elastomeric parts type 1 as defined in ISO 8871-1.

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 manufacturers 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 pharmacopoeia.

5 Packaging and marking

In order to avoid adhesion of the plungers to each other when packaged, spacers such as interrupted 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.

Bibliography

- [1] *European Pharmacopoeia*
- [2] *United States Pharmacopoeia*

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