BRITISH STANDARD

BS EN
13726-1:2002

Test methods for primary wound dressings —

Part 1: Aspects of absorbency

The European Standard EN 13726-1:2002 has the status of a British Standard

ICS 11.120.20

National foreword

This British Standard is the official English language version of EN 13726-1:2002.

The UK participation in its preparation was entrusted by Technical Committee CH/117, Medical textiles, to Subcommittee CH/117/1, Test methods for non-wovens for use in compresses, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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English version

Test methods for primary wound dressings - Part 1: Aspects of absorbency

M6thodes d'essai pour les pansements primaires en contact avec la plaie - Partie 1: Absorption

Prufverfahren fur primare Verbandstoffe (Wundauflagen) - Teil 1: Aspekte des Saugverhaltens (Absorption)

This European Standard was approved by CEN on 25 February 2002.

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Contents

Foreword

This document EN 13726-1:2002 has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2002, and conflicting national standards shall be withdrawn at the latest by September 2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

EN 13726 will consist of the following parts under the general title Test methods for primary wound dressings:

- Part 1 : Aspects of absorbency

- Part 2 : Moisture vapour transmission rate of permeable film dressings

- Part 3 : Waterproofness

- Part 4 : Conformability

- Part 5 : Bacterial barrier properties

- Part 6 : Odour control

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Introduction

EN 13726 specifies test methods and does not contain performance requirements. Part 1 of this standard describes test methods for different aspects of absorbency.

Test methods for other aspects of primary wound dressings are described in other parts of EN 13726.

1 Scope

Part 1 of EN 13726 specifies test methods recommended for the evaluation of some aspects of absorbency of primary wound dressings.

2 Terms and definitions

For the purposes of this European Standard the following terms and definitions apply.

2.1
alginate dressing
dressing containing salts of alginic acids which interact with physiological fluids to form a gel

2.2
amorphous hydrogel
semi-solid gel that contains hydrophilic polymers and water

2.3
fluid affinity of a wound dressing
ability to absorb fluid from or donate fluid to a simulated wound

2.4
fluid handling capacity
sum of the fluid absorbed and the fluid transpired through the dressing

2.5
free swell absorptive capacity
total absorptive capacity in the presence of excess test liquid and in the absence of any applied load

2.6
primary wound dressing
material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound

NOTE Primary wound dressings are used as mechanical barriers, for the absorption or transmission of exudates, to manage the micro-environment of the wound, and can enable the wound to heal by primary or secondary intent. Devices which have a metabolic, pharmacological or immunological interaction as their primary intent are excluded.

3 Test methods for absorbency

3.1 Test conditions

Unless otherwise stated, condition the test samples and carry out the tests at a temperature of (21 ± 2) °C and a relative humidity of 60 % RH ± 15 % RH.

3.2 Free swell absorptive capacity

3.2.1 Significance and use

The test is intended to assess the performance of dressings, typically used on moderately to heavily exuding wounds, where total absorptive capacity is an important feature.

It is only appropriate for dressings which will stay physically intact and which will reach their maximum absorptive capacity within 30 min, under the test conditions.

NOTE The test is suitable for use with, for example, most types of alginate dressings in either the sheet or rope (packing) form. In the case of alginate dressings, the ratio of test liquid to sample weight is an important factor due to the interaction which takes place.

3.2.2 Equipment

3.2.2.1 **Petri dishes,** (90 ± 5) mm in diameter.

3.2.2.2 **Laboratory oven,** with forced air circulation, capable of maintaining a temperature of (37±1) °C.

3.2.2.3 **Test solution A,** consisting of sodium chloride and calcium chloride solution containing 142 mmol of sodium ions and 2,5 mmol of calcium ions as the chloride salts. This solution has an ionic composition comparable to human serum or wound exudate. It is prepared by dissolving 8,298 g of sodium chloride and 0,368 g of calcium chloride dihydrate in deionised water and making up to 1 litre in a volumetric flask.

3.2.2.4 **Balance,** capable of weighing 100 g with to the nearest 0,000 1 g.

3.2.3 Procedure

3.2.3.1 Place a single, weighed 5 cm x 5 cm (as presented to the wound) or 0,2 g (for cavity dressing) sample in a Petri dish.

3.2.3.2 Add a quantity of test solution warmed to (37 ± 1) °C corresponding to 40 times the mass of sample being examined, ± 0,5 g.

3.2.3.3 Transfer to the oven and allow to stand for 30 min at (37 ± 1) °C.

3.2.3.4 Using forceps suspend the sample being examined, either by one corner or by one end as appropriate, for 30 s and then weigh it.

3.2.3.5 Repeat 3.2.3.1 to 3.2.3.4 with a further nine samples

3.2.4 Calculation of results

Express absorptive capacity as the average mass of solution retained per 100 cm^2 (as presented to the wound) or per gram of sample (for cavity dressing).

3.2.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

b) any deviations from the test method;

c) individual and average absorptive capacity results;

d) date of test;

e) identity of the person(s) who carried out the test.

3.3 **Fluid handling capacity** (absorbency plus moisture vapour transmission rate, liquid in contact)

3.3.1 Significance and use

This test is intended to assess the fluid handling capacity of waterproof wound dressings typically used for more than 24 h and when absorption of exudate and management of the micro-environment are important.

3.3.2 Equipment

3.3.2.1 **Five clean, dry cylinders,** made of corrosion-resistant material with an internal diameter of (35,7 ± 0,1) mm (cross-sectional area 10 cm^2) having a flange at each end and able each to accommodate 20 ml of test solution. (An example of a cylinder that has been found to be adequate is given in Figure 1).

At one end of the cylinder is an annular clamping plate with an orifice area of 10 cm^2. To prevent transpiration through the edges of the dressing an impermeable tape or alternative sealant may be used in this area. At the other end of the cylinder is a solid metal plate the full diameter of the flange. A sealing ring is also advisable to ensure an effective seal against the flange. The plates at both ends are clamped in position against the flanges.

3.3.2.2 **Test solution A,** as specified in 3.2.2.3.

3.3.2.3 **A calibrated pipette.**

3.3.2.4 **Oven or incubator,** having a circulating fan and capable of maintaining a temperature of (37 ± 1) ^{C}C, and being of a design to distribute the air evenly throughout the oven or incubator so as to maintain relative humidity at less than 20 % RH throughout the test.

3.3.2.5 **Humidity meter,** capable of detecting whether or not the **20** % RH limit has been exceeded.

3.3.2.6 **Balance,** as specified in 3.2.2.4.

3.3.3 Procedure

3.3.3.1 Cut a circular sample of dressing suitable to be clamped over the test apparatus to prevent leakage. If appropriate, remove the release liner and affix to the upper flange of a cylinder with the wound contact surface facing inwards.

3.3.3.2 Place the retaining ring on the outer surface of the dressing and fasten in place.

3.3.3.3 Weigh the cylinder together with the base and clamps (W_1). Invert the cylinder and, using a suitable pipette, add approximately 20 ml of test solution A. Fix the solid plate in position and reweigh *(W_2).* Repeat the procedure four times so as to prepare five samples.

3.3.3.4 Place the assembled cylinder in the incubator.

3.3.3.5 After 24 h, remove the cylinders from the incubator, allow them to equilibrate at room temperature for 30 min and reweigh (W_3).

3.3.3.6 Remove the solid plate from each cylinder, gently pour out any excess fluid and leave the cylinder to drain in the inverted position for (15 ± 2) min.

Reweigh the cylinder and all its associated components, including the dressing (W_4).

3.3.3.7 Repeat steps 3.3.3.1 to 3.3.3.6 using fresh samples for a contact time of 48 h.

3.3.4 Calculation of results

3.3.4.1 Calculate the mass of moisture vapour lost through the dressing (W_2-I/V_3,) and the mass of fluid absorbed by the material (W_4-W_1) for the 24 h and the 48 h periods.

3.3.4.2 Record the vapour lost through the dressing and the fluid absorbed by the dressing. Additionally, record the sum of the two measurements, which is the fluid handling capacity of the dressing at 24 h and 48 h.

3.3.4.3 The test is invalid if the humidity levels within the oven / incubator rise to more than 20 % RH during the test period.

3.3.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

b) any deviations from the test method;

c) individual and average results;

d) date of test;

e) identity of the person(s) who carried out the test.

3.4 Fluid affinity of amorphous hydrogel dressings

3.4.1 Significance and use

This test method measures the ability of hydrogel wound dressings to donate liquid to or absorb liquid from test substrates made from gelatine or agar respectively.

NOTE This test method is suitable for the evaluation of the hydroaffinity of amorphous hydrogel wound dressings.

3.4.2 Equipment

3.4.2.1 **Ten syringes,** of nominal graduated capacity 50 ml or 60 ml, having an internal diameter of (30 ± 2) mm with the nozzles cut off, and a low-profile plunger (see Figure 2).

3.4.2.2 **Test solution A,** as specified in 3.2.2.3.

3.4.2.3 **Gelatin powder,** (175 bloom)

3.4.2.4 **Agar powder,** (bacteriological agar type 1)[1]

3.4.2.5 **Selection of suitable laboratory glassware**

3.4.2.6 **Balance,** capable of weighing up to 100,00 g to the nearest 0,01 g

3.4.2.7 **Laboratory autoclave,** suitable for the sterilization of liquids in closed containers

3.4.2.8 **Impermeable film or foil**

3.4.2.9 **Laboratory incubator,** capable of maintaining a temperature of (25 ± 2) °C

3.4.2.10 **Laboratory incubator,** capable of maintaining a temperature of (60 ± 2) °C.

[1] Bacto agar from Difco Laboratories is an example of a suitable product available commercially. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.

NOTE The same incubator can be used for 3.4.2.9 and 3.4.2.10 if the test procedure is arranged such that both temperatures are not needed simultaneously.

3.4.3 Procedure

3.4.3.1 Add sufficient test solution A to (2,00 ± 0,01) g of agar powder in a suitable container to produce a total mass of reagent of (100,00 ± 0,02) g. Seal the container and hold the resulting mixture at (121 ± 1) °C in an autoclave for 20 min. Remove the container and allow it to cool to (60 ± 5) °C prior to use.

3.4.3.2 Add sufficient gelatin powder to (65,00 ± 0,02) g of test solution A in a suitable wide mouth container to produce a total mass of reagent of (100,00 ± 0,02) g. Seal the container, shake it until the gelatine powder is dispersed and then hold it at a temperature of 60 °C for at least 12 h but no longer than 18 h. At the end of this time, check that the gelatin has formed a clear homogenous solution.

3.4.3.3 Withdraw the plunger of a syringe until the fiducial line on the piston is level with the 30 ml graduation mark.

3.4.3.4 To the syringe add (10,0 ± 0,1) g of agar or gelatin as appropriate. To prevent evaporation of water vapour, cap the open end of the syringe using an impermeable film or foil, secured in place.

3.4.3.5 Repeat 3.4.3.3 and 3.4.3.4 until the required number of syringes have been set up (5 with agar and 5 with gelatin for each product under test).

3.4.3.6 Place the syringes in the incubator and allow them to stand vertically for 3 h at (25 ±2) <C to allow the test substrate to set. Remove the caps from the syringes to eliminate any condensation formed during the setting process.

3.4.3.7 Weigh each syringe together with its contents and record the mass (W_1).

3.4.3.8 To each syringe add (10,0 ± 0,1) g of test sample, ensuring an even distribution over the surface of the agar or gelatine. Weigh the syringe, substrate and test sample and record the mass (W_2).

3.4.3.9 Seal the syringes with a new cap using impermeable film or foil.

3.4.3.10 Place the syringes in the incubator and allow them to stand vertically for 48 h ± 30 min at (25 ± 2) °C, after which time remove the caps. Weigh each syringe together with the test substrate and gel and record the mass (W_3).

3.4.3.11 Move the plunger in each syringe until the upper surface of the material is exposed, enabling the gel to be removed whilst ensuring that the substrate layer remains intact.

3.4.3.12 Weigh the syringe and test substrate and record the mass (W_4).

3.4.4 Calculation of results

Calculate the percentage weight change of the gel *(W_5)* using the formula below:

$$W_5 = \{[(W_3 - W_4) - (W_2 - W_1)] / (W_2 - W_1)\} \times 100$$

If the value of $W_3 - W_2$ exceeds 0,1 g, repeat the test.

3.4.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

b) any deviations from the test method;

c) individual and average results;

d) date of test;

e) identity of the person(s) who carried out the test.

NOTE The results can be expressed in tabular form as exemplified in Table 1.

Table 1 - Example of percentage change in mass of the hydrogel sample

Agar (absorption)		**Gelatin** (donation)	
Type	Fluid Affinity (%) increase in gel weight	**Type**	Fluid Affinity (%) loss in gel weight
1	0-10	a	0-5
2	>10-20	b	>5-10
3	>20-30	c	>10-15
4	>30-40	d	>15-20
5	>40-50	e	>20-25

NOTE Fluid affinity of hydrogel dressings can be expressed according to their ability to absorb or donate fluid as determined in the fluid affinity test in terms of the percentage absorbed or donated. Thus a dressing that absorbs a large volume of fluid from agar but which does not donate significant amounts of fluid to gelatine can be categorized as a type 3a hydrogel. Conversely, a dressing that donates fluid well but is less able to absorb liquid can be categorised as a type 1c.

3.5 Gelling characteristics

3.5.1 Significance and use

This test is designed to distinguish between fast and slow gelling dressings when in the presence of excess liquid.

These wound dressings are typically used on moderately to heavily exuding wounds, where gel formation is a key feature. Gel formation occurs as a result of the interaction between the dressing and wound exudate. This reduces adherence to the wound and helps create a moist environment. Knowledge about the rate of gelling can assist in selecting the most appropriate dressing for a particular wound type.

This test is only appropriate for dressings which will disintegrate in the required manner, as described in the test procedure.

NOTE The test is suitable for use with, for example, fibrous dressings such as alginates which, according to their precise polymer composition, can exhibit different gelling rates.

3.5.2 Equipment

3.5.2.1 **Sieve,** of 250 micron, or other means of achieving a similar level of disintegration of the sample.

3.5.2.2 **Balance,** as specified in 3.2.2.4.

3.5.2.3 **Conical flasks.**

3.5.2.4 **Test solution A,** as specified in 3.2.2.3.

3.5.2.5 **Filter paper, 4** cm to **5** cm in diameter[2].

3.5.2.6 **Büchner funnel and waterjet pump,** capable of achieving a pressure reduction of at least 60 kPa, or similar apparatus.

3.5.2.7 **Reference solution,** consisting of 5 g/l calcium chloride dihydrate solution in distilled or deionised water.

3.5.2.8 **Stop-watch.**

3.5.3 Procedure

3.5.3.1 Grate a sample of the fibrous dressing by rubbing through the sieve.

3.5.3.2 Weigh (0,2 ± 0,01) g of the grated fibre into a conical flask.

3.5.3.3 Add 20 ml of test solution A and shake for 60 s to allow any gelling to take place.

3.5.3.4 Filter under reduced pressure at 60 kPa and then transfer to a conical flask.

3.5.3.5 Repeat 3.5.3.3 and 3.5.3.4 a further four times, retaining the final residue on the filter paper.

3.5.3.6 Repeat 3.5.3.1 to 3.5.3.5, using the reference solution in place of the test solution, to produce an ungelled residue for comparison.

3.5.4 Results

Compare the residues from the test procedure. The sample will have either gelled or not gelled, this being evident by comparison with the ungelled reference sample.

3.5.5 Test report

The report shall include at least the following information:

a) type of dressing; including lot number;

b) any deviations from the test method;

c) individual results: gelled or not gelled;

d) date of test;

e) identity of the person(s) who carried out the test.

3.6 Dispersion characteristics

3.6.1 Significance and use

This test is designed to distinguish between fibre wound dressings which do or do not disperse when being gently swirled in excess liquid.

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[2] Whatman No 451 is an example of a suitable product available commercially. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.

The test is useful for assessing the performance of dressings, typically used on moderately to heavily exuding wounds, where total saturation of (at least part of) the dressing will commonly take place. The test will assist in selecting a suitable method of removal from the wound.

It will distinguish between those dressings which readily lose integrity and disperse under the test conditions and those which stay intact. Dressings losing integrity in this manner are likely to be removable from the wound site using irrigation.

NOTE The test is suitable for use with, for example, fibrous dressings such as alginates. Alginate dressings might or might not readily disperse under these conditions depending upon their precise polymer composition and fabric structure.

3.6.2 Equipment

3.6.2.1 **Conical flask,** 250 ml, wide-necked.

3.6.2.2 **Test solution A,** as specified in 3.2.2.3.

3.6.2.3 **Measuring cylinder,** of capacity 50 ml, or similar apparatus.

3.6.2.4 **Stop-watch.**

3.6.3 Procedure

Place a 5 cm x 5 cm sample of the material being examined into a flask containing (50 ± 1) ml of test solution A and swirl without causing a vortex for 60 s. Inspect the contents of the flask visually.

3.6.4 Results

Separation of fibres to leave no evidence of the original fabric structure indicates dispersion of the dressing. Clear evidence of the original fabric structure indicates non-dispersion.

3.6.5 Test report

The report shall include at least the following information:

a) type of dressing; including lot number;

b) any deviations from the test method;

c) individual results, dispersion or non-dispersion;

d) date of test;

e) identity of the person(s) who carried out the test.

3.7 Dispersion/solubility of hydrogel dressings

3.7.1 Significance and use

This test is useful to determine the physical properties of amorphous hydrogel wound dressings in the presence of significant quantities of exudate.

3.7.2 Equipment

3.7.2.1 **Measuring cylinder,** of capacity 250 ml, or similar apparatus.

3.7.2.2 **Test solution A,** as specified in 3.2.2.3.

3.7.2.3 **Laboratory shaker,** capable of operating at 300 Hz to 350 Hz.

3.7.2.4 **Stop-watch**

3.7.3 Procedure

3.7.3.1 Add (200 ±2) ml of test solution A to (15 ± 0,1) g of hydrogel in a stoppered 250 ml measuring cylinder.

3.7.3.2 Shake the cylinder for 2 min to allow dispersion or dissolution and allow to stand for 2 h ± 10 min at room temperature. Inspect the contents of the cylinder visually.

3.7.4 Results

If the sample dissolves in the test solution, describe it as soluble, but if it remains in two distinct phases or disperses uniformly and then settles out to form two distinct layers, describe it as dispersible. If the sample retains its structure, describe it as non-dispersible.

3.7.5 Test report

The report shall include at least the following information:

a) type of dressing; including lot number;

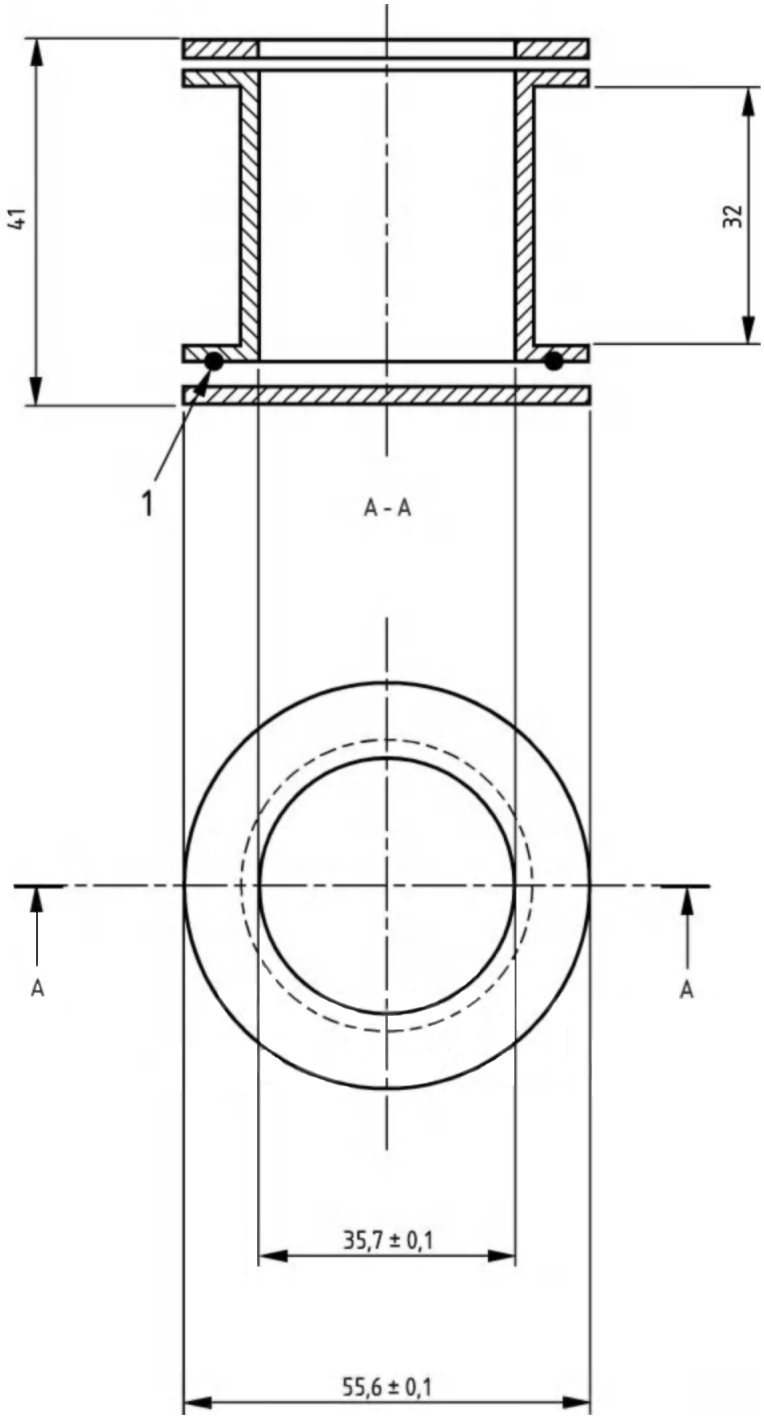
b) any deviations from the test method;

c) the results dispersed / not dispersed / dissolved / not dissolved;

d) date of test;

e) identity of the person(s) who carried out the test.

Dimensions in millimetres

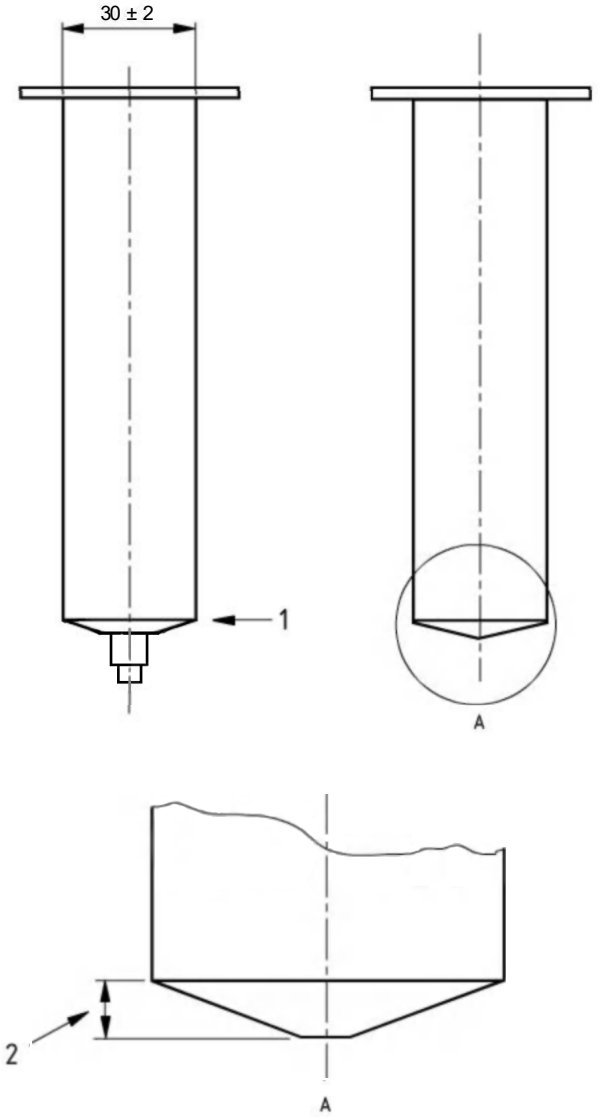


Key

1 Sealing ring

Figure 1 - Example of a cylinder that has been found to be adequate

Dimensions in millimetres



Key

1 Cut and chamfer here

2 Max. 5 mm

Figure 2 - Syringe specification

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