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(71) Applicant *(for all designated States except US)*: **DSM IP ASSETS B.V.** [NL/NL]; Het Overloon 1, NL-6411 TE Herleen (NL).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **GLAUNER, Martin** [DE/DE]; Lörracherstrasse 33F, 79639 Grenzach-wyhlen (DE). **KRÜGER, Benjamin** [DE/DE]; Benediktenwandstrasse 7, 84545 München (DE).

(74) Agent: **IPRIS GMBH**; Birsigstrasse 4, PO BOX 445, CH-4003 Basel (CH).

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(54) Title: LYOPHILIZATION CAP AND ASSEMBLY

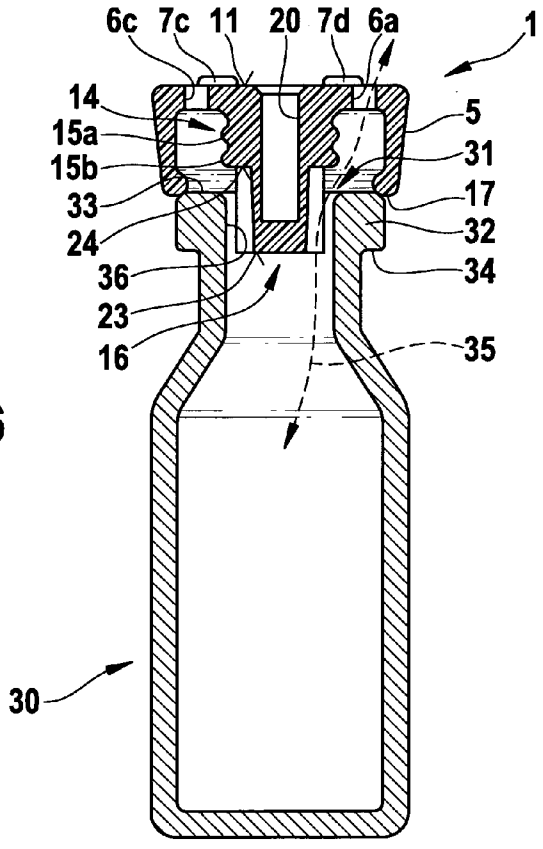


Fig. 6
(B-B)

(57) Abstract: The present invention relates to a lyophilization cap (1) for sealing a vial (30) having a mouth ring (32), said cap (1) comprising: a neck portion (2) having sealing means (14) for sealing said vial (30); and a head portion (3) having at least one elastically deformable element (5) for engaging be¬ hind said mouth ring (32) of said vial (30).

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Lyophilization Cap and Assembly

FIELD OF THE INVENTION

The present invention relates to a lyophilization cap and to an assembly comprising such a cap and a vial.

BACKGROUND

Lyophilization, also known as freeze drying, is a dehydration process typically used to preserve a perishable substance or to make a substance more convenient for transport. Lyophilization is accomplished by freezing the substance and then reducing the surrounding pressure to allow the frozen water in the substance to sublimate directly from the solid phase to the gas phase. The greatly reduced water content that results inhibits the action of microorganisms and enzymes that would usually spoil or degrade the substance.

The freeze-dried substance must be sealed to prevent the reabsorption of moisture. In this sealed condition, the substance may be stored at room temperature without refrigeration while being protected against spoilage for many months or years. This is of particular importance when it comes to pharmaceutical or diagnostic applications.

One way of sealing a freeze-dried substance in a lyophilization vial is to press a stopper into the bottleneck of the vial directly after lyophilization. This is done either under vacuum or under a dry inert gas atmosphere to avoid any contact of moisture with the freeze-dried substance. Thereafter, the glass vial is locked with a screw cap, which is screwed onto a screw thread on the bottleneck.

This results in a laborious procedure not only for sealing but also for opening the vial. For sealing the vial, the user has to insert the stopper and then screw on the screw cap. For opening the vial, the user has to unscrew the screw cap and then lift the stopper.

Furthermore, a single-handed opening of the vial is not possible due to the nature of the required movements.

SUMMARY OF THE INVENTIION

It is therefore an object of the present invention to provide an improved lyophilization cap and assembly, which in particular allows for an easier and more economical production

and opening of the vial.

This object is achieved by means of a lyophilization cap comprising the features of claim 1 and/or a lyophilization assembly comprising the features of claim 23 and/or a lyophilization cap and vial comprising the features of claim 25.

The invention provides a lyophilization cap for sealing a vial having a mouth ring, said cap comprising: a neck portion having sealing means for sealing said vial; and a head portion having at least one elastically deformable element for engaging behind said mouth ring of said vial.

The advantage of the invention is that it allows for an kinematically simplified opening and closing of the vial. This is due to the movements required for a deformation of the elastically deformable element being of a much simpler kinematic nature than the movements required for inserting a stopper in a lyophilization vial and screwing a screw cap on the same. Therefore, the lyophilization cap according to the invention can be handled more easily by a user and is well suited to automation. Specifically, a single-handed opening of the vial by a user is allowed. In addition, only a single part has to be produced and placed during filling of the vials, resulting in considerable time and cost savings.

The invention further provides a lyophilization assembly comprising: a vial having a mouth and an outwardly extending mouth ring, wherein said mouth has an inner wall and wherein said mouth ring has a first shoulder facing said mouth and a second shoulder facing away from said mouth; and the lyophilization cap provided by the invention.

The invention further provides a lyophilization cap and a vial, wherein said cap is used for sealing said vial and wherein said vial has a mouth and an outwardly extending mouth ring, said mouth having an inner wall and said mouth ring having a first shoulder facing said mouth and a second shoulder facing away from said mouth, said cap comprising: a neck portion having sealing means for sealing said mouth; and a head portion having at least one elastically deformable element for engaging behind said mouth ring of said vial; wherein said cap has a lyophilization position, in which said at least one elastically deformable element abut against said first shoulder and said sealing means stay clear of said mouth; wherein said cap has a sealing position, in which said at least one elastically deformable element engages said second shoulder and said sealing means press elastically against said inner wall of said mouth to seal the same; wherein said

at least one elastically deformable element deforms elastically when operating said cap between a lyophilization position and said sealing position.

According to one embodiment said at least one elastically deformable element has an at least partially annular shape. The annually shape increases the holding force that can be provided by the at least one elastically deformable element on the second shoulder of the mouth ring.

According to a further embodiment said at least one elastically deformable element has a tapering shape. The tapering shape further increases the holding force provided by the at least one elastically deformable element on the second shoulder of the mouth ring.

According to a further embodiment said head portion further comprises a base portion having an upper and a lower surface. The base portion serves as a basis, which connects other elements of the cap.

According to a further embodiment of the invention said base portion has at least one through-hole allowing air or vapor to escape from the vial during lyophilization. Thus, air or water vapor can escape from the vial through the top of the lyophilization cap. Hence, no through-hole need to be provided on the sides of the cap as is the case with some of the lyophilization caps known to the applicant. Since a great number of lyophilization vials with the lyophilization caps in place are lyophilized simultaneously, wherein the vials and caps are arranged such that they are more or less in contact with one another on their respective sides, it is advantageous to remove the vapor, which escapes during lyophilization, via the top of the lyophilization cap. This reduces the possibility of vapor exiting the through-holes condensing on surfaces in the immediate proximity, which would inhibit a clean lyophilization process.

According to a further embodiment of the invention said upper surface of said base portion comprises at least one bump to prevent adhesion of said cap during handling. When the lyophilization cap is handled by automatic means, in particular an automatic suction gripper, there is a risk of the upper surface of the lyophilization cap sticking to a surface of the gripper, particularly due to the comparatively light weight of the cap. The at least one bump effectively decreases the surface area of the lyophilization cap that can potentially be in contact with a surface of the suction gripper, thus preventing an unintentional adhesion of the cap to

the gripper. Furthermore, the bumps ensure that gases can escape from the cap even though a substantially even surface may be covering the upper surface of the cap.

According to another embodiment of the invention said at least one bump is arranged around a suction gripper interface surface on said upper surface of said base portion. Thus, the at least one bump does not hamper the handling of the cap by means of a suction gripper head being at least temporarily in contact with the suction gripper interface surface.

According to further embodiment of the invention said at least one elastically deformable element extends from said lower surface of said base portion. Preferably, said at least one elastically deformable element is connected to an outer edge of said lower surface.

According to another embodiment of the invention said at least one elastically deformable element extends further than said sealing means from said lower surface. This ensures that the sealing means are spaced apart from the mouth of the vial thus allowing lyophilization when the cap is in the lyophilization position, wherein the at least one elastically deformable element abuts a first shoulder of the mouth ring.

According to a further embodiment of the invention said bumps are arranged alternatingly with said through-holes on a substantially circular line. This ensures, that the through-holes are at no time blocked by external bodies, thus allowing lyophilization at all times.

According to a further embodiment of the invention said neck portion extends away substantially perpendicularly from said lower surface along a center axis of said elastically deformable element. This feature ensures a proper seat of the cap on the vial.

According to a further embodiment a hole extends from said upper surface along said center axis inside said neck portion. This feature allows for a more or less constant wall thickness of the cap improving its manufacturability. Typically, the lyophilization cap is manufactured by vulcanization in a mold. Preferably a pin cooperates with the hole and thereby further increases the manufacturability of the cap. It is of course understood that a lyophilization cap can also be designed without a hole which would then have the advantage of an increased rigidity of the cap.

According to a further embodiment said neck portion further

comprises a centering portion for insertion into the mouth of said vial and thereby transversely stabilizing said lyophilization cap on said vial. The transverse stability reduces the risk of the cap falling off the vial for instance during placement of the cap on the vial specifically when a suction gripper releases the cap. Inaccuracies in the placement can thus be compensated by a cap with the above features.

According to a further embodiment of the invention the sealing means are arranged adjacent to said lower surfaces and said centering portion is arranged adjacent to said sealing means. Preferably, the sealing means are not only arranged between the lower surface and the centering portion but also in immediate proximity to the lower surface and the centering portion is arranged in immediate proximity to the sealing means.

According to a further embodiment said centering portion extends further from said lower surface than said deformable element. This feature ensures that the centering portion extends into the mouth of the vial when the cap is in the lyophilization position on the vial as the deformable element abuts the mouth ring of the vial. Such centering means reduces the process accuracy required for placing the cap on the vial. To this end, preferably, the centering portion is itself tapered further decreasing the process accuracy required to place the cap on the vial.

According to a further embodiment of the invention said sealing means comprise one or more, in particular two ring shape seals being spaced apart from one another. In this way, the required leak tightness of the cap in the sealing position can be achieved thus preventing fluids from escaping from the vial through its mouth.

According to a further embodiment of the invention said centering portion of said neck comprises at least one channel for fluidly connecting an end of said neck portion to said through-holes of said head portion. This allows a lyophilization of the vial in the lyophilization position of the cap, wherein the deformable element abuts against the mouth ring.

According to a further embodiment the centering portion of said neck portion has a circular cross section with substantially semicircular recesses defining webs between them. The webs serve for example for defining the channels and as a leading portion for leading the neck portion into a respective mouth of a vial, respectively. Furthermore, the webs can be formed in order to compensate tolerances. Preferably the

webs are arranged symmetrically and for example there are provided four webs. The recess form the cross sections of the channels respectively. Such recesses are simple to manufacture.

According to a further embodiment said webs are elastically deformable for a friction grip with an inner wall of said mouth of said vial. Hence, a more reliable fit of the cap on the vial is achieved, particularly in the lyophilization position. More preferably, the webs comprise noses extending in the lengthwise direction of the webs respectively. Preferably, the noses are of a semicircular circular shape. The noses have a reduced cross section compared to the webs allowing them to be deformed elastically with a lower force. This reduces the forth required for insertion of the cap into the vial, particularly during placement of the caps on the vials in the lyophilization position.

According to a further embodiment the cap consists of a single piece. Due to the elasticity of the cap, it can be manufactured in a simple two piece mould, thus reducing production cost. According to a further embodiment the cap comprises bromobutyl. Bromobutyl is appropriate to most medical and pharmaceutical applications and is not destroyed or deteriorated by the lyophilization process.

According to a further embodiment sound producing means are provided, which produce sound when removing the cap from the vial. This will inform the user that the cap has been removed - even without a line of sight contact. Preferably, the sound is only produced on a first removal of the cap from the vial. This will prevent the unintentional use of substances that have been in contact with air or moisture possibly degrading the substances in the vial.

According to a further embodiment of the invention the elastically deformable element has an outer diameter larger than the inner diameter of said mouth ring and an inner diameter smaller than a outer diameter of said mouth ring. This feature ensures that the at least one elastically deformable element abuts against the mouth ring in the lyophilization position.

According to a further embodiment, said sealing means are spaced apart from said mouth in said lyophilization position of said cap and said sealing means are in a sealing contact with said inner wall of said mouth in a sealing position of said cap. This allows for the removal of fluids from the vial in the lyophilization position of the cap and further pre-

vents the substance from absorbing moisture when the cap is in the sealing position on said vial.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective top view of a lyophilization cap according to a first embodiment of the present invention;

Figure 2 is a perspective bottom view of the lyophilization cap of Figure 1;

Figure 3 is a side view of the lyophilization cap of Figure 1;

Figure 4 is a cross sectional view A-A of Figure 3;

Figure 5 is a top view of the lyophilization cap of Figure 1, wherein the lyophilization cap is placed on a lyophilization vial;

Figure 6 shows a cross sectional view B-B of Figure 5, wherein the lyophilization cap is in the lyophilization position;

Figure 7 shows the cross sectional view B-B of Figure 5, wherein the lyophilization cap is in the sealing position;

Figure 8 shows the top view of Figure 5, wherein the sealing cap is rotated around an axis normal to the paper plane compared to the view of Figure 5;

Figure 9 shows a cross section C-C of Figure 8, wherein the lyophilization cap is in the lyophilization position;

Figure 10 shows the cross section C-C of Figure 8, wherein the lyophilization cap is in the sealing position;

Figure 11 shows the cross section of Figure 10 with a lyophilization cap according to a second embodiment of the present invention;

Figure 12 shows a perspective view of a lyophilization cap according to a third embodiment of the present invention;

Figure 13 is a cross sectional view of the lyophilization cap of Figure 12 arranged on a vial, wherein the lyophilization cap is in the lyophilization position;

Figure 14 is a side view of the lyophilization cap of Figure 12 arranged on a vial, wherein the lyophilization cap is in the lyophilization position; and

Figure 15 shows the lyophilization cap and vial of Figure 14, wherein the lyophilization cap is in the sealing position.

DETAILED DESCRIPTION OF EMBODIMENTS

In the following, a first embodiment of the present invention is explained. In the figures, equal or functionally equivalent parts have equal reference signs.

According to this first embodiment, a lyophilization cap 1, hereinafter referred to as cap 1, comprises a neck portion 2 and a head portion 3, as illustrated in Figures 1 to 4. As will be explained in more detail at a later stage, it is one primary function of the head portion 3 to allow lyophilization of a substance in a vial whilst the cap 1 is arranged in a lyophilization position on the vial. Furthermore, it is another primary function of the head portion 3 to fasten the neck portion 2 inside the mouth of the vial for sealing the same in a sealing position of the cap 1.

The head portion 3 of the cap 1 has a base portion 4 of preferably circular shape. At its perimeter, the base portion 4 is connected to an elastically deformable element 5. The deformable element 5 is preferably of an annular shape and tapers in a direction away from the base portion 4.

The base portion 4 has through-holes 6a...6d, for example of an elongated shape, allowing gases to escape from the vial during lyophilization.

Furthermore, the base portion 4 comprises bumps 7a...7d on its upper surface 11. The bumps 7a...7d have the function to

prevent adhesion of the cap 1 during handling, for example to prevent adhesion to a surface of a suction gripper.

At the same time the through-holes 6a...6d and bumps 7a...7d are arranged around a preferably circular area 8 for interfacing with a suction gripper. This allows for an easy automated handling of such caps 1. Even more preferably the bumps 7a...7d are arranged alternatingly with said through-holes 6a...6d on a substantially circular line concentric with the base portion 4. Such a preferably symmetric arrangement of the bumps 7a...7d and through-holes 6a...6d can lead to advantages during handling of the cap 1.

As can be seen from Figure 2, the neck portion 2 is connected to a lower surface 12 of the base portion 4. At the same time, the neck portion 2 extends away from the lower surface 12 of the base portion in the same direction as the elastically deformable element 5 and extends along a center axis 13 passing through the center of the base portion 4. Preferably, the deformable element 5 is concentric with the neck portion 2 and tapers in a direction away from the lower surface 12 of the base portion 4.

The neck portion 2 comprises sealing means 14 arranged adjacent to the lower surface 12. The sealing means 14 are preferably sealing rings, in particular two sealing rings 15a and 15b, concentric with the center axis 13. The sealing rings 15a and 15b are spaced apart from each other.

Adjacent to the sealing means 14, preferably bordering directly onto the sealing ring 15b, in a direction away from the lower surface 12 of the base portion 4, the neck portion 2 has a centering portion 16 for insertion into the mouth of the vial. For this purpose, the centering portion 16 preferably extends further from said lower surface 12 than a bottom end 17 of the elastically deformable element 5. At the same time, it is preferred that the bottom end 17 is spaced further from the lower surface 12 than the sealing means 14. The advantages of such a design will be explained in connection with Figures 6 and 7 in more detail.

As illustrated in Figures 2 and 4, the centering portion 16 preferably has a circular cross section with substantially semi-circular recesses 18a...18d. The recesses define webs 19a...19d between them respectively. The recesses 18a...18d form channels 22a...22d which connect a bottom end surface 23 of the neck portion 2 with a bottom end surface 24 of the sealing means 14 respectively.

According to the first embodiment, the webs 19a...19d have substantially semi-circular noses 25a...25d extending along the center axis 13. Preferably the noses 25a...25d are elastically deformable for a friction grip with an inner wall of the mouth of the vial as will be explained in more detail later.

Moreover, a hole 20 extends from the upper surface 11 at the center of the base portion 4 through the base portion 4 into the neck portion 2 along the center axis 13. The hole 20 serves as a means for positioning of a suction gripper head on the suction gripper interface surface 8. Further, the hole 20 ensures the cap 1 having approximately the same wall thickness throughout, which leads to a better vulcanization process. Furthermore, the hole 20 simplifies demolding during production of the cap 1. However, embodiments without the hole 20 are also conceivable. The extra material would then provide the cap 1 with additional rigidity.

According to this first embodiment of the present invention, the cap 1 is made preferably of a single piece of material, preferably bromobuthyl. However, it is also conceivable to make the cap 1 of multiple parts and/or multiple materials. Preferably the cap 1 is made by vulcanization.

Preferably, the cap 1 is of a mirror symmetrical shape, wherein the axis of symmetry passes through the center axis 13. This simplifies staging processes and handling of the cap 1.

In the following, the working principle of the cap 1 according to the first embodiment of the present invention will be explained with reference to Figures 5 to 10.

Figure 6 shows the cap 1 of the first embodiment placed on a vial 30 as typically used in pharmaceutical applications.

The vial 30 comprises a mouth 31, which is used for charging the vial 30. Preferably, the vial 30 further has a mouth ring 32, which outwardly extends from the vial 30. In the arrangement as shown in Figure 6, the mouth ring 32 has a first shoulder 33, which is identical with the top end of the vial 30. However, other vials are conceivable, wherein the mouth ring 32 is positioned a predetermined distance away from the top surface, in which case the first shoulder 33 of the mouth ring 32 is not identical with the top surface of the vial 30. Moreover, the mouth ring 32 has a second shoulder 34 facing away from the first shoulder 33.

In the lyophilization position as depicted in Figure 6, the bottom end 17 of the head portion 3 abuts against the first shoulder 33, i.e. the top surface according to the embodiment of Figure 6, of the vial 30. For this purpose, the elastically deformable element 5 has an outer diameter larger than the inner diameter of the element (the first shoulder 33 according to the first embodiment of the invention) against which it abuts and an inner diameter smaller than an outer diameter of that element.

In the lyophilization position, the sealing rings 15a and 15b stay clear of the mouth 31 of the vial 30. This is due to the deformable element 5 extending further from the lower surface 12 than the sealing means 14 as explained earlier. As a result, fluid, typically water vapor, can flow along the path 35 from a substance within the vial through the channels 22a...22d and through the throughholes 6a...6d to the outside of the assembly to allow lyophilization (and vice versa).

It is advantageous to have the bottom end surface 23 of the centering portion 16 extend beyond the bottom end surface 17 of the head portion 3. This results in the centering portion 16 extending into the mouth 31 whilst the cap 1 is in the lyophilization position on the vial 30. This provides for a support of the cap 1 on the vial 30 in the transverse direction during lyophilization. Thus, the likelihood of the cap 1 falling off the top surface 17 during lyophilization, for instance due to inaccuracies in the gripping process, can be reduced.

Preferably, the centering portion 16 tapers in a direction away from the lower surface 12 of the base portion 4. This allows for an easier insertion of the centering portion 16 into the mouth 31 of the vial 30.

In the light of rationalizing production, it is advantageous to handle the cap 1 by means of a suction gripper (not shown). A centering pin on the suction gripper head cooperating with the hole 20 allows for an easy pick up of the cap 1 from a staging tray (not shown). At the same time, the suction gripper interface surface 8 allows for an easy gripping of the cap 1 when applying vacuum to the suction gripper. Even vials 30 with caps 1 being arranged in immediate proximity to one another, wherein the caps 1 are more or less touching one another, can be handled with ease. In another step, the cap is placed on the vial 30. The vacuum is switched off and the bumps 7a...7d prevent adhesion of the cap 1 on the suction gripper and ensure that throughholes 6a...6d are at no time covered thus allowing lyophilization

whilst the suction gripper is in contact with the suction gripper interface surface 8. Next, the cap 1 is pressed down on the vial 30 by means of application of a force, preferably on the upper surface 11 of the head portion 3. Thereby, the deformable element 5 expands elastically around the mouth ring 32 and contracts thereafter, thus engaging behind the second shoulder 34. The tapered shape of the deformable element 5 advantageously increases the force required to remove the cap 1 from the vial 30. In this position, the sealing means 14 extend into the mouth 31, wherein the sealing rings 15a and 15b lie tightly against an inner wall 36 of the mouth 31 and thereby sealing the same.

The hardness of the material used for making the cap 1 preferably ranges from 40 to 70 , more preferably from 50 to 56 Shore hardness and most preferably from 52 to 54 Shore hardness. These hardness levels provide a cap, which is sufficiently rigid for efficient handling, ensures a sufficiently tight sealing of the mouth 31 of the vial 30 and furnishes the deformable element 5 with a sufficient holding force to prevent the cap 1 from coming loose accidentally from the vial 30.

Usually, a great number of caps 1, for instance 100 - 20.000, are operated simultaneously from the lyophilization position to the sealing position by a single tool. If the suggested hardness values are chosen for the material of the cap 1, the force required on the tool will remain within reasonable bounds.

Figures 8 to 10 correspond to Figures 5 to 7 respectively, the difference being that in Figures 8 to 10 the cross sectional plane C-C is rotated relative to the cross sectional plane B-B of Fig. 5 to 7 about an axis normal to the plane of the paper.

Figure 9 shows the noses 25a...25d on the webs 19a...19d lying against the inner wall 36 of the vial 30 in the lyophilization position. This ensures a firm hold of the cap 1 on the vial 30. In this state, the noses 25a...25d are elastically compressed and thus generate friction forces between the cap 1 and the vial 30.

Figure 11 shows a cap 40 according to a second embodiment of the invention, which differs from the cap 1 of the first embodiment in that a bottom end 41 of a deformable element 43 has a chamfer 44 facing a vial 45. The chamfer 44 allows for a simple, single-handed opening of the vial 45. A user can hold the vial 45 using his fingers and using his thumb 46,

specifically his thumb nail 47, reach underneath the chamfer 44 and press substantially upwards and away from the vial 45 in order to deform the elastically deformable element 43 and thus remove the cap 40 from the vial 45 with one hand only.

Figures 12 to 15 illustrate a lyophilization cap 60 with a vial 61 according to a third embodiment of the present invention. In the following, only differences between the lyophilization cap 60 according to the third embodiment and the cap 1 according to the first embodiment will be explained.

A deformable element 62 is composed of only two partially annular segments 63a and 63b being attached to a substantially rectangular base portion 64. The third embodiment can result in a saving of material over the first embodiment.

Although the present invention has been described in accordance with specific embodiments, it is obvious for a person skilled in the art that modifications are possible in all embodiments.

Reference signs

1	lyophilization cap
2	neck portion
3	head portion
4	base portion
5	deformable element
6a	throughhole
6b	throughhole
6c	throughhole
6d	throughhole
7a	bump
7b	bump
7c	bump
7d	bump
8	suction gripper interface surface
11	upper surface
12	lower surface
13	center axis
14	sealing means
15a	sealing ring
15b	sealing ring
16	centering portion
17	bottom end
18a	recess
18b	recess
18c	recess
18d	recess
19a	web
19b	web
19c	web
19d	web
20	hole
22a	channel
22b	channel
22c	channel
22d	channel
23	bottom end surface
24	bottom end surface
25a	nose
25b	nose
25c	nose
25d	nose
30	vial
31	mouth
32	ring
33	first shoulder
34	second shoulder
35	flow path

36 inner wall
40 cap
41 bottom end
43 deformable element
44 chamfer
45 vial
46 thumb
47 nail
60 cap
61 vial
62 deformable element
63a segment
63b segment
64 base portion

Claims

1. Lyophilization cap (1) for sealing a vial (30) having a mouth ring (32), said cap (1) comprising:

a neck portion (2) having sealing means (14) for sealing said vial (30); and

a head portion (3) having at least one elastically deformable element (5) for engaging behind said mouth ring (32) of said vial (30).

2. Lyophilization cap according to claim 1, wherein said at least one elastically deformable element (5) has an at least partially annular shape.

3. Lyophilization cap according to claim 1 or 2, wherein said at least one elastically deformable element (5) has a tapering shape.

4. Lyophilization cap according to at least one of the preceding claims, wherein said head portion (3) further comprises a base portion (4) having an upper and a lower surface (11; 12).

5. Lyophilization cap according to claim 4, wherein said base portion (4) has at least one through-hole (6a...6d) allowing fluids to escape from the vial (30) during lyophilization.

6. Lyophilization cap according to claim 4 or 5, wherein said upper surface (11) of said base portion (4) comprises at least one bump (7a...7d) to prevent adhesion of said cap (1) during handling.

7. Lyophilization cap according to claim 6, wherein said at least one bump (7a...7d) is arranged around a suction gripper interface surface (8) on said upper surface (11) of said base portion (4).

8. Lyophilization cap according to at least one of the claims 4 to 7, wherein said at least one elastically deformable element (5) extends from said lower surface (12) of said base portion (4).

9. Lyophilization cap according to at least one of the claims 4 to 8, wherein said at least one elastically deformable element (5) extends further than said sealing means (14) from said lower surface (12).

10. Lyophilization cap according to at least one of the claims 5 to 9, wherein said bumps (7a...7d) are arranged alternatingly with said through-holes (6a...6d) on a substantially circular line.

11. Lyophilization cap according to at least one of the claims 4 to 10, wherein said neck portion (2) extends away substantially perpendicularly from said lower surface (12) along a center axis (13) of said elastically deformable element (5).

12. Lyophilization cap according to claim 11, wherein a hole (20) extends from said upper surface (11) along said center axis (13) inside said neck portion (2).

13. Lyophilization cap according to at least one of the preceding claims, wherein said neck portion (2) further comprises a centering portion (16) for insertion into a mouth (31) of said vial (30) and thereby transversely stabilizing said cap (1) on said vial (30).

14. Lyophilization cap according to at least one of the claims 4 to 13, wherein said sealing means (14) are arranged adjacent to said lower surface (12) and said centering portion (16) is arranged adjacent to said sealing means (14).

15. Lyophilization cap according to claim 13 or 14, wherein said centering portion (16) extends further from said lower surface (12) than said at least one deformable element (5).

16. Lyophilization cap according to at least one of the preceding claims, wherein said sealing means (14) comprises one or more, in particular two ring-shaped seals (15a, 15b) being spaced apart from one another.

17. Lyophilization cap according to at least one of the claims 13 to 16, wherein said centering portion (16) of said neck portion (2) comprises at least one channel (22a...22d) for fluidly connecting an end of said neck portion (2) to said through-holes (6a..6d) of said head portion (3).

18. Lyophilization cap according to at least one of the claims 13 to 17, wherein said centering portion (16) of said neck portion (2) has a circular cross section with substantially semicircular recesses (18a...18d) defining

preferably four symmetrically arranged webs (19a...19d) between them.

19. Lyophilization cap according to claim 18, wherein said webs (19a...19d) are elastically deformable for a friction grip with an inner wall (36) of said mouth (31) of said vial (30).

20. Lyophilization cap according to at least one of the preceding claims, wherein the cap (1) is comprised of a single piece.

21. Lyophilization cap according to at least one of the preceding claims, wherein the cap (1) comprises bromobutyl.

22. Lyophilization cap according to at least one of the preceding claims, wherein sound producing means are provided, which produce a sound on removing the cap (1) from the vial (30).

23. Lyophilization assembly, comprising:

a vial (30) having a mouth (31) and an outwardly extending mouth ring (32), wherein said mouth (31) has an inner wall (36) and wherein said mouth ring (32) has a first shoulder (33) facing said mouth (31) and a second shoulder (34) facing away from said mouth (31); and

a lyophilization cap (1) according to at least one of the preceding claims 1 to 22.

24. Lyophilization assembly according to claim 22, wherein said at least one elastically deformable element (5) has an outer diameter larger than the inner diameter of said mouth ring (31) and an inner diameter smaller than an outer diameter of said mouth ring (31).

25. Lyophilization cap (1) and vial (30), wherein said cap (1) is used for sealing said vial (30) and wherein said vial (30) has a mouth (31) and an outwardly extending mouth ring (32), said mouth (31) having an inner wall (36) and said mouth ring (32) having a first shoulder (33) facing said mouth and a second shoulder (34) facing away from said mouth (31), said cap (1) comprising:

a neck portion (2) having sealing means (14) for sealing said mouth (31); and

a head portion (3) having at least one elastically deformable element (5) for engaging behind said mouth ring (32) of said vial (30);
wherein said cap (1) has a lyophilization position, in which said at least one elastically deformable element (5) abuts against said first shoulder (33) and said sealing means (14) stay clear of said mouth (31);

wherein said cap (1) has a sealing position, in which said at least one elastically deformable element (5) engages said second shoulder (34) and said sealing means (14) press elastically against said inner wall (36) of said mouth (31) to seal the same;

wherein said at least one elastically deformable element (5) deforms elastically when operating said cap (1) between said lyophilization position and said sealing position.

26. Lyophilization cap and vial according to claim 24, wherein said sealing means (14) are spaced apart from said mouth (31) in said lyophilization position of said cap (1) and wherein said sealing means (14) are in a sealing contact with said walls (36) of said mouth (31) in a sealing position of said cap (1).

27. Lyophilization cap and vial according to claim 24 or 25, wherein said at least one elastically deformable element (5) extends further from a lower surface (12) of said head portion (3) then said sealing means (14) spacing said sealing means (14) from said mouth (31).

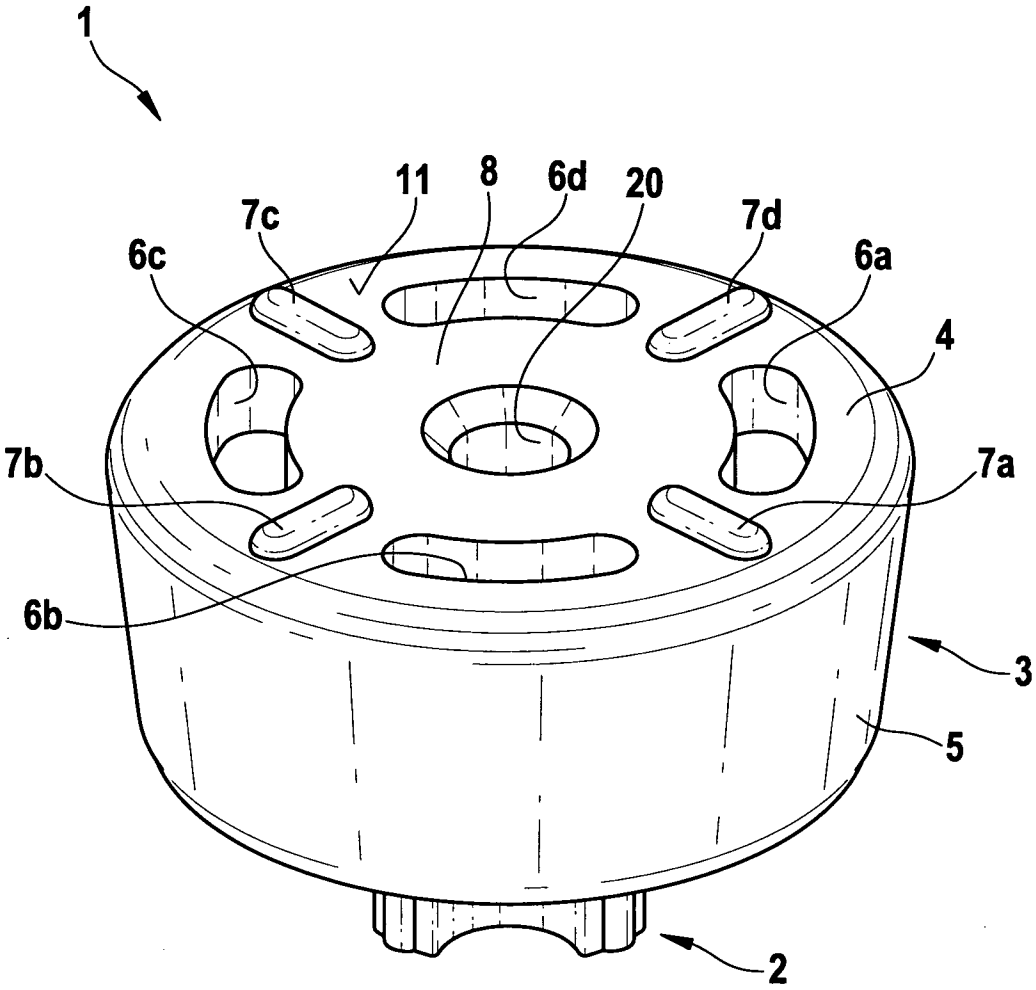


Fig. 1

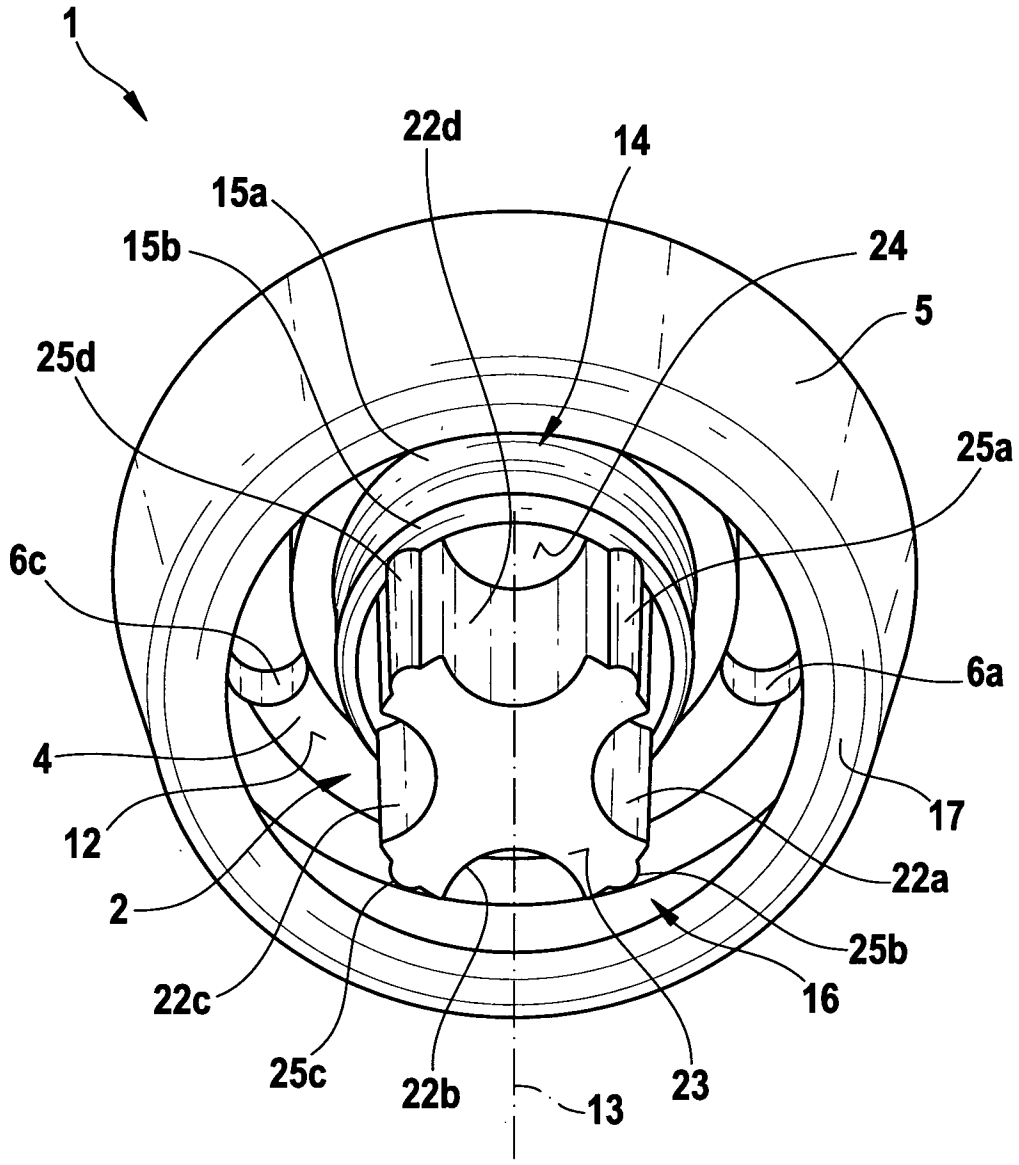

1
22d
14
15a
15b
24
5
25d
25a
6c
6a
4
17
12
22a
2
25b
16
22c
25c
22b
13
23

Fig. 2

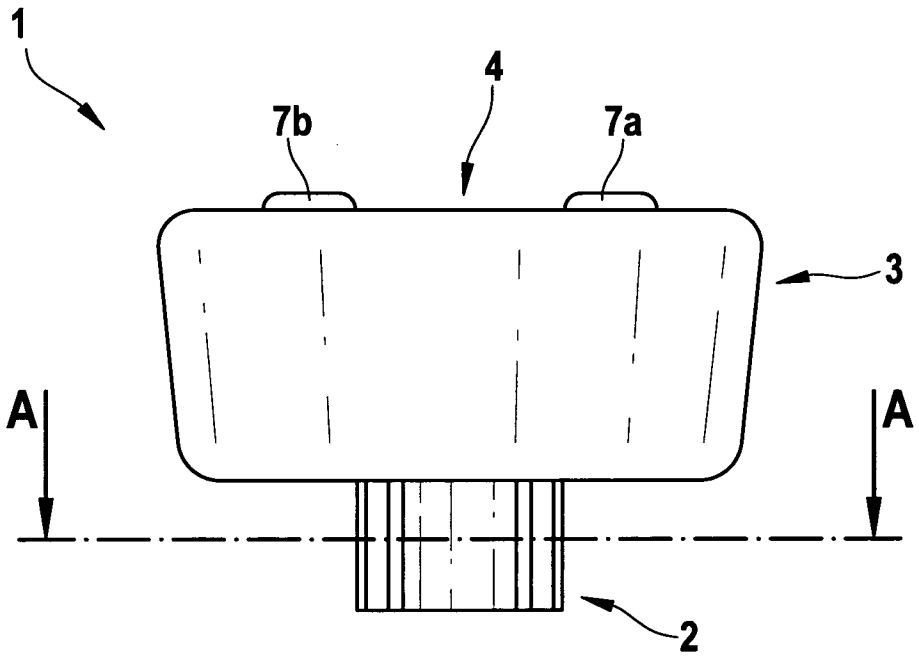

1
4
7b
7a
3
A
A
2

Fig. 3

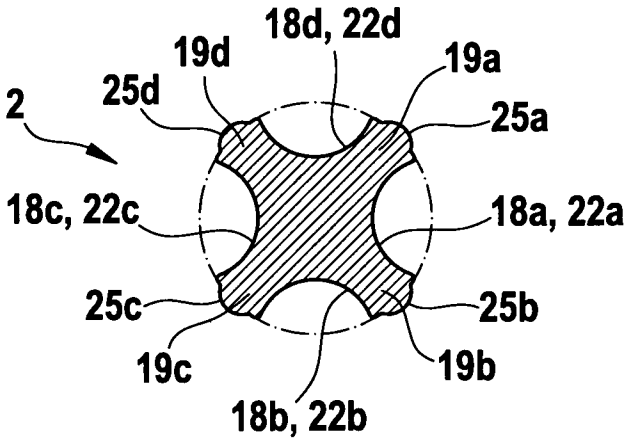

18d, 22d
19d
19a
25d
2
25a
18c, 22c
18a, 22a
25c
25b
19c
19b
18b, 22b

Fig. 4
(A-A)

Fig. 5

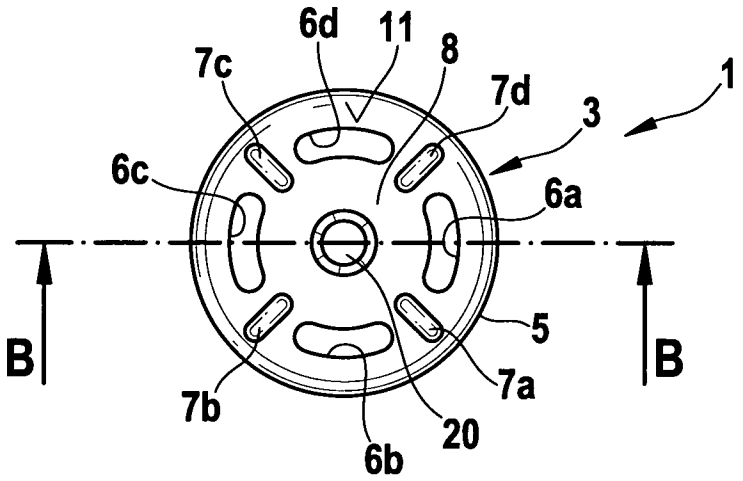
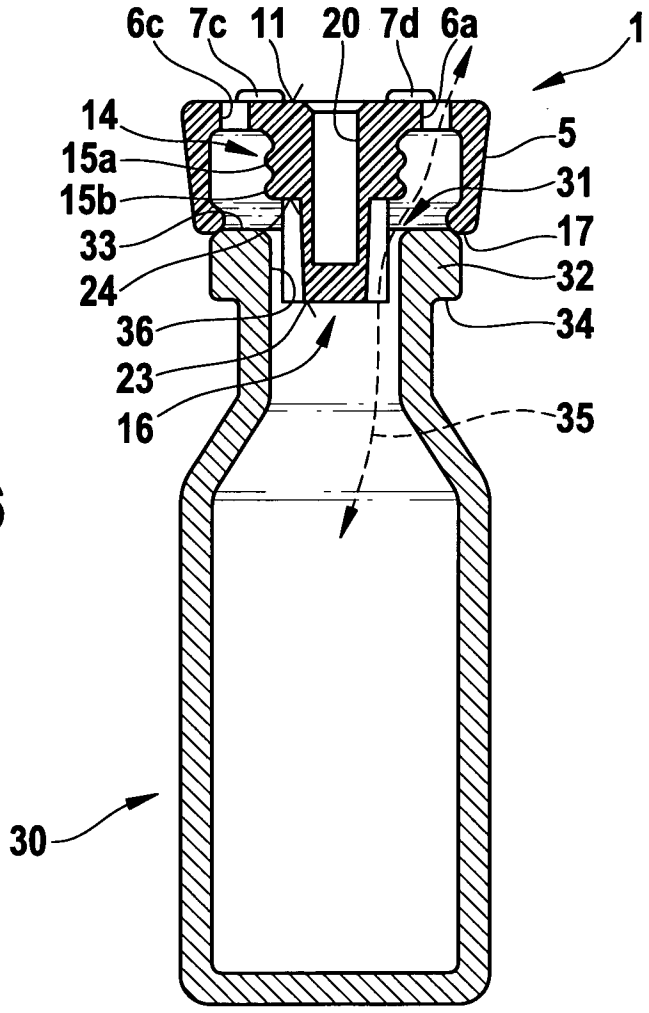

6d
11
8
7c
7d
1
3
6c
6a
B
B
5
7a
7b
20
6b

Fig. 6
(B-B)


6c
7c
11
20
7d
6a
1
14
15a
15b
33
24
36
23
16
5
31
17
32
34
35
30

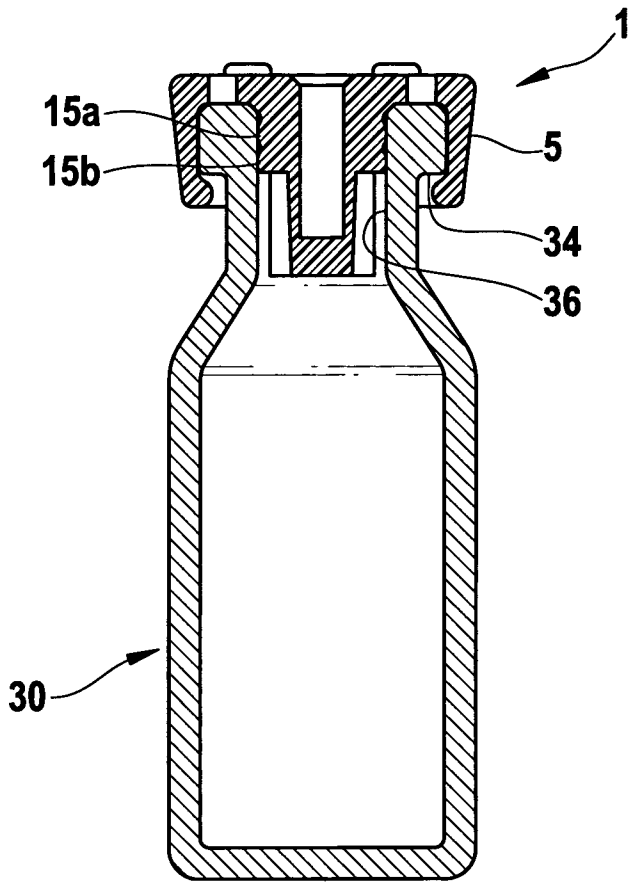


Fig. 7
(B-B)

Fig. 8

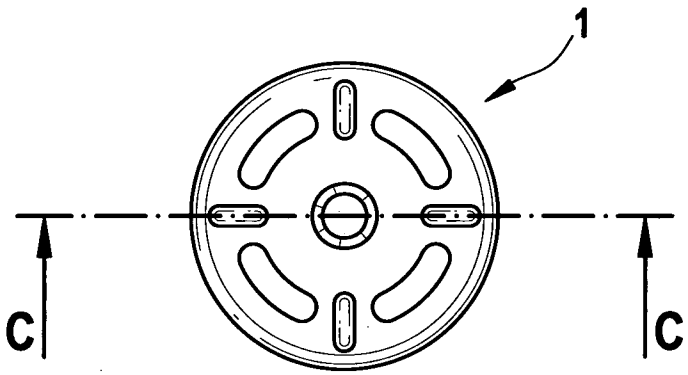
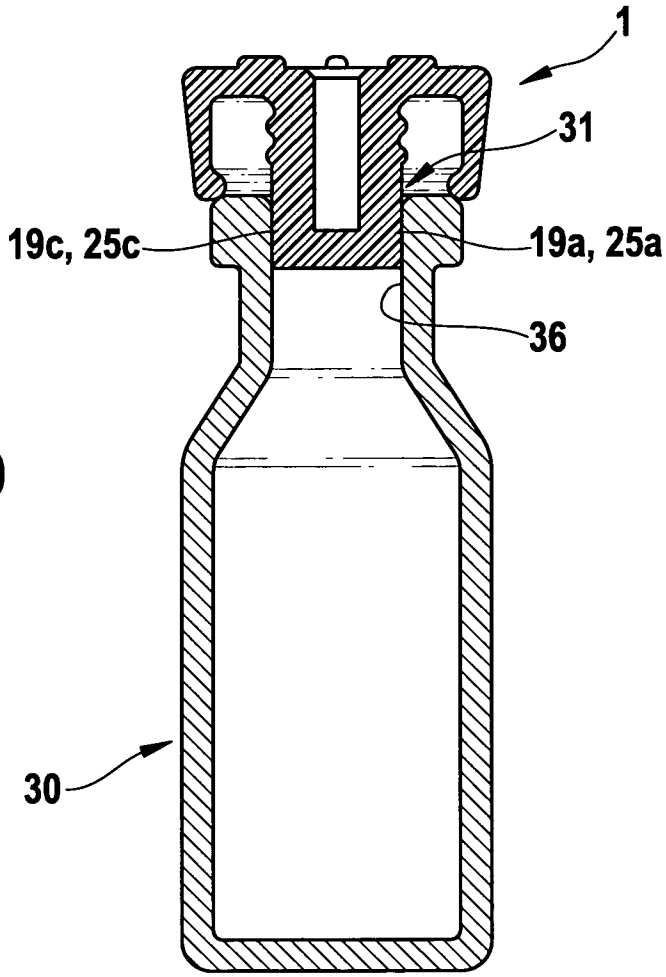


Fig. 9
(C-C)



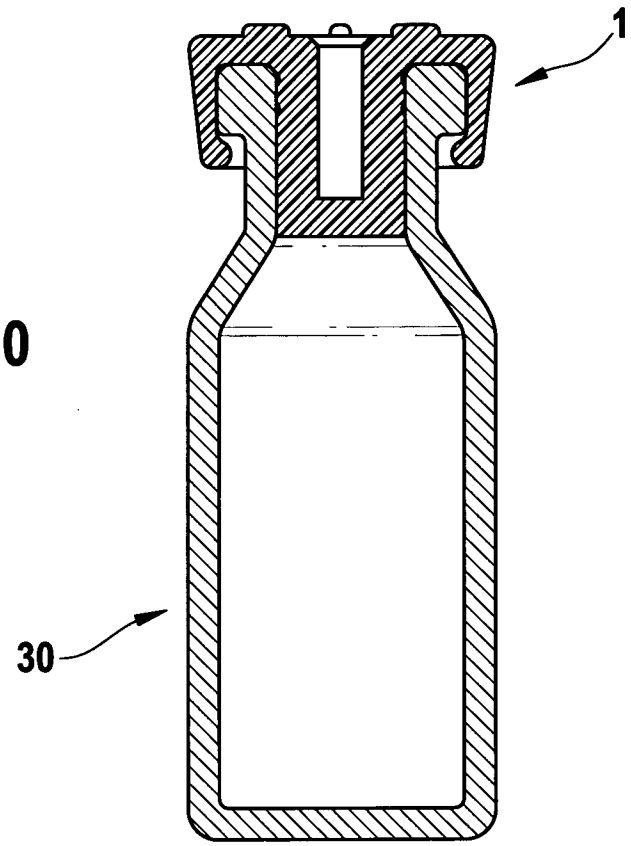


Fig. 10
(C-C)

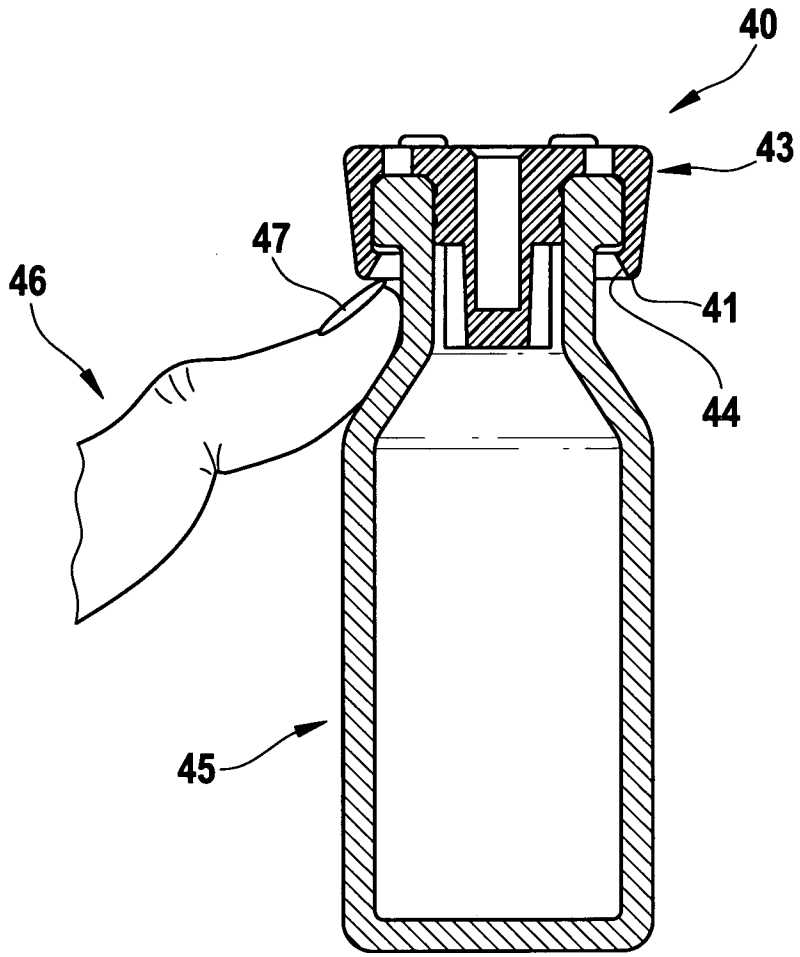


Fig. 11

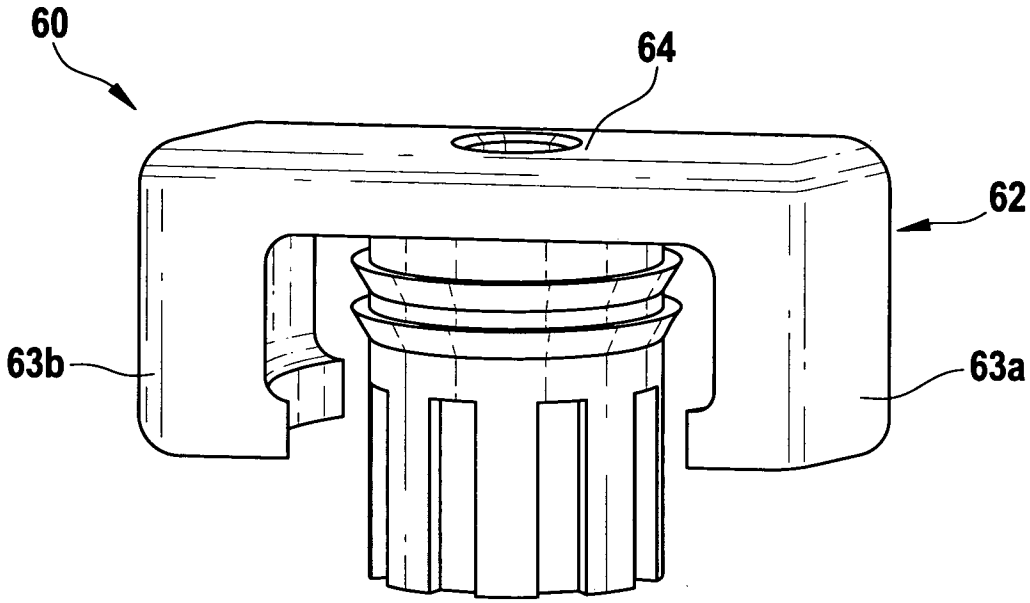


Fig. 12

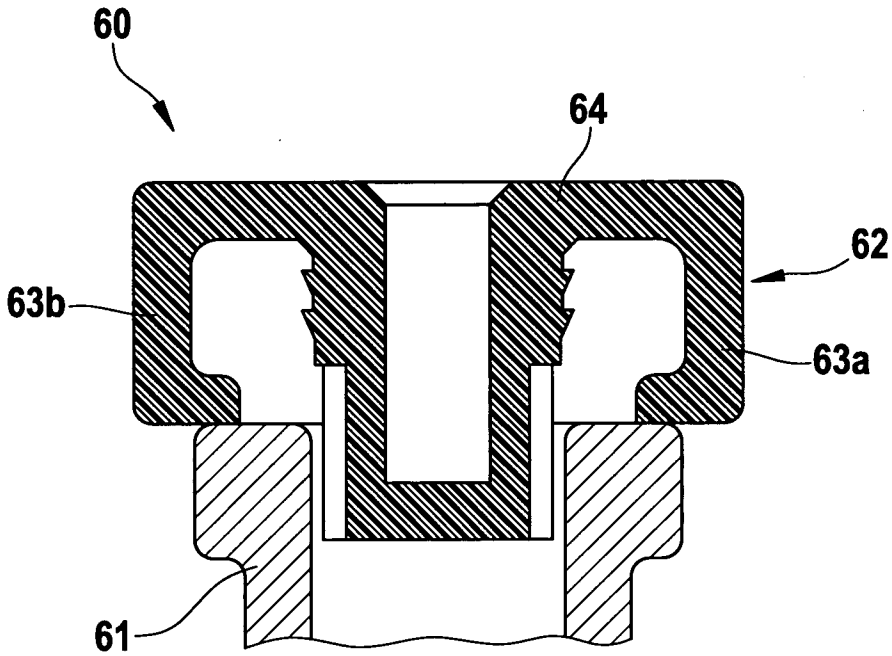


Fig. 13

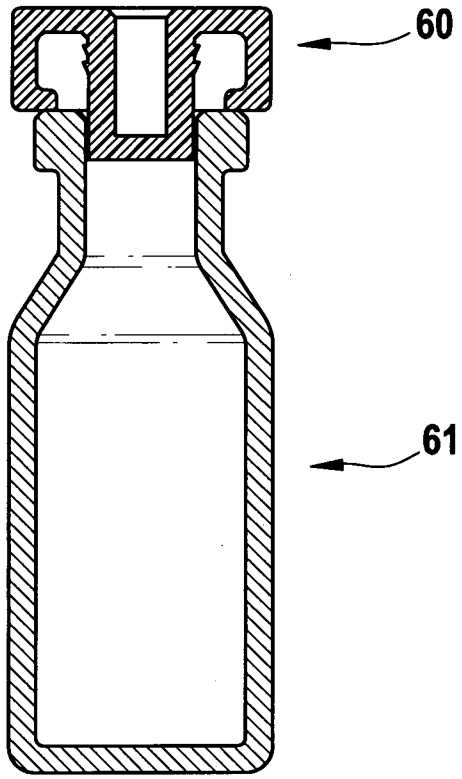


Fig. 14

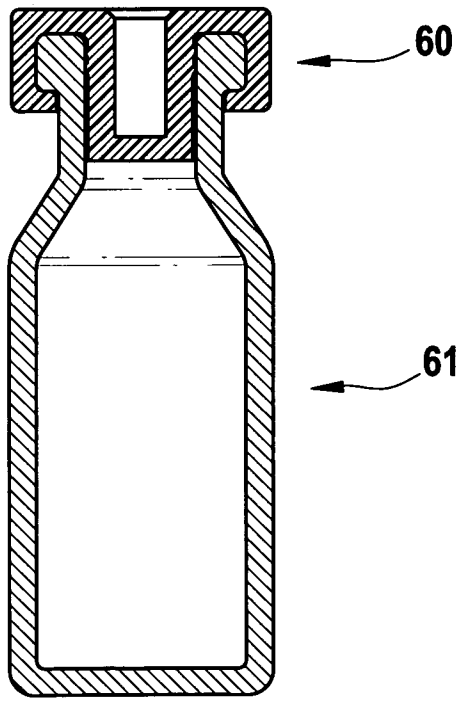


Fig. 15

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2008/000991

A. CLASSIFICATION OF SUBJECT MATTER
INV. B65D51/24
ADD. B65D41/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B65D B01L F26B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 881 626 A (BARTELL RALPH A) 6 May 1975 (1975-05-06)	1,2,4,8, 11, 13-15, 20,23
Y	column 2, line 49 - column 4, line 14; figures 1-3	6,7,12, 16-19, 21,22

X	FR 1 599 228 A (LALOUX CAMILLE MÉDARD) 15 July 1970 (1970-07-15)	1,2,4,8, 9,11,13, 14,20, 23,25-27
	page 2, line 14 - line 34 figures 1-4	

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
4 September 2008	16/09/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Fitterer, Johann

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2008/000991

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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