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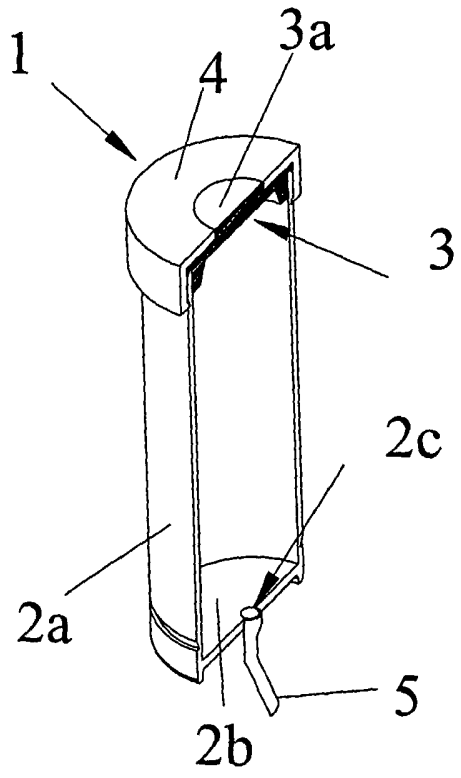
(54) Title: AIRTIGHT CONTAINER FOR STORING A PRODUCT, AND IN PARTICULAR A MEDICAMENT, AND ASEPTIC PROCESS FOR FILLING SAID CONTAINER



(57) Abstract: The airtight container (1) for storing a product (liquid, powder, granulates) comprises a rigid vial (2) with at least one filling hole (2c), an external filling pipe (5) for filling the vial (2) through the filling hole (2c), said filling pipe (5) airtightly sealing the filling hole (2c) of the vial (2), and a housing cap (12) designed to be assembled to the vial (2) and forming an housing (12a) for the filling pipe (5) once assembled to the vial (2). The container is particularly suitable for storing prior to use a product, such as for example a medicament (vaccines or the like), under sterile conditions.

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AIRTIGHT CONTAINER FOR STORING A PRODUCT, AND IN PARTICULAR A MEDICAMENT, AND ASEPTIC PROCESS FOR FILLING SAID CONTAINER

Field of the invention

The present invention generally relates to an airtight container that is being used for storing a product under sterile conditions. A preferred application of the invention is a small-sized airtight container that is being used preferably in the pharmaceutical field for storing for example a medicament such as vaccines or the like.

Prior Art

In the pharmaceutical field, medicaments, such as vaccines, are usually stored, prior to use, in small-sized airtight containers constituted by a rigid vial that is typically made of glass or plastic, and that is airtight sealed by a closing cap. The closing cap is typically made of vulcanized rubber or similar resilient material that neither contaminates nor affects the medicament, and that can be manually punctured or pierced by using a sharp element such as a syringe or a needle, in order to empty the vial.

For example when the medicament is a liquid, the closing cap is manually pierced by using a syringe and is sucked outside of the vial. When the medicament is a solid, for example a powder, the closing cap is pierced by using a syringe or the like, and a liquid, for example water, is introduced into the vial by using the syringe. The vial is then shaken so as to mix the powder and the liquid, and the solution inside the vial is for example sucked out of the vial, though the closing cap, by using a syringe or the like.

A major technical problem in this technical field is to avoid the contamination of the product (medicament or the like) stored inside the container, and thus to guarantee the sterility of the inside of the container during the filling process and also after the filling process.

According to one first known aseptic filling procedure, the vial and

the cap are sterilized separately, then the vial is filled with the medicament or the like, and the cap is assembled to the vial in order to seal the medicament in the vial. One major drawback of this first filling procedure is that it is difficult to maintain the sterility of the cap and vial during the assembly step. In addition, it is difficult to maintain the sterility of the vial and cap during transportation and storage prior filling.

In an attempt to overcome said risk of contamination of the vial and cap, it has been proposed in the past to use a second aseptic filling procedure wherein: in a first step, the cap is assembled to the vial so as to hermetically seal the vial ; in a second step the vial and the cap are sterilized, for example by gamma irradiation or the like ; in a third step, the vial is filled with the medicament by using a sterile syringe or like injection element that is temporarily inserted through the cap.

A first major drawback associated with this second aseptic filling procedure is that when the injection member (syringe, needle or the like) is temporarily inserted through the cap, and then withdrawn, a tiny hole is being formed in the cap.

The hole resulting from the insertion of the needle or the like shrinks somewhat due to the resiliency of the cap. In practise, the tiny hole that is formed in the cap is small enough to keep the medicament from leaking out, but is typically not small enough to prevent air or other gases from passing through the hole and into the vial. In addition, a resilient material such as vulcanized rubber is infusible. It is thus not possible to fuse such material in situ, for example with a suitable laser, in order to hermetically close the said tiny hole formed in the cap. Finally, when the aforesaid second filling procedure is being used, because of this tiny hole resulting from the insertion of the needle or the like, there is still a high risk of spoiling and/or contamination of the medicament stored in the vial.

A second major drawback associated with the aforesaid second filling procedure is that the exhaust of the air contained in the vial during the

filling step is difficult, because of the very small diameter of the needle used for filling the vial ; said exhaust of air typically involves the use of an additional duct acting as a vent, and it is in practise difficult to correctly measure out the medicament introduced in the vial.

In US patent N° 6,604,561, it is further disclosed a heat resealable cap comprising a first base portion formed of vulcanized rubber or like material known for providing a stable environment for the medicament contained in the vial, and a second heat resealable portion overlying the base portion. In particular, the second heat resealable portion is made of low-density polyethylene or like material, that can be manually punctured by a needle or similar. The aforesaid second filling procedure is used for filling the vial with the liquid medicament, and once the needle or the like is being withdrawn, the penetrated region of the cap is fused by laser or direct heat sealing, in order to hermetically seal the needle hole in the cap. The use of said composite cap (heat resealable portion/ vulcanized rubber base portion) disclosed in US patent N° 6,604,561 solves the problem of contamination due to the formation of the needle hole in the cap after filling.

The use of the composite heat resealable cap disclosed in US patent N° 6,604,561 does not however solve the aforesaid major second drawback linked to the exhaust of air during filling. In particular, referring for example to figure 3 of US patent N° 6,604, 561, an additional venting needle or syringe (referenced "142") has to be used for venting the vial during the filling step.

Furthermore, the use of the composite heat resealable cap disclosed in US patent N° 6,604,561 involves at least one additional drawback. There is a risk that part of the liquid contained in the vial passes trough the needle hole made in the vulcanized rubber base portion or the like, and detrimentally comes into contact with the upper heat sealable portion of the cap, which heat sealable portion of the cap is not compatible with the liquid. The risk is higher when the vial is turned upside down, or

when the vial and cap are slightly deformed by a small negative internal pressure.

Objective of the invention

It is an objective of the invention to propose a new technical solution for storing a product under sterile conditions, and in particular (but not only) a medicament, in a container, which solution enables to maintain the sterility of the inside of the container, and overcomes all the aforesaid drawbacks of the prior art.

Summary of the invention

This objective is achieved by the new airtight container of claim 1 and by the aseptic filling process of claim 18.

A major advantage of the invention is to avoid any perforation of the container part for filling the container. According to the invention, the filling of the container is performed through the filling pipe of the container, once said filling pipe has been temporarily opened ; the invention thus overcomes all the drawbacks of the prior art that were associated to the formation of the hole in the closing cap during the filling step and to the closing of said hole once the filing step is terminated.

Furthermore, in one particular embodiment of the invention, when the container is closed by a closure element that can be easily and manually pierced or punctured with a sharp element such as a syringe or a needle for emptying the vial, the structure of the said closure element can be very simple and the said closure element can be made of any material that is compatible with the stored product. In particular, said material does not need to be resealable.

Another advantage of the invention is that in practise the filling pipe can easily have a diameter that is large enough for enabling an easy exhaust of the air contained in the vial, during the filling step.

According to a further advantage of the invention, the equipment used for filling the vial or the equipment used for closing the filling pipe

comes into contact with the filling pipe only, and does necessarily penetrate inside the vial.

Other characteristics and advantages of the invention will become readily apparent in view of the following detailed description of several preferred embodiments of the invention and the accompanying drawings, which description and drawings are given by way of non-exhaustive and non-limiting examples of the invention.

Brief description of the drawings

- Figure 1 is a perspective view of an empty container of the invention, prior to the filling step ;
- Figure 2 is a perspective view of an half of the container of figure 1 showing the inside of the container ;
- Figure 3 is a cross-sectional view of the bottom part of the container prior to the filling step, and shows a first embodiment for the fixing means of the filling pipe ;
- Figure 4 is a cross-sectional view of the bottom part of the container prior to the filling step, and shows a second embodiment for the fixing means of the filling pipe;
- Figure 5 is a cross sectional view of the distal end of a filling pipe closed by a cap ;
- Figure 6 is a cross-section view of the distal end of a filling pipe closed by a clip ;
- Figures 7 to 10 schematically shows the successive steps for filling the container of figure 2 with a product (in particular a liquid, or powder or granulates), and
- Figure 11 is a perspective view of the final container filled with the product.

Detailed description

Figures 1 and 2 show an empty container 1 of the invention, prior aseptic filling with a product (liquid, powder, granulates), such as for example

a medicament or the like. The invention is however not limited to the storage of medicament, but is useful for storing any product, in particular under sterile conditions.

Said container 1 comprises :

- a rigid vial 2 constituted by a cylindrical sidewall 2a and a bottom wall 2b, said bottom wall 2b having a small central filling hole 2c,
- a closure element in the form of a rubber vulcanized cap 3 which is slidably received in the open end of the vial 2 (opposite to the bottom end 2b) ; such a cap 3 is also commonly referred as a "stopper" ;
- a locking ring 4, for example made of aluminium or plastic, that is crimped in place onto the vial 2 in order to lockably connect and airtight seal the cap 3 to the vial 2;
- an add-on external filling pipe 5 which is fixed at one end on the bottom wall 2b of the vial 2.

The vial 2 can be made of any sterilizable and inert material that is compatible with the product that has to be stored. The vial 2 can be for example made of glass or plastic.

The cap 3 can be made of any sterilizable material that is compatible with the product stored in the container, and that can be easily and manually punctured or pierced with a sharp element such as a needle or a syringe. The cap 3 is preferably (but not necessarily) made of a resilient material, and more preferably made of vulcanized rubber.

The filling pipe 5 defines an internal fluid passage 6 (figure 3) having an open proximal end 6a, and is airtightly fixed to the bottom end 2b of the vial 2 by any suitable means, in such a way that the open proximal end 6a of the fluid passage 6 communicates with the bottom filling hole 2c of the vial 2. It is important for the seal between the filling pipe 5 and the vial 2 to be airtight, in order to avoid any risk of contamination of the inside of the vial 2.

In the particular embodiment of figure 3, the filling pipe 5 has a proximal end 5a in the form of a "T", and is locked onto the vial 2 by an

additional locking cap 7 which squeezes the proximal end 5a of the filing pipe against the external face of the bottom end 2b of the vial 2. Said fixing means does not limit the scope of the invention, and can be replaced by any other suitable airtight fixing means. In particular, the proximal end 5a of the filling pipe 5 could be inserted and airtightly fixed through the bottom filling hole 2c of the vial 2 (as shown on figure 2). Figure 4 shows another variant for airtightly fixing the filling pipe 5 on the vial 2. In another variant, the filling pipe 5 could be welded on the vial.

The filling pipe 5 is made of any sterilizable material that is compatible with the product that will be stored inside the vial 2. The pipe is preferably flexible and is for example made of any biocompatible polymer and more particularly any biocompatible elastomer.

As shown in the particular embodiment of figure 3 or figure 4, the distal end 5b of the filling pipe is airtightly closed. The filling pipe 5 thus airtightly seals the filling hole 2c of the vial 2, in order to avoid the accidental penetration of any contaminant (solid, liquid or gaz) inside the vial 2.

More particularly, in the embodiment of figure 3 or 4, the opening of the distal end 5b of the filling pipe (during the filling step) can be performed by simply pinching the distal end 5b of the pipe 5, so as to create an internal fluid passage 6 on the whole length of the filling pipe. When the pinching pressure is released, the distal end 5b of the filling pipe 5 comes back to its closed state, as illustrated on figure 3 or figure 4.

The process for the aseptic filling of the container 1 with a product, such as a medicament, comprises the following steps.

(a) The empty container 1 of figure 1 or figure 2 is sterilized by using any well-known sterilization process and for example by using gamma radiations.

(b) The distal end 5b of the filling pipe of the sterilized empty container 1 is temporarily opened by two jaws 11 (figure 7) that pinch the filling pipe ; advantageously, the opening system (jaws 11) does not

penetrate inside of the vial 2 . Then a sterile filling nozzle 10 is inserted inside said opened distal end 5b ; advantageously, the filling nozzle 10 does not penetrate inside the vial 2, but is inserted only inside the filling pipe 5.

(c) The product (for example liquid, powder, or granulates) is injected inside the vial 2 through the filling pipe 5 and through the bottom filling hole 2c. In order to enable the exhaust of the air contained in the vial 2 during this filling step, the external diameter of the filling nozzle 10 has to be smaller than the internal diameter of the filling pipe 5.

(d) The filling nozzle 10 is removed from the filling pipe 5 and the distal end 5b of the filling pipe is hermetically closed (figure 8), by releasing the pressure exerted by the jaws 11.

(e) The filling pipe 5 is definitely closed.

The final closing step (e) can be performed in different ways. For example the filling pipe 5 is pressed in order to airtightly close the pipe 5, and the distal end 5b of the pipe 5 is thermally sealed (by laser or by using any thermal source for fusing the distal end of the pipe). Then the filling pipe 5 is preferably fold up as depicted on figure 9. This can be achieved by a mechanical action eventually combined with a local heating of the pipe in order to locally soften the pipe 5. Advantageously, all the equipments used for definitely closing the filling pipe (step e) do not come into contact with the inside of the vial 2

Finally, a housing cap 12 is definitely fixed onto the bottom end 2b of the vial 2, said bottom cap 12 forming with the vial 2 an housing 12a for the pipe 5. The pipe 5 is thus no longer accessible. The housing cap 12 protects the filling pipe 5, and avoids any risk of detrimental manipulation thereof.

Preferably, said housing cap 12 is first sterilized and then assembled to the vial 2, in order to avoid any risk of contamination of the filling pipe 5.

In the particular embodiment of figure 11, the housing cap 12 also

advantageously forms a stable and aesthetic base for the container 1.

According to the invention, thanks to the use of the external filling pipe 5, there is advantageously no need to perforate the vial 2 or the cap 3 during the filling process. There is thus no risk of contamination of the inside of the vial by particles or the like coming from the vial, the cap or from any equipment used during the aseptic filling process.

It should be also noted that during the filling step (c) and the closing steps (d) and (e), the product stored inside the vial 2 is advantageously not subjected to any pressure variations or to any thermal variations. There is thus no modification of the properties of said product.

It is important for the invention that the filling pipe 5 is airtightly closed, prior the filling step (b), so as to preclude the penetration of any contaminant inside the vial during the process. But the invention is not limited to the particular filling pipe shown in figures 3 and 4.

In another variant shown on figure 5, the distal end 5b of the filling pipe 5 is airtightly closed by a removable cap 8.

In another variant shown on figure 6, the distal end 5b of the filling pipe 5 is airtightly closed by a removable clip 9.

In another variant (not shown), the distal end 5b of the filling pipe 5 could be thermally fused so as to be hermetically closed, and the opening of the pipe (step (b)) could be performed by cutting the closed end the pipe 5 (for example by using a laser or any mechanical cutting means).

The final container 1' containing the product is shown on figure 11. The emptying of the container 1' is performed by puncturing the cap 3 (in the area 3a that is not surrounded by the locking ring 4) with a needle or syringe, and by sucking through the cap 3 the product contained inside the vial 2. When the product stored inside the vial is a powder, a liquid such as water can be previously introduced inside the vial 2 through the closing cap 3, in order to dilute the powder and form a solution inside the vial 2.

The invention is not limited to the use of a rubber cap 3 for closing

the vial 2. In other embodiments of the invention (not shown on the drawings) the cap 3 can be replaced by any closure element that can be removed from the vial during the emptying step (for example a removable cap screwed onto the vial), or by any closure element that can be pierced, or broken, or torn off the vial, or torn on, for emptying the vial.

Claims

1. An airtight container (1) comprising a rigid vial (2) with at least one filling hole (2c), an external filling pipe (5) for filling the vial (2) through the filling hole (2c), said filling pipe (5) airtightly sealing the filling hole (2c) of the vial (2), and a housing cap (12) designed to be assembled to the vial (2) and forming an housing (12a) for the filling pipe (5) once assembled to the vial (2).
2. The container of claim 1 wherein the filling pipe (5) is flexible.
3. The container of claim 1 or 2 wherein the filling pipe (5) can be opened by exerting a pressure on the pipe.
4. The container of claim 1 or 2 wherein the filling pipe (5) is airtightly sealed by a removable cap (8).
5. The container of claim 1 or 2 wherein the filling pipe (5) is airtightly sealed by a removable clip (9).
6. The container of any one of claims 1 to 5 wherein the vial (2) comprises an opening for emptying the vial (2), said opening being closed by a closure element (3).
7. The container of claim 6 wherein said closure element (3) is a made of a material that can be easily pierced by a sharp element such as a syringe or a needle.
8. The container of claim 7 wherein said closure element (3) is made of a resilient material.
9. The container of claim 8 wherein said closure element (3) is made of an elastomeric material.
10. The container of claim 9 wherein said closure element (3) is made of vulcanized rubber.
11. The container of claim 1 and 6 wherein the filling pipe (5) is fixed on a bottom end (2b) of the vial (2), said bottom end (2b) being opposite to the opening for emptying the vial (2), and said bottom end (2b) comprising said filing hole (2c).

12. The container of any one of claim 1 to 11 wherein the vial (2) is cylindrical.

13. The container of any one of claim 1 to 12 wherein the housing cap (12) forms a stable base for the vial (2) once the housing cap (12) is assembled to the vial (2).

14. A container according to any one of claims 1 to 13, wherein the vial (2) is containing a product and the filling pipe (5) is definitely airtightly sealed.

15. The container of claim 14 wherein the housing cap (12) is definitely assembled to the vial (2), and forms a protective housing (12a) for the filling pipe (5).

16. The container of claim 14 or 15 wherein the stored product is selected from the group: liquid, powder, granulates.

17. The container of any one of claims 14 to 16 wherein the product is a medicament, and in particular a vaccine.

18. Aseptic process for filling a container (1) according to anyone of claims 1 to 17 with a product, said process comprising the following steps :

- sterilizing the empty container (1),
- temporarily opening the filling pipe (5) and introducing the product inside the vial (2) through the filling pipe (5),
- definitely and airtightly sealing the filling pipe (5).

19. The process of claim 18 wherein the housing cap (12) is definitely assembled to the vial (2), said cap (12) forming a protective housing (12a) for the filling pipe (5).

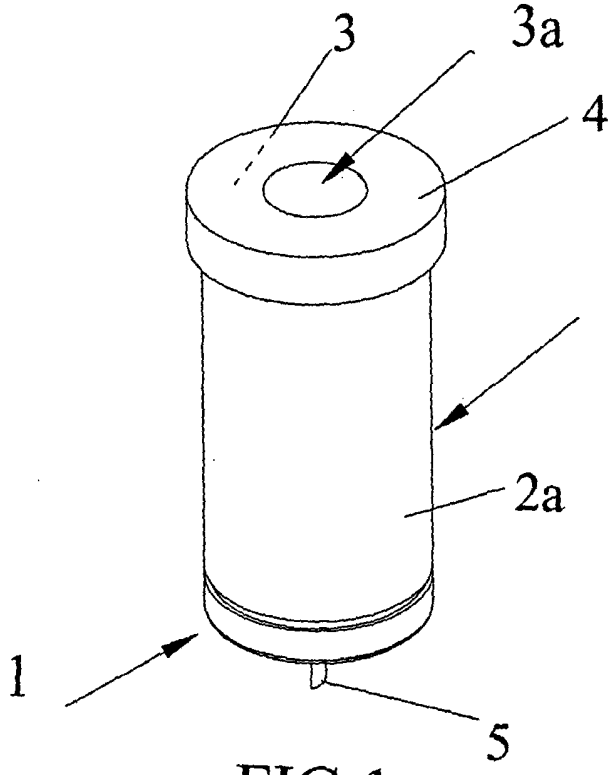

FIG 1

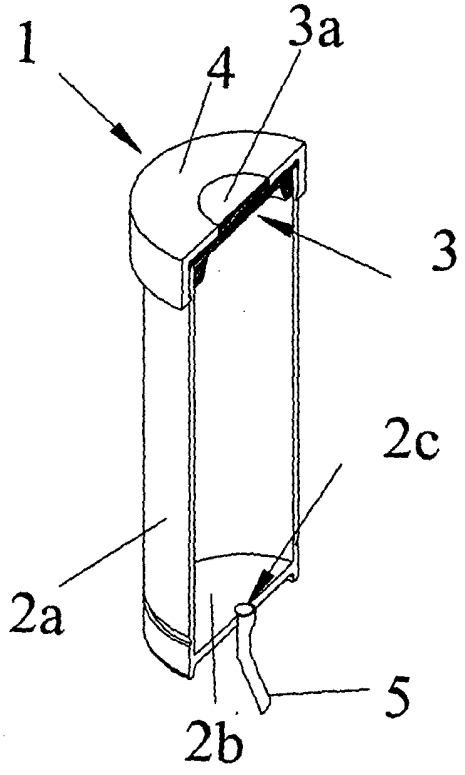

FIG 2

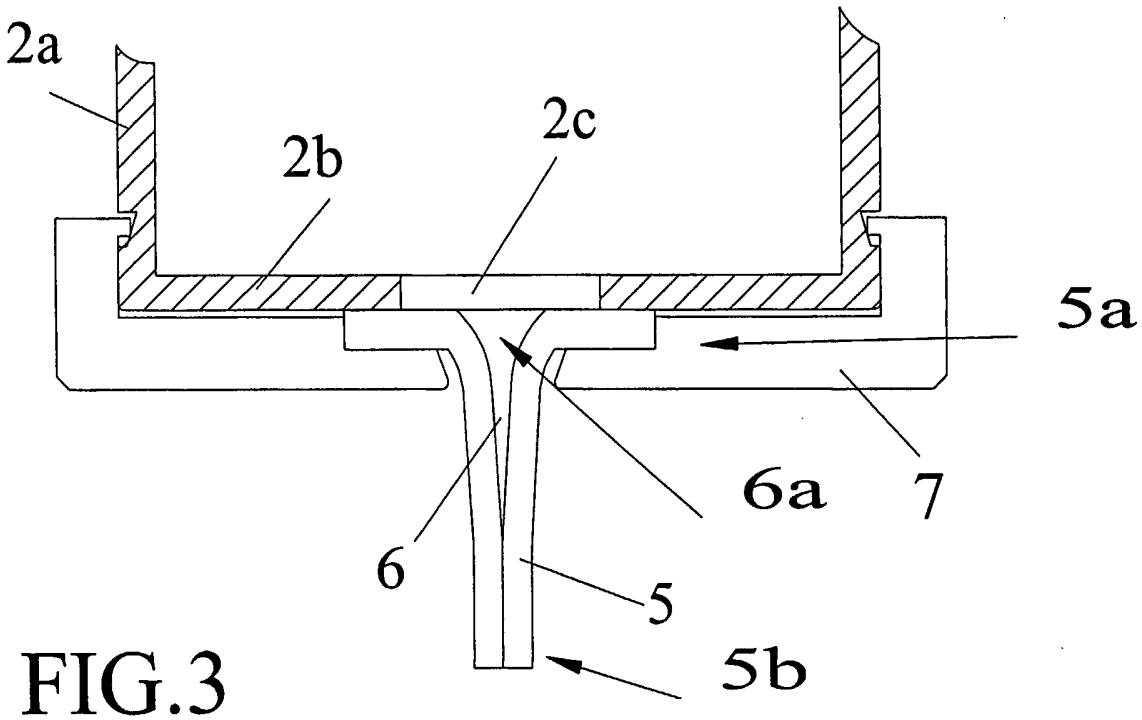

FIG.3

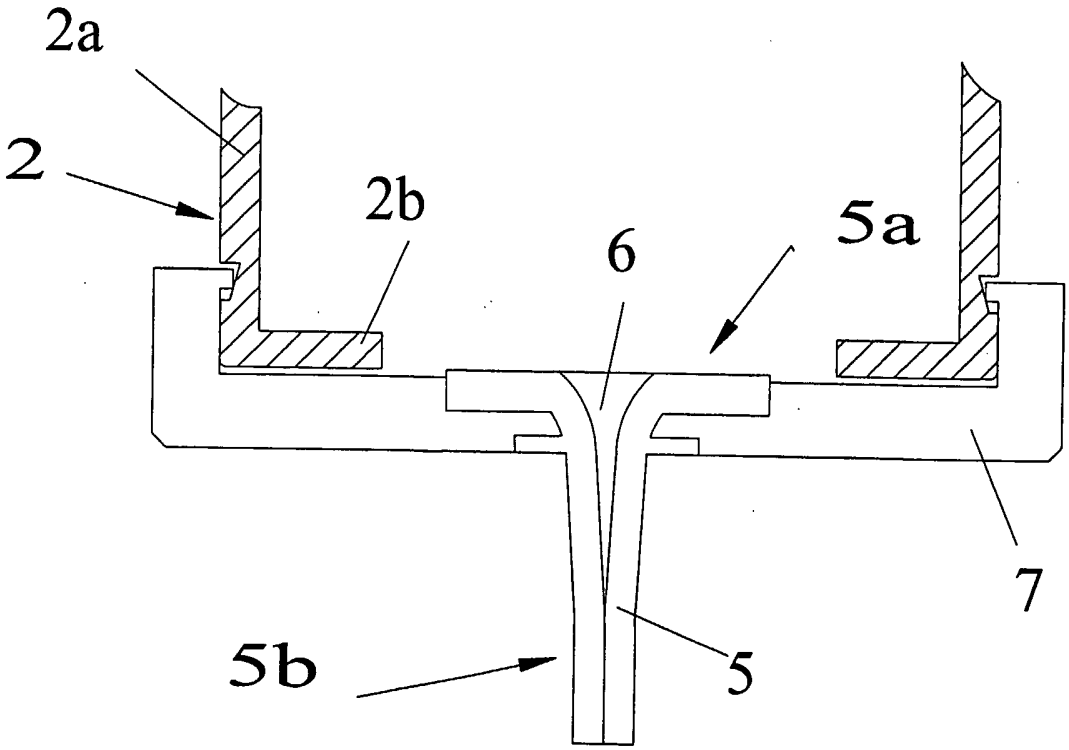

FIG.4

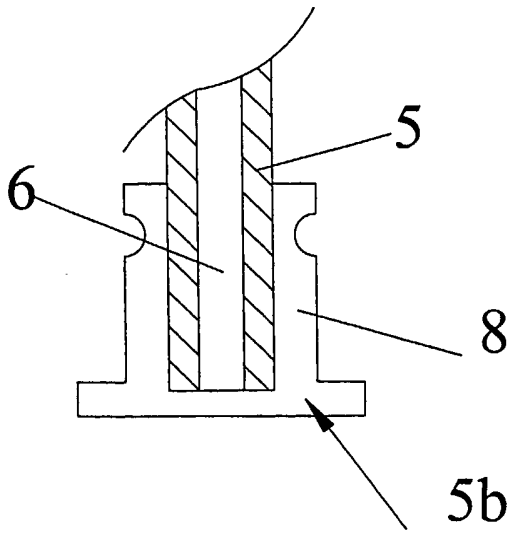

FIG.5

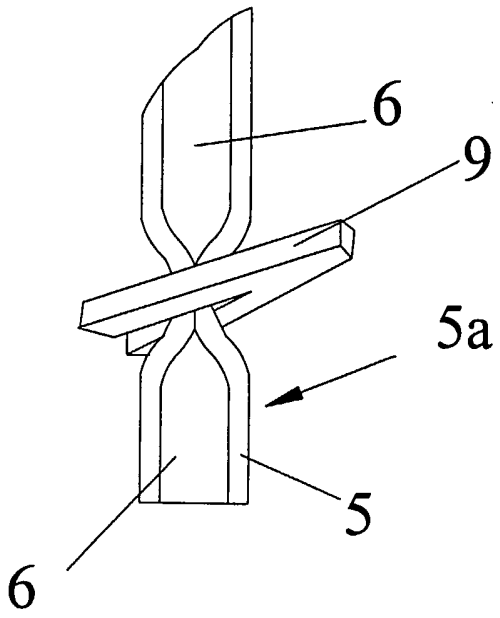

FIG.6

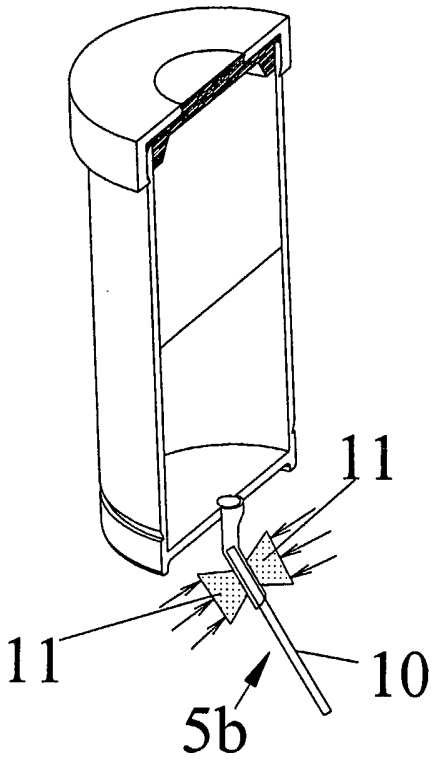

FIG.7

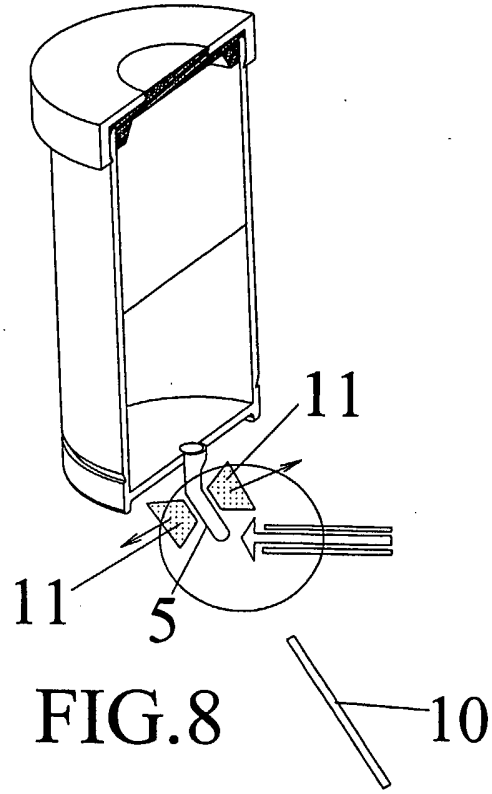

FIG.8

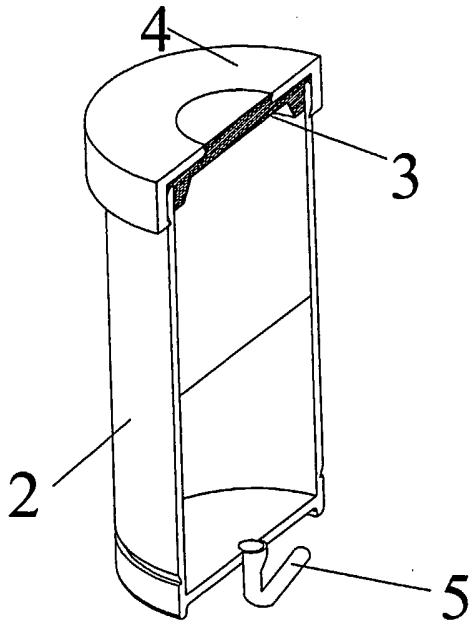

FIG.9

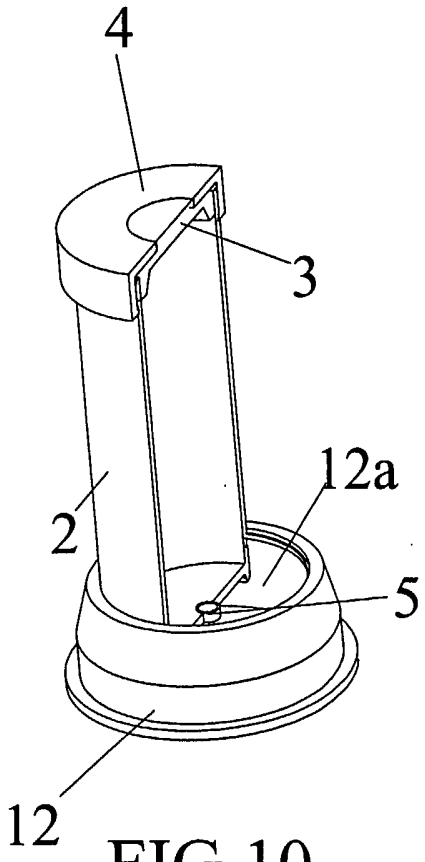

FIG.10

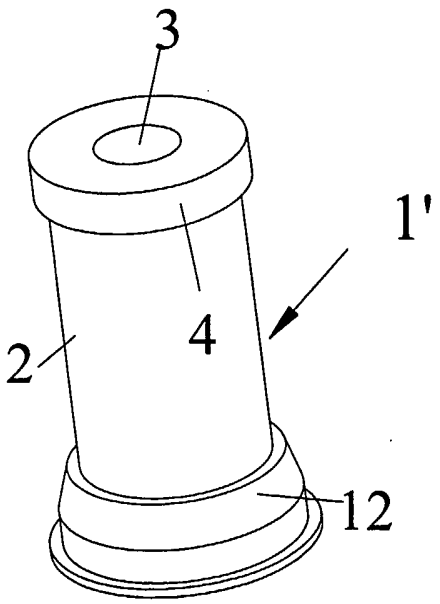

FIG.11

INTERNATIONAL SEARCH REPORT

PCT/EP2005/005489

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J1/00 F16K7/02

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)
IPC 7 A61J A61M F16K B65D

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 2 896 619 A (JR. DAVID BELLAMY,) 28 July 1959 (1959-07-28) column 2, line 65 - column 3, line 20 column 3, line 67 - column 4, line 2; figures 1,5-7	1-17
X	US 4 439 192 A (LEURINK ET AL) 27 March 1984 (1984-03-27)	18,19
A	column 2, line 58 - line 67; figures	14
A	GB 2 032 006 A (FRUTIN B D) 30 April 1980 (1980-04-30) abstract; figures	1-17
A	US 1 579 996 A (OWEN BANES GLENN) 6 April 1926 (1926-04-06) page 1, line 50 - line 62; figures	1,18

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

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
2 August 2005	08/08/2005

Name and mailing address of the ISA	Authorized officer
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A	WO 95/13786 A (REINA GIUSEPPE) 26 May 1995 (1995-05-26) page 3, line 6 - page 4, line 7; figures	1-11, 16-18
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