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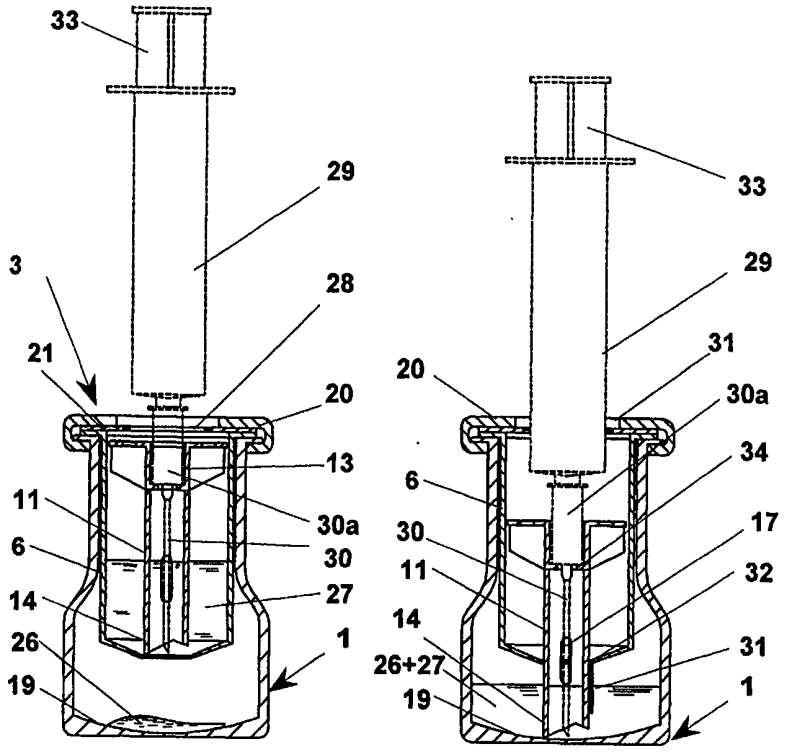
(54) Title: CONTAINER FOR TWO PHASES INJECTABLE DRUGS

(57) Abstract

A container for injectable drugs in two phases comprises an ampoule (1), with a first phase of a drug (26), having an upper opening (2) stopped by a closure member (20), internal means (4) in the ampoule for keeping the two phases separate from each other, means (5) for allowing the introduction of the needle (30) of a syringe (29). The internal means (4) comprises a cup (6), containing the second phase of the drug (27), having an upper opening (10) and at the bottom a septum (7) with a weakened line (8) that can be broken at the moment of use. The means (5) for allowing the introduction of the needle (30) comprise a tubular hollow piston (11), slidably engaging in the cup (6), having the lower end (12) suitble for breaking in use the septum (7), and a recess (13) for engaging with the support (13a) of the needle (30). The piston (11) breaks the septum (7) causing the two phases (26 and 27) to mix, and guiding the needle (30) towards the bottom (19) of the ampoule where the drug resulting therefrom (26+27) can be sucked directly. The stopping means are formed by a metal apertured plate (20), by a pierceable disc (21) and by a plastics ring (22), which can be used after the injection for maintaining the needle in the container and for disposing of the container and the needle together.



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TITLE

CONTAINER FOR TWO PHASES INJECTABLE DRUGS

Field of the invention

The present invention relates to a container used to carry and prepare injectable drugs consisting in two phases to be mixed, such as, but not exclusively, a liquid phase of physiological solution and a solid phase of lyophilized active composition.

Furthermore, the invention relates to a container that allows to isolate the used needle after the injection of the drug.

Background of the invention

Injectable drugs, consisting in two phases to be mixed, are usually provided in two distinct ampoules that contain respectively a liquid phase of physiological solution and a solid phase of a lyophilized active composition.

The preparation of an injectable drug can then be outlined in a plurality of successive steps:

- opening the first ampoule, which contains the physiological solution;
- inserting a syringe in this first ampoule;
- sucking the physiological solution by the syringe;
- extracting the syringe needle from the first ampoule once emptied;
- inserting the needle in the second ampoule, which contains the active lyophilized composition;
- bringing the physiological solution from the syringe into the second ampoule;
- stirring the ampoule for mixing the solid and liquid phases thus homogenizing the solution, i.e. the drug to inject;
- separating the syringe body from the needle, which

remains inserted in the second ampoule containing the drug to inject;

- introducing air into the second ampoule, that still contains the drug to inject, through the syringe needle;
- combining again needle and syringe and sucking the drug to inject into the syringe;
- extracting the syringe from the second ampoule ready for the injection.

These eleven different steps must be carried out carefully, as well as a supporting surface is required for the two ampoules.

Furthermore, these lengthy steps represent a problem especially in emergency cases and when many injections have to be done.

A further drawback is given by the way of opening the ampoule that contains the physiological solution, which is normally a glass ampoule with ends to be broken, since the user can get injured by the sharp edges of the broken end.

Finally, once the drug has been injected, the problem arises of eliminating the used needle, which is usually covered with a cap and then disposed of. This phase has to be carried out carefully since there is the risk of contamination through the infected needle and the cap has a very small inlet opening. Furthermore the cap can withdraw accidentally from the needle thus creating danger for the operators.

Summary of the invention

It is an object of the present invention to provide a container to prepare injectable drugs formed by two phases to be mixed, such as, but not exclusively, a liquid phase of physiological solution and a solid phase of lyophilized active composition, which is easy to use and that allows to mix such phases in a few fast steps.

It is another object of the present invention to provide a container for injectable drugs consisting in two phases to be mixed, which allows to isolate the used needle after the drug injection.

These and other objects are achieved, according to the present invention, by a container for injectable comprising:

- an ampoule with an opening for the introduction of a syringe;
- a first phase of a drug put into the ampoule;
- stopping means of the opening;
- internal means in the ampoule for keeping a second phase of the drug separate from the first phase;
- means for allowing the introduction of the needle of a syringe suitable for causing the break of a portion of the internal means allowing the union of the two phases of the drug, whereby the two phases can be directly mixed and then sucked by the needle.

The internal means may comprise a cup element in the ampoule, the first phase of drug being arranged between the cup and the bottom of the ampoule. The cup has a bottom with a weakened line suitable for being broken by the movement of introduction of the syringe.

The means for allowing the introduction of the needle and for breaking the weakened line preferably comprise an open tubular piston slidably engaging in the cup and having a sharpened end, the piston housing the needle and its length being such that contact is avoided between the needle and the cup. At the other end, opposite to the sharpened end, the piston may have a recess suitable for engaging with the support of the needle or with the body of the syringe, whereby the recess blocks the syringe same in axial direction so that the syringe when pushed can break the weakened line. The piston has

advantageously a flanged upper edge having diameter equal to the inner diameter of the cup. The piston can be equipped with axial stiffening and guiding ridges.

The bottom of the cup may have tapered bottom walls converging towards the weakened portion, whereas its upper edge is flanged for engaging with the rim of the ampoule.

The piston preferably has a lower sharp end with asymmetrical shape comprising two points of different length, capable of breaking the weakened line, the points of different length having the function of protecting the needle of the syringe.

Alternatively, the piston has two points of equal length, for positioning the needle of the syringe at the right distance from the bottom of the ampoule.

In a different embodiment of the invention the piston has a lower end linked directly to the basis of the cup by a weakened line, which has the function of keeping the two phases separate form each other.

The flanged upper edge of the piston has advantageously holes for allowing the passage of air for sucking the drug. Moreover, the piston has side apertures located for making easier the flow of the phase present in the cup towards the bottom of the ampoule and in order to make easier the sucking of the drug.

Advantageously, the ampoule has a concave bottom for making easier the sucking of all the drug with the needle of the syringe.

The closure member means of the ampoule comprises an apertured plate, a pierceable disc and a plastics ring, the ring being engageable in the apertured plate and has internal diameter slightly less than the support of the needle of a syringe, whereby after an injection, the ring can be forced in the plate and the needle can be forced in

the ampoule, allowing a withdrawal of the syringe without needle.

In a further embodiment, the means for allowing the introduction of the needle and for breaking the weakened line comprises an open tubular piston integral to he needle of the syringe, suitable for being slidably inserted into the cup after breaking the closure member of the ampoule, and having a sharpened end, the piston being suitable for receiving the needle and its length being such that the contact of the needle with the cup is avoided.

Brief description of the drawings

Further characteristics and the advantages of the container for injectable drugs, according to the present invention, will be made clearer with the following description of some embodiments thereof, exemplifying but not limitative, with reference to attached drawings, wherein:

- figure 1 shows an exploded view of a first embodiment of the container, according to the present invention;
- figure 2 shows a cross sectional view of the container of figure 1 assembled and ready for use;
- figures 3A, 3B, 3C show three steps of use of the container of figure 2;
- figure 4 shows an exploded view of a second embodiment of the container, according to the present invention;
- figure 5A and 5B show a cross sectional view of a third embodiment of the container, according to the present invention and of a special syringe to it associated, respectively withdrawn from and introduced in the container.

Description of a preferred embodiment

With reference to figure 1, a container, according to the present invention, has an ampoule 1, comprising: an upper opening 2 stopped by a closure member 3, a wall 4

for keeping separate a first phase 26 from a second phase 27 of the drug, and an element 5 for guiding the introduction of the needle 30 of a syringe 29 (fig. 3A-3C).

Wall 4 is arranged in ampoule 1 and has the shape of a cup 6, containing the second phase 27 of the drug, having an upper opening 10 and having at the bottom a septum 7 with a weakened line 8 that can be broken at the moment of use.

The side bottom walls 9 of cup 6 are tapered towards septum 7 whereas the edge of upper opening 10 is flanged.

Guiding element 5 comprises a tubular hollow piston 11 slidably engaging in cup 6 and having a lower end 14 suitable for breaking in use septum 7, as well as a recess 13 for the introduction of needle 30 of syringe 29 (fig. 3A-3C) and of support 30a to which needle 30 is connected. At the bottom of this recess 13 a hole 36 is made through which needle 30 of syringe 29 passes.

In this first embodiment, lower end 12 of tubular piston 11 is sharp and of asymmetric shape, comprising two points 14 of different length that have the function of preventing needle 30 of the syringe from hitting septum 7 which, once broken at weakened line 8, folds under push of piston 11 and then hangs from cup 6.

Piston 5 may have a flanged upper edge 15 having diameter equal to the inner diameter of cup 6 for slidably guiding the piston in cup 6. Furthermore, piston 5 may have guiding and stiffening ridges 25.

Edge 15 provides through holes 16 that allow the passage of air from the outer environment into cup 6 that contains second phase 27 of the drug, and then to the space below that contains first phase 26 of the drug, through apertures 17.

Ampoule 1 has a variation of cross section at 18 so

that that the level reached by the drug 26+27 (fig. 3B) in this zone is contained in the lower portion of the ampoule same. Furthermore, ampoule 1 has a bottom 19 with a concave shape in order to make easier the sucking of all drug 26+27 with needle 30 of syringe 29.

Closure member 3 is a metal element 20 with central hole 31, a pierceable disc 21 and a plastics disc 22 with central hole 38.

Pierceable disc 21 comprises a central portion 23 that can be torn by means of a tongue 24; this portion 23, as known, is made of a material capable of assuring sterility of the drug inside the ampoule.

With reference to figure 2, the apertured plate 20 keeps together the assembly comprising ampoule 1, wall 4 and pierceable disc 21, that separates the inside of the container from the environment. In this embodiment liquid phase 27 is contained by cup 6 and solid phase 26 is at the bottom of ampoule 1.

As shown in figure 3A the container according to the invention has been opened tearing tongue 24 (fig. 1) and removing the central portion 23 of pierceable disc 21, thus creating an opening 28 wherein syringe 29 has been introduced.

Support 30a of needle 30 is forced into recess 13 so that the sharp end of needle 30 is not damaged at the bottom of cup 6.

Then, on syringe 29 a pressure is applied sufficient to break septum 7. The force applied on syringe 29 is transferred to the lower end 12 of tubular piston 11 which breaks septum 7 owing to the longer of the two asymmetrical points 14; the shorter point 14 protects needle 30 from the accidental contact with the broken septum 7.

The movement of septum 7 creates a hole 32 through

which tubular piston 11 passes bringing lower point 14 onto bottom 19 of ampoule 1 so that needle 30 is very close to this bottom 19 but it does not touch it.

Always with reference to figure 3B, liquid phase 27 (shown in figure 2) contained in cup 6 falls down into ampoule 1 through aperture 17 and reaches first phase 26 of the drug (fig. 2); ampoule 1 can be then stirred for mixing the solution 26+27.

Then the drug 26+27 is sucked by withdrawing piston 33 of syringe 29 without the need of introducing air into ampoule 1, because holes 16 and aperture 17 allow the inner pressure of ampoule 1 to maintain at the environment pressure. For sucking all the product 26+27 syringe body 29 can be pushed towards the bottom since further small displacements are allowed in axial direction, owing to elasticity of the material of which piston 11 is made. Furthermore, the shape of points 14 and the basis 34 of the support 13 allow also small displacements.

Once drug 26+27 has been sucked all syringe 29 with needle 30 is withdrawn for making the injection to the patient.

In figure 3C is shown the container according to the invention that is used for disposing of and isolating needle 30 of syringe 29 after the injection.

Disc 22, which is in the kit of the container according to the invention, is forced into opening 31 of the metal apertured plate 20, by snap fit engagement. Then support 30a of needle 30 can be forced in the inner hole 38 of disc 22, whose diameter is slightly less than support 30a. Disc 22 can have of radial cuts not shown for increasing the flexibility of the edges of inner hole 38.

Always as shown in figure 3C, support 30a is introduced in the empty container, and by withdrawing syringe body 29 it remains in recess 13 and can be

disposed of together with the used container.

This way needle 30 of syringe 29 can be disposed of very easily, quickly and safely, avoiding the risks if injuries and contamination.

In figure 4 is shown an exploded view of a second embodiment of the container, which is different from the first since the weakened line 8 is directly formed on the piston 11. The latter has longitudinal ridges 40 that protrude from piston 11 for enlarging hole 32 indicated in figure 3A. Furthermore, the ridges 40 have function of stiffening and guiding piston 11.

In this second embodiment the space of cup 6 is always in communication with the ampoule, since the aperture 17 allows flow of air and of drug.

As shown in figure 5, in a further embodiment the piston 11 can be supplied along with the cap of the syringe needle, instead of being provided in the container. In this case, points 14 first pierce portion 23 of the closure member 3, and then carry out the steps described hereinabove for the first embodiment of figures 1, 2 and 3A-3C.

In figure 5 is shown a different ampoule 1, with cross section having fixed diameter. Obviously, other advantageous shapes of the ampoule are possible.

The foregoing description of a specific embodiment will so fully reveal the invention according to the conceptual point of view, so that others, by applying current knowledge, will be able to modify and/or adapt for various applications such an embodiment without further research and without parting from the invention, and it is therefore to be understood that such adaptations and modifications will have to be considered as equivalent to the specific embodiment. The means and the materials to realise the different functions described herein could

have a different nature without, for this reason, departing from the field of the invention. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

CLAIMS

1.Container for injectable drugs in two phases to mix together, comprising:

- an ampoule with an opening for the introduction of a syringe;
- a first phase of a drug put into said ampoule;
- stopping means of said opening;

characterised in that it comprises:

- internal means in the ampoule for keeping a second phase of said drug separate from said first phase;
- means for allowing the introduction of the needle of a syringe suitable for causing the break of a portion of said internal means allowing the union of said two phases of the drug, whereby said two phases can be mixed and then sucked by said needle.

2.Container for injectable drugs according to claim 1, wherein said internal means for keeping said second phase of drug separate from said first phase comprise a cup element in the ampoule, said first phase of drug being arranged between said cup and the bottom of said ampoule.

3.Container for injectable drugs according to claim 1, wherein said internal means have a bottom with a weakened line suitable for being broken by the movement of introduction of said syringe.

4.Container for injectable drugs according to claim 1, wherein said means for allowing the introduction of the needle and for breaking the weakened line comprise an open tubular piston slidably engaging in said cup and having a sharpened end, the piston housing the needle and its length being such that contact is avoided between the needle and the cup.

5.Container for injectable drugs according to claim 4, wherein said piston at the other end, opposite to the sharpened end, has a recess suitable for engaging with the

support of the needle or with the body of the syringe, whereby the recess blocks the syringe same in axial direction so that the syringe when pushed can break the weakened portion.

6.Container for injectable drugs according to claim 4, wherein said tubular hollow piston has a flanged upper edge having diameter equal to the inner diameter of said cup.

7.Container for injectable drugs according to claim 2, wherein the bottom of said cup has tapered bottom walls converging towards the weakened portion, whereas its upper edge is flanged for engaging with the rim of the ampoule.

8.Container for injectable drugs according to claim 3, wherein said open tubular piston is equipped with axial stiffening and guiding ridges.

9.Container for injectable drugs according to claim 8, wherein said piston has a lower sharp end with asymmetrical shape comprising two points of different length, capable of breaking the weakened line, said points of different length having the function of protecting the needle of the syringe.

10. Container for injectable drugs according to claim 3, wherein said means for allowing the introduction of the needle of a syringe comprises a tubular piston with a lower end linked directly to the basis of said cup by a weakened line, which has the function of keeping the two phases separate form each other.

11. Container for injectable drugs according to claim 10, wherein said tubular piston has a symmetrical lower sharp end comprising at least two points of equal length, for positioning the needle of the syringe at the right distance from the bottom of the ampoule.

12. Container for injectable drugs according to claim 6, wherein said flanged upper edge has holes for allowing the

passage of air for sucking the drug.

13. Container for injectable drugs according to claim 4, wherein said piston has side apertures located for making easier the flow of the phase present in the cup towards the bottom of the ampoule and in order to make easier the sucking of the drug.

14. Container for injectable drugs according to the previous claims, wherein said ampoule has a concave bottom for making easier the sucking of all the drug with the needle of the syringe.

15. Container for injectable drugs according to the previous claims, wherein said closure member of the ampoule comprises an apertured plate, a pierceable disc and a plastics ring, said ring being engageable in the apertured plate and has internal diameter slightly less than the support of the needle of a syringe, whereby after an injection, the ring can be forced in the plate and the needle can be forced in the ampoule, allowing a withdrawal of the syringe without needle.

16. Container for injectable drugs according to the previous claims wherein said means for allowing the introduction of the needle and for breaking the weakened line comprises an open tubular piston integral to he needle of the syringe, suitable for being slidably inserted into the cup after breaking the closure member of the ampoule, and having a sharpened end, said piston being suitable for receiving the needle and its length being such that the contact of the needle with the weakened the cup is avoided.

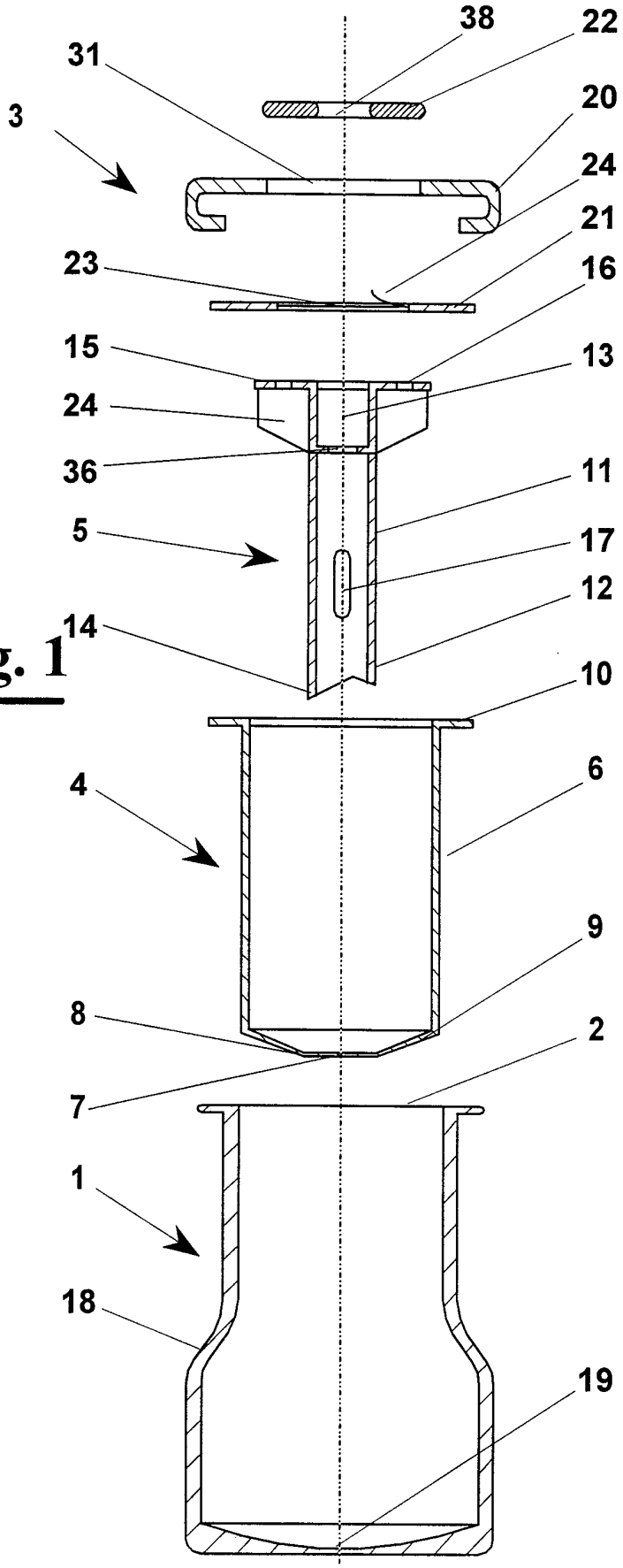


Fig. 1

Fig. 2

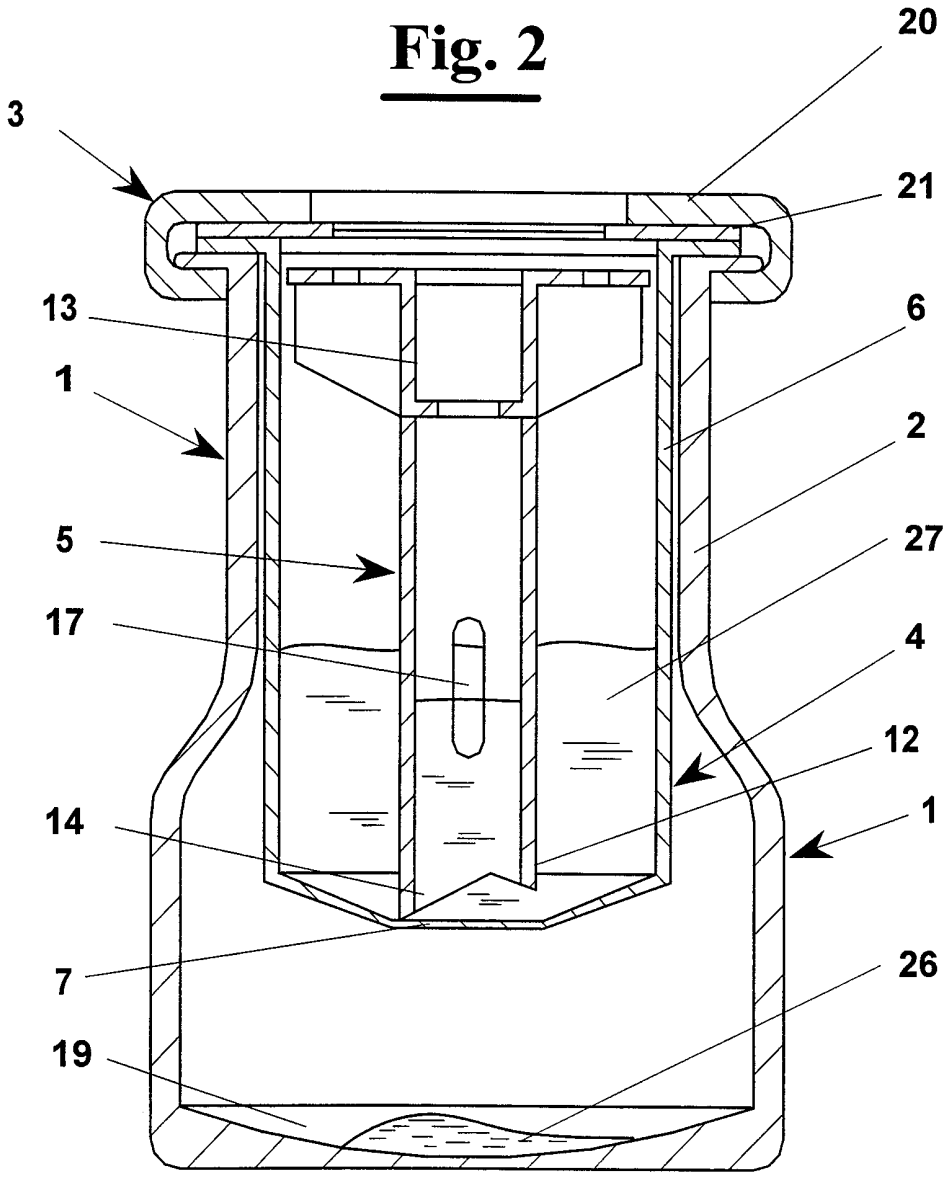


Fig. 3A

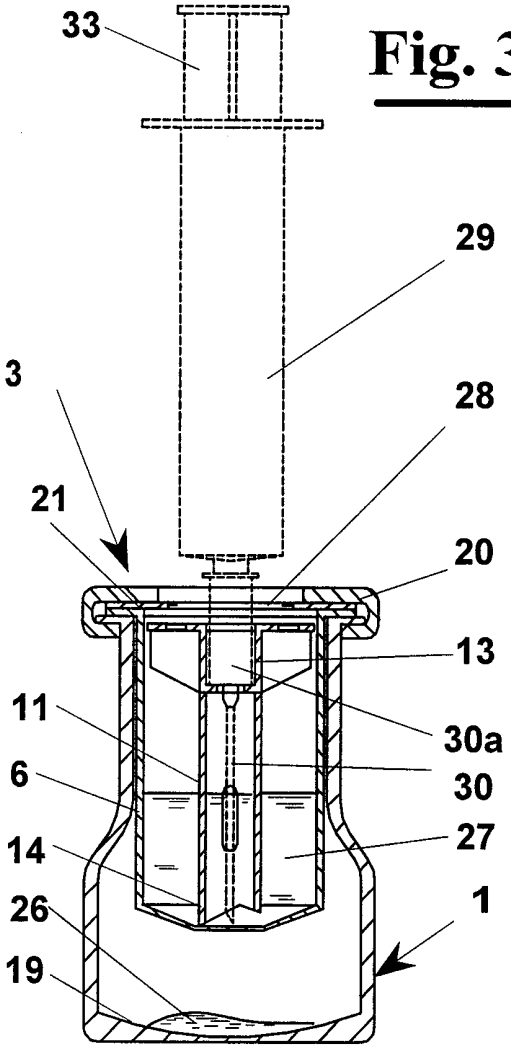
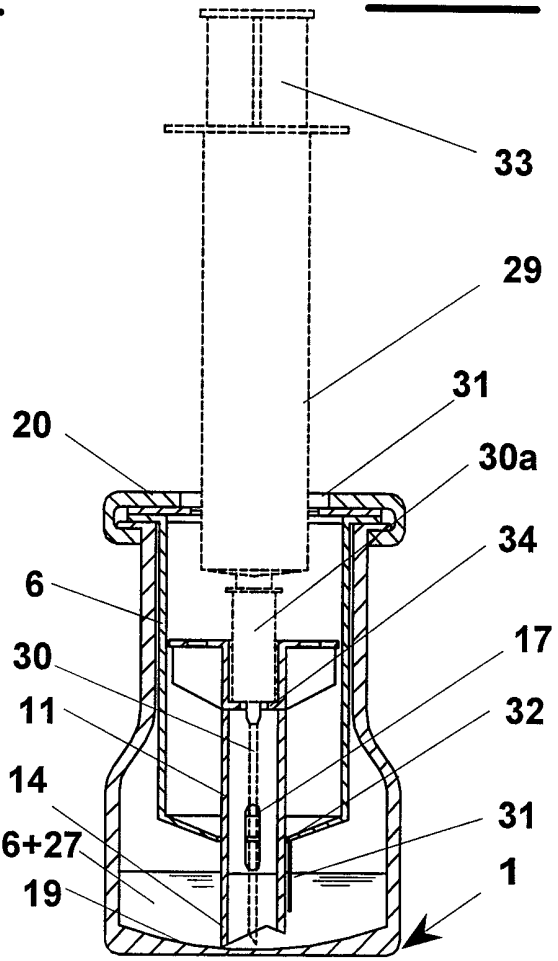


Fig. 3B



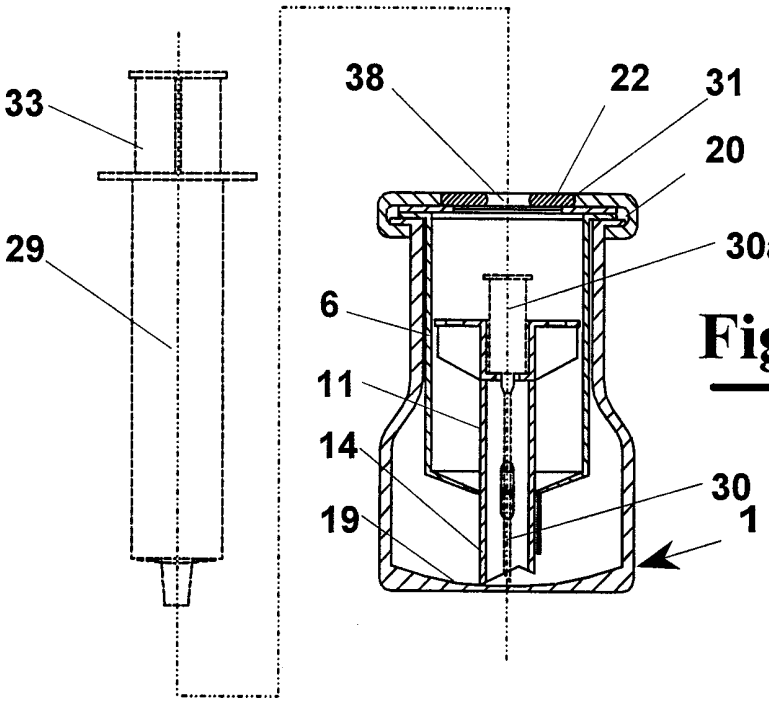


Fig. 3C

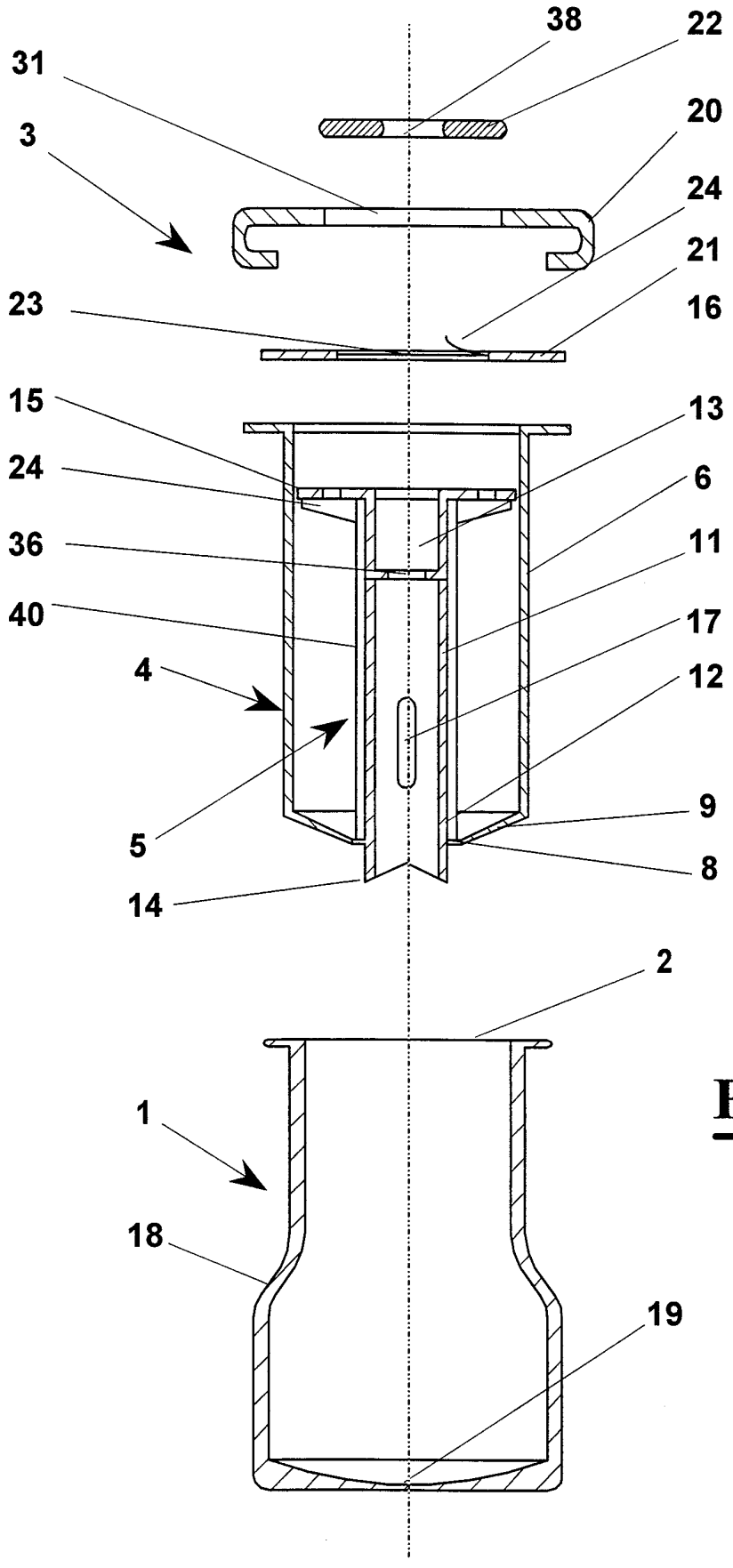


Fig. 4

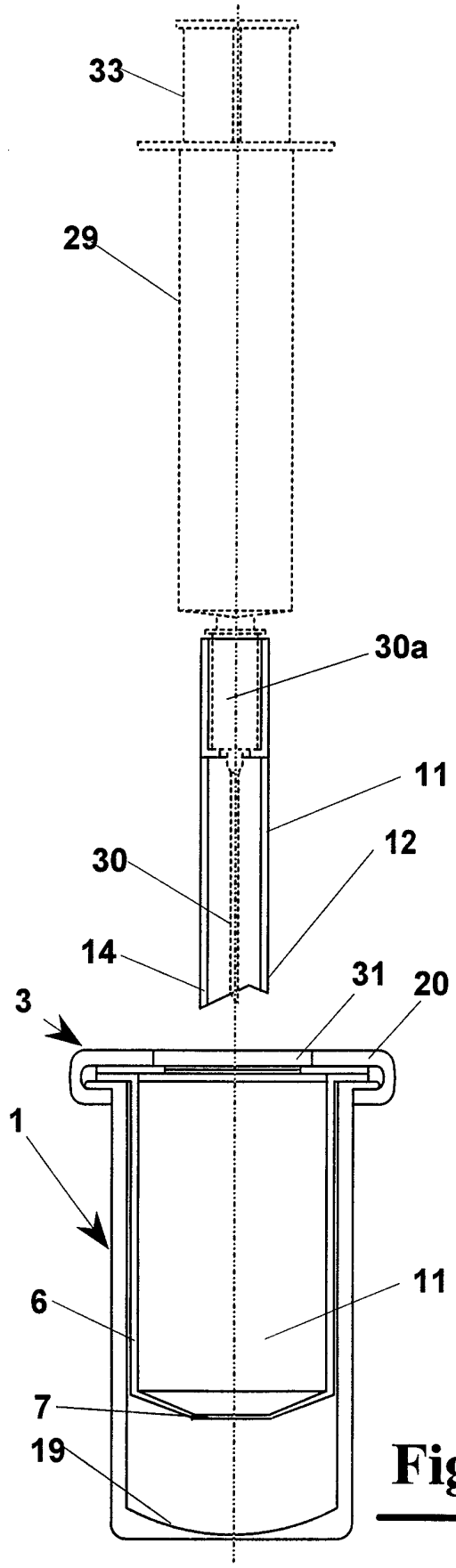


Fig. 5A

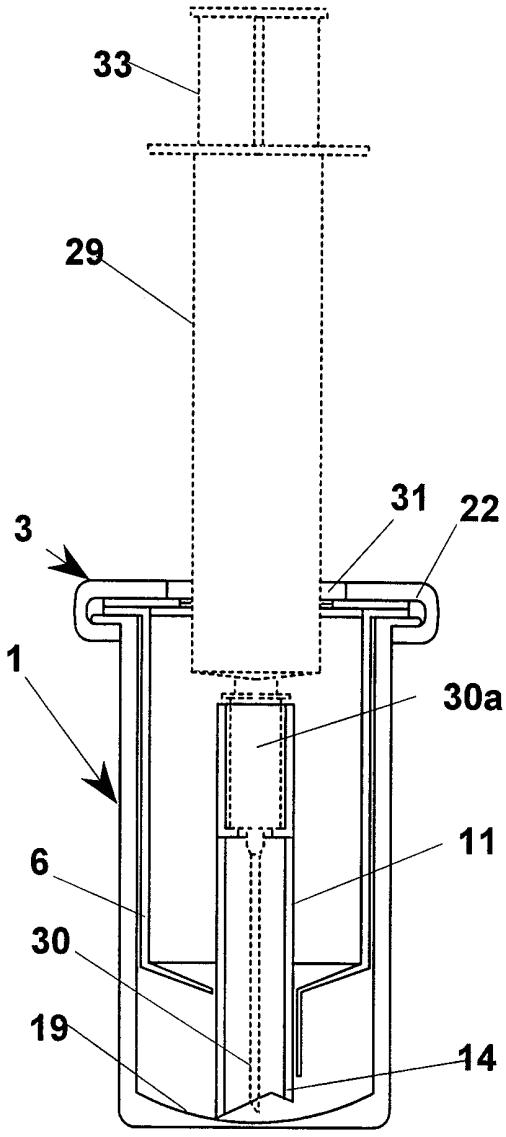


Fig. 5B

INTERNATIONAL SEARCH REPORT

Int tional Application No
PCT/EP 99/07336

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61J1/00

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 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)

C. 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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Date of the actual completion of the international search	Date of mailing of the international search report
11 February 2000	18/02/2000

Name and mailing address of the ISA	Authorized officer
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

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