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(54) **A mixing unit**

(57) A mixing unit (1) for mixing dry drug with liquid comprising a first (2) and second housing part (3) movable connected to each other and containing a vial (5) with dry drug and a reservoir (6) with liquid. Inside the housing parts there is provided an intermediate part (8) with a first spike (10) for penetrating a septum (11) of the vial and a second spike (13) for penetrating the reservoir, the first and second spike together defining a fluid connection between the vial and reservoir. A piston (15) is provided in said reservoir for forcing the liquid from the reservoir to the vial, and the piston comprises a liquid channel (20) for connecting a liquid outlet with the internal of the vial via the established fluid connection.

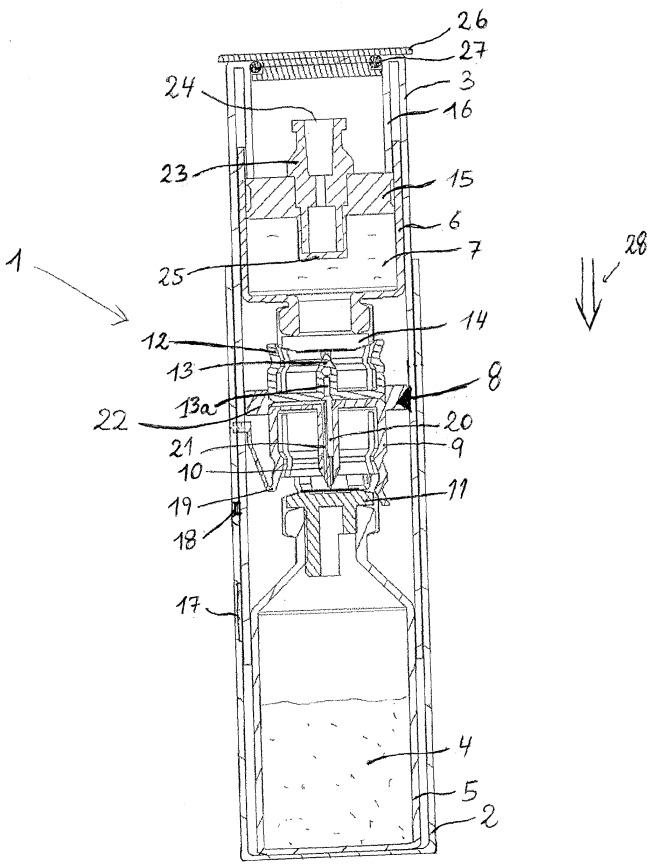

Fig. 1

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Description

FIELD OF THE INVENTION

[0001] The present invention relates to a mixing unit for reconstituting a dry drug. More particularly, the present invention relates to such a mixing unit which is suitable for being operated using one hand only.

BACKGROUND OF THE INVENTION

[0002] It is sometimes necessary or desirable to store a drug in dry form, such as lyophilized form. This may, e.g., be in order to reduce degradation of the drug during storage. In this case it is, however, necessary to reconstitute the drug before it is delivered to a person, i.e. it is necessary to mix the lyophilized drug with a liquid, thereby forming a liquid drug. This is normally done by means of an ordinary syringe with an ordinary needle. Liquid is sucked into the syringe, the needle is then inserted in a vial containing the lyophilized drug to be reconstituted, and the liquid is forced from the syringe into the vial by means of a movable piston of the syringe. When the lyophilized drug has been properly reconstituted, the movable piston is pulled out, and the reconstituted drug is thereby retrieved to the syringe. The reconstituted drug may subsequently be delivered from the syringe to a person. There is a relatively complicated procedure with a high risk of contamination of the drug or the syringe during the described procedure due to the exposure of the surfaces and the needle to free air and dirt.

[0003] US 2002/0022804 discloses a syringe device comprising a barrel having inner walls defining a compartment in the barrel, a closable nozzle at the base of the barrel and a plunger movable longitudinally within the barrel compartment. The plunger has inner walls defining a chamber suitable to receive a vial. A hollow needle extends through the plunger to enable fluid communication between the plunger chamber and barrel compartment. A compressible and puncturable sealing element within the plunger chamber provides a sterile seal for the needle and barrel compartment.

[0004] US 3,330,280 discloses a syringe in which liquid and powder can be stored and mixed immediately before use. It comprises a hollow vial adapted to contain a medicament in liquid or powder form, a syringe barrel which may also contain liquid, a stopper separating the two and means for communicating the vial and the barrel when desired.

SUMMARY OF THE INVENTION

[0005] It is an object of the invention to provide a mixing unit for reconstituting dry drug, such as lyophilized drug, the unit being operable using one hand.

[0006] It is a further object of the invention to provide a mixing unit for reconstituting dry drug, where the unit can be delivered as an 'all-in-one' package.

[0007] It is an even further object of the invention to provide a drug mixing unit for reconstituting lyophilized drug, wherein the risk of contamination of the reconstituted drug is reduced as compared to prior art devices.

[0008] According to the invention the above and other objects are fulfilled by providing a mixing unit for mixing dry drug with liquid, the unit comprising;

- a first and second housing part movable connected to each other and containing;
  - a vial with dry drug,
  - a reservoir with liquid,
- an intermediate part provided inside the housing parts for establishing a fluid connection between the reservoir and the vial upon moving the first and second housing part towards each other, said intermediate part comprising a first spike for penetrating a septum of the vial and a second spike for penetrating the reservoir, the first and second spike together defining a common fluid connection, and
- a piston provided in said reservoir for forcing the liquid from the reservoir to the vial, via an established fluid connection, thereby causing the dry drug to become reconstituted, the piston comprising a liquid channel for connecting a liquid outlet of the unit with the internal of the vial via the established fluid connection.

[0009] The first and second housing part is preferably positioned inside each other so that one part can slide telescopically into the other part. The first part is preferably closed in the end opposite to the second housing part, the vial being positioned in that end of the first part. Alternatively, the first part may be openable in this end so that the vial may be interchanged with a new vial, when it has been used.

[0010] The second housing part is openable in the end opposite the first part, so that the user can get access to the internal of the unit and in particular to the liquid outlet. This end is preferably closed by a removable cover, which together with a seal defines a sealed closure of the unit. The cover may stay attached to the unit after having been removed in order to leave the user with less pieces of waste material as possible.

[0011] The reservoir may be any suitable kind of reservoir, such as a cartridge, a syringe, a flexible reservoir, e.g. a bag, forming part of the unit. The liquid contained in the reservoir is preferably a solvent liquid being suitable for reconstitution of a lyophilized drug contained in the vial. The amount and kind of liquid in the reservoir is preferably chosen in such a manner that it matches a specific lyophilized drug. Thereby it is ensured, that when a vial containing that specific lyophilized drug is positioned in the vial adapter, the lyophilized drug is reconstituted correctly and in a suitable manner.

[0012] The intermediate part provided inside the hous-

ing parts comprises a first spike being adapted to penetrate a septum of the vial, and a second spike adapted to penetrate a septum of the reservoir. Thus, the vial is positioned adjacent the first spike and the reservoir is positioned on the opposite side of the intermediate part adjacent the second spike.

[0013] The intermediate part preferably comprises a vial adapter for receiving and retaining the vial in a fixed position in relation to the first spike, and a reservoir adapter for receiving and retaining the reservoir in a fixed position in relation to the second spike when the first and second housing parts are moved towards each other. The adapters are preferably shaped in such a manner that a vial and reservoir is positioned there in a manner which substantially fixes them relatively in the intermediate part. Thus, the adapters may comprise means for gripping a part of the vial and reservoir, e.g. a neck or shoulder part thereof. The flexibility of the gripping means of the vial adapter is preferably greater than the flexibility of the gripping means of the reservoir adapter resulting in the vial adapter receiving and retaining the vial before the reservoir adapter receives and retains the reservoir when moving the first and second housing parts towards each other. This is to ensure that the first spike penetrates the vial before the second spike penetrates the reservoir.

[0014] The first and second spike is hollow spikes, the hollow part thereby giving access to the interior of the vial and reservoir, respectively, once the spikes have penetrated the septum, respectively. The first and second spikes may advantageously form part of a double pointed hollow needle establishing a fluid connection between the reservoir and the vial. The fluid connection is established between the reservoir and the vial by moving the first and second housing part towards each other. The first spike is preferably longer than the second spike, so that the first spike is adapted to penetrate the septum of the vial before the second spike penetrates the septum of the reservoir, when moving the first and second housing parts towards each other.

[0015] The piston (or plunger) is positioned in the reservoir in such a manner that the liquid is forced out of the reservoir, via the established fluid connection provided by the spikes, when the piston is moved in a specified direction. The piston is preferably in connection with a part of the second housing part, or a part of the above mentioned cover and by pressing the second housing part towards the first housing part, the piston is forced in said specified direction forcing liquid from the reservoir into the vial. Thereby the lyophilized drug contained in the vial will be reconstituted. When the drug has been reconstituted, the drug is ready for infusion. To get easy access to the reconstituted drug inside the vial, the piston comprises a liquid channel for connecting a liquid outlet of the unit with the internal of the vial via the established fluid connection. Thus, by removing the cover of the second housing part, the user can get access to the internal of the vial via this channel and suck out the drug directly from the vial and does not need to disassemble the unit first. The liquid outlet preferably forms an end of the channel, and the outlet may be adapted for connection to an infusion device, such as a syringe. The outlet may e.g. be a Luer-lock connection.

[0016] The channel is preferably sealed by a membrane to make sure that drug or liquid does not enter the channel, while the piston is moved. The membrane is preferably adapted to be penetrated by the second spike, when the piston reaches its end position in the reservoir.

[0017] The unit preferably comprises locking means for locking the first housing part in relation to the second housing part, when the piston has reached an end position in which the liquid has been forced into the vial. The first and second housing parts are preferably guided in relation to each other by slots, and the locking means may be provided by a "snap-lock" provided in said slots. The "snap-lock" may e.g. by a loaded tap that enters a groove or hole in the slot, when the second part reaches an end position in relation to the first part.

[0018] The second spike may comprise two separate channels; a first channel defining said fluid connection in combination with the first spike, and a second channel defining a fluid connection between the internal of the vial and an air outlet for equalising pressure provided in the vial. The second channel preferably comprises a filter being air permeable, but not liquid permeable. Thus, air from the vial may escape as liquid is forced from the reservoir into the vial. Thereby the pressure in the vial is equalized as the liquid enters the vial. Alternatively, the pressure equalization may be obtained by use of a unidirectional valve allowing passage of, e.g., air or liquid in a direction out of the vial, but preventing such passage in a direction into the vial.

[0019] According to a preferred embodiment of the invention at least the first and second housing part, the intermediate part, the reservoir, the piston and the vial forms a substantial integral unit. In the present context the term 'integral unit' should be interpreted to mean a unit which is manufactured and operated as one unit.

[0020] According to this embodiment these parts may be delivered as an 'all-in-one' and/or a 'ready-to-use' package which is easy to operate. Thus, it is only necessary to operate the first and second housing part in relation to each other which results in establishment of a fluid connection and forcing of the liquid from the reservoir to the vial. Furthermore, in this embodiment of the invention, it is ensured that the amount and kind of liquid in the reservoir matches the lyophilized drug of a specific kind of vial. Thereby the risk of incorrect reconstitution of the drug is reduced. As the drug is reconstituted, the user can easily get access to the drug via the channel provided in the piston, which is very convenient. The pieces of waste material is reduced to a minimum, as the user only needs to remove the cover to get access to the drug and does not need to disassemble the unit and/or remove the vial or reservoir from the unit before getting access to the reconstituted drug.

[0021] The mixing unit according to the invention pro-

vides i.a. the following advantages; the number of steps needed to be performed by the user is reduced, the risk of contamination is reduced, the risk of incorrect reconstitution and dosage is reduced, and the unit is easy to operate, e.g. using just one hand.

[0022] According to another aspect of the invention the above and other objects are fulfilled by providing a mixing unit comprising:

- a reservoir containing a liquid,
- a vial containing a lyophilized drug,
- means for establishing a fluid connection between the reservoir and the vial,
- forcing means for forcing the liquid from the reservoir to the vial, via an established fluid connection, thereby causing the lyophilized drug to become reconstituted,
  wherein the reservoir, the vial, the means for establishing a fluid connection and the forcing means form an at least substantially integral unit.

[0023] The unit according to this aspect may comprise any of the features and elements mentioned in connection with the first mentioned aspect of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0024] The invention will now be described in further details with reference to the accompanying drawings in which
Fig. 1 is a cross-sectional view of a mixing unit according to an embodiment of the invention, and
Fig. 2 is a perspective view of a mixing unit according to another embodiment of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

[0025] Fig. 1 is a cross-sectional view of a mixing unit 1 according to an embodiment of the invention. The unit 1 comprises a first housing part 2 and a second housing part 3 which are connected to each other so that they can move telescopically into each other. The first housing part 2 has a closed end in which a vial 5 containing dry drug 4 is positioned. A reservoir 6 in the form of a cartridge is positioned opposite to the vial 5 and contains liquid 7 to be mixed with the drug 4.

[0026] An intermediate part 8 is provided between the vial 5 and reservoir 6 for establishing fluid connection there between. The intermediate part 8 comprises a vial adapter 9 for receiving and retaining the neck of the vial 5 when the first and second housing parts are moved towards each other. The vial adapter 9 comprises a first spike 10 adapted to penetrate a septum 11 of the vial. The intermediate part 8 further comprises a reservoir adapter 12 for receiving and retaining the neck of the cartridge 6. A second spike 13 with one channel 13a at the reservoir adapter is adapted to penetrate the septum 14 of the cartridge 6.

[0027] When the first spike 10 has penetrated the septum 11 and the second spike 13 has penetrated the septum 14, a fluid connection is established between the cartridge 6 and the vial 5 via the hollow parts of the spikes 10, 13.

[0028] A piston 15 is movable inside the cartridge 6 in a downwards direction and is forced downwards by means of the part 16 of the second housing part 3 abutting the piston, when the two housing parts are moved towards each other. Thereby the piston 15 forces liquid 7 from the cartridge 6 through the hollow parts of the spikes 10, 13 and into the vial 5. Thereby the lyophilized drug in the vial 5 is reconstituted.

[0029] As the neck of the vial 5 and cartridge 6 enters their respective adapters 9, 12, the adapters flex outwards in order to grip around the neck. In order to make sure that the septum 11 is penetrated by the first spike 10 before the septum 14 is penetrated by the second spike 13, the vial adapter 9 is made more flexible than the reservoir adapter and the first spike 10 is made longer than the second spike 13.

[0030] The first housing part 2 has guide slots 17 provided inside, which guides the two housing parts in relation to each other, and the slots 17 further comprise a hole or groove 18 in which the "snap-lock" 19 enters when the second part 3 has reached an end position. Thereby, the two housing parts are interlocked.

[0031] The first spike 10 has two channels 20, 21; one channel 20 forming part of the fluid connection between the cartridge and vial, and one channel 21 acting as a pressure equalizing outlet. Thereby, the air in the vial can escape through channel 21 when liquid enters the vial. The channel comprises a filter 22 which is permeable to air but not to liquid. The channel 21 extends further into the vial than the channel 20, which ensures that the air, that is sucked back into the vial as the vial is being emptied, is not sucked around and into the spike 10.

[0032] The piston 15 comprises a liquid channel 23 for connecting a liquid outlet 24 with the internal of the vial 5 via the established fluid connection 10, 13. A membrane 25 ensures that liquid is not entering the channel during pressing the piston 15 downwards. When the piston reaches an end position, the membrane 25 is penetrated by the second spike 13, and an open liquid channel 23 is provided between the vial and the outlet 24.

[0033] The second housing part 3 is closed by a removable cover 26 having a seal 27. After having removed the cover 26, the outlet 24 can be connected to a syringe, and the reconstituted drug can be sucked out from the vial 5 via the channel 24 and the fluid connection 10, 13.

[0034] The unit functions as follows;

[0035] In fig. 1 no fluid connection between the cartridge 6 and the vial 5 has been established yet. In order to operate the unit 1, the user pushes the housing part 3 in the direction indicated by arrow 28. Thereby the unit

1 is compressed, and the cartridge 6 is pressed towards the intermediate part. As the vial adapter 9 is made more flexible than the reservoir adapter 12 (as mentioned above), the vial 5 will enter the vial adapter 9 and the first spike 10 will penetrate the septum 11 before the cartridge 6 enters the reservoir adapter 12, and the second spike 13 penetrates the septum 14. As the spikes 10, 13 have penetrated each septum, respectively, the fluid connection is established. By pushing the unit 1 further in the direction of the arrow 28, the movable piston 15 is pushed further into the cartridge 6. As liquid is transferred from the cartridge 6 to the vial 5 via the hollow parts of the spikes 10, 12, air is allowed to leave the vial 5 via the channel 21, thereby providing equalization of the pressure in the vial 5. The liquid 7 in the cartridge 6 is forced into the vial 5 via the established fluid connection, and the lyophilized drug in the vial 5 is reconstituted.

[0036] When the piston 15 reaches an end position, in which all liquid is forced into the vial, the second spike 13 will penetrate the membrane 25. The housing parts are now locked to each other as the "snap-lock" 19 enters the groove or hole 18. Now, the cover 26 can be removed and a syringe can be connected to the outlet 24, and the reconstituted drug can be sucked out from the vial 5.

[0037] The membrane 25 could be substituted by a valve system that opens when a syringe or any other infusion device is connected to the outlet.

[0038] Fig. 2 is a perspective view of a mixing unit 1 according to another embodiment of the invention. A housing part 2 contains a vial 5 with dry drug 4, an intermediate part 8 having a vial adapter 9 with a spike 10 to penetrate the septum 11.

[0039] A piston 15 closes a reservoir 6 containing liquid 7, and the piston 15 comprises a liquid channel 23 through which the liquid is forced into the vial. As the vial 5 is pressed downwards, the spike 10 first penetrates a rubber stopper 29 placed over the spike and then the septum 11 of the vial. The fluid connection is now established, and the liquid is forced into the vial by pressing the vial and thus the piston further downwards, and the drug will be reconstituted. The piston 15 is now in an end position (not shown) and a sealing 30 provided in the bottom of the reservoir is penetrated by a spike 31 on a syringe connector 32, and a liquid channel is provided between the vial and the syringe 33.

[0040] This unit is not closed in one end, which allows for pooling of vials, as the vial can be changed with a new one.

Claims

1. A mixing unit for mixing dry drug with liquid, the unit comprising;

   - a first and second housing part movable connected to each other and containing;
     - a vial with dry drug,
     - a reservoir with liquid,
   - an intermediate part provided inside the housing parts for establishing a fluid connection between the reservoir and the vial upon moving the first and second housing part towards each other, said intermediate part comprising a first spike for penetrating a septum of the vial and a second spike for penetrating the reservoir, the first and second spike together defining a common fluid connection, and
   - a piston provided in said reservoir for forcing the liquid from the reservoir to the vial, via an established fluid connection, thereby causing the dry drug to become reconstituted, the piston comprising a liquid channel for connecting a liquid outlet of the unit with the internal of the vial via the established fluid connection.

2. A mixing unit according to claim 1, further comprising locking means for locking the first housing part in relation to the second housing part, when the piston has reached an end position in which the liquid has been forced into the vial.

3. A mixing unit according to claim 1 or 2, wherein the second spike comprises two separate channels;

   - a first channel defining said fluid connection in combination with the first spike,
   - a second channel defining a fluid connection between the internal of the vial and an air outlet for equalising pressure provided in the vial, said outlet comprising a filter being air permeable but not liquid permeable.

4. A mixing unit according to any of claims 1-3, wherein the intermediate part comprises a vial adapter for receiving and retaining the vial in a fixed position in relation to the first spike, and a reservoir adapter for receiving and retaining the reservoir in a fixed position in relation to the second spike when the first and second housing parts are moved towards each other.

5. A mixing unit according to claim 4, wherein the vial adapter is adapted to receive and retain the vial before the reservoir adapter receives and retains the reservoir when moving the first and second housing parts towards each other.

6. A mixing unit according to any of claims 1-5, wherein the first spike is longer than the second spike, the first spike being adapted to penetrate the septum of the vial before the second spike penetrates the septum of the reservoir, when moving the first and second housing parts towards each other.

7. A mixing unit according to any of claims 1-6, wherein the first and second housing, the intermediate part, the reservoir, the piston and the vial forms a substantial integral unit.

8. A mixing unit according to any of claims 1-7, wherein the liquid outlet of said channel is adapted to be connected to an infusion device, such as a syringe.

9. A mixing unit according to any of claims 1-8, wherein the liquid channel of the piston comprises a membrane to be penetrated by said second spike for opening the channel.

10. A mixing unit according to any of claims 1-9, wherein the second housing part comprises a cover being removable for getting access to the internal of the housing part.

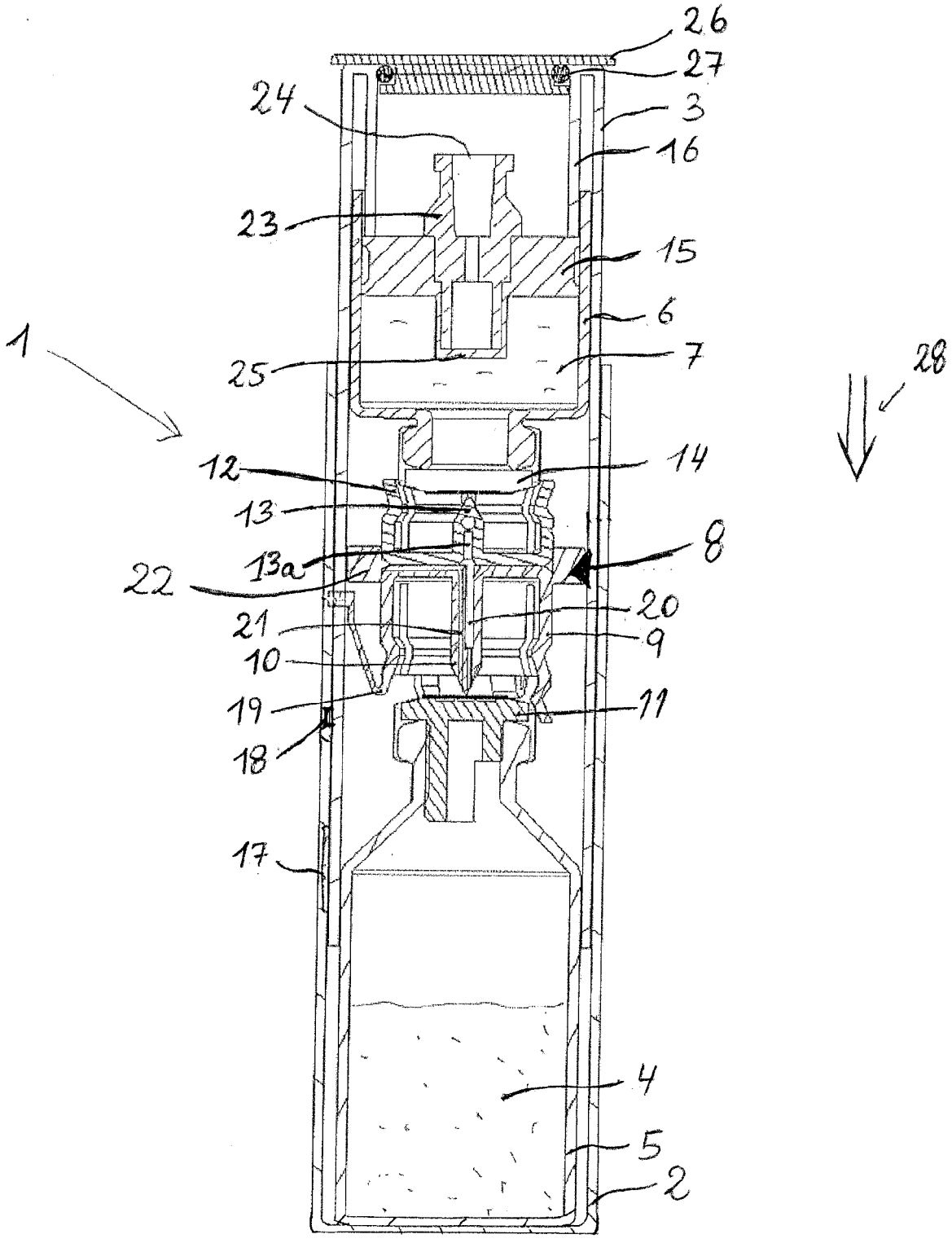
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Fig. 1

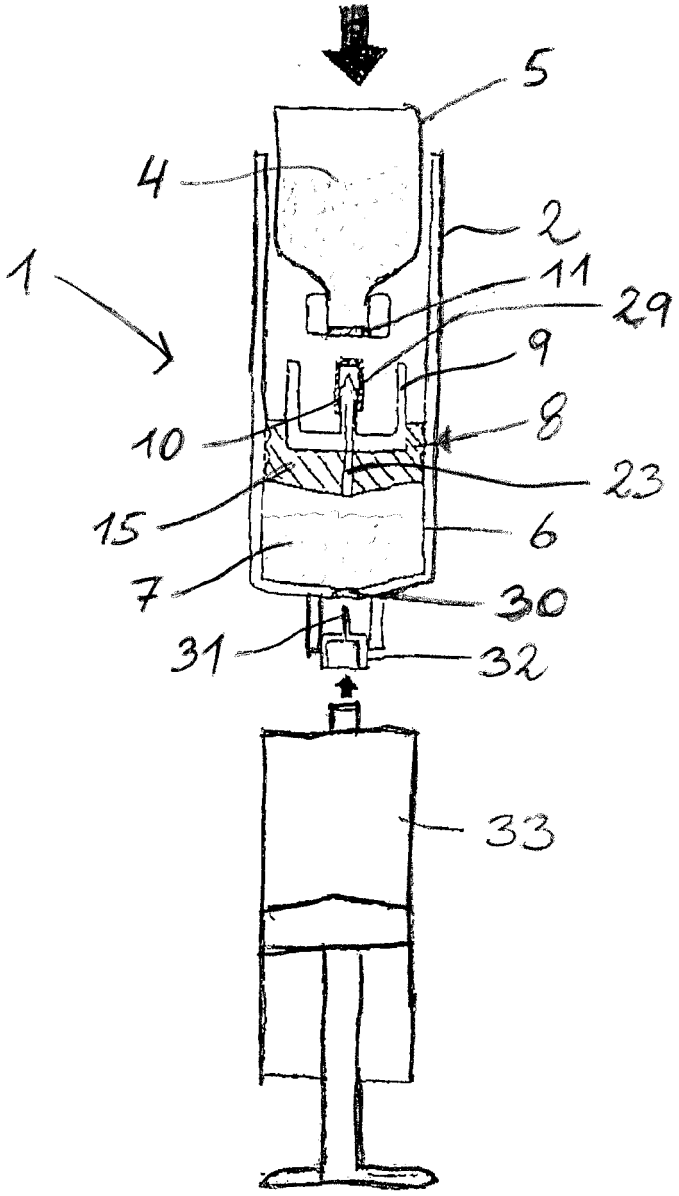

Fig. 2

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
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DOCUMENTS CONSIDERED TO BE RELEVANT

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			TECHNICAL FIELDS SEARCHED (IPC) A61J

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	20 March 2007	Bielsa, David

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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