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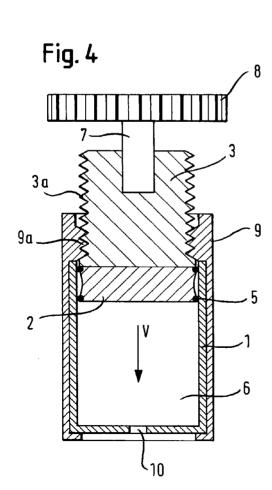
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(54) Title: AMPOULE UNIT WITH THREAD



(57) Abstract: Ampoule unit for an administering device, comprising an ampoule with a distal end with an opening for dispensing a product and a proximal end with an opening for accommodating a displacement body unit, and the proximal end of the ampoule has a thread which can be placed in a thread engagement with a complementary thread which is part of the displacement unit or a displacement body unit.

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Ampoule unit with thread

The invention relates to an ampoule unit with an ampoule for fitting in an administering device, preferably an injection device or, less preferably a syringe, the ampoule having a thread at its proximal end. The invention further relates to an ampoule unit with an ampoule and an adapter. In this case, the ampoule can be connected to the adapter, which has a thread, so that it is locked in rotation and translation but in a way other than by means of this thread.

From the prior art, numerous administering devices for dispensing fluids are known, for example medicaments such as insulin, hormone preparations or other medical or cosmetic substances. With most of these devices, especially if dispensing is effected via a needle at the distal end of the ampoule or device, the fluid is dispensed by a linearly guided plunger. Particularly in the case of low basal rates, slip-stick problems can occur due to the fact that the stopper or plunger causing the dispensing action, driven by a plunger rod for example, simultaneously assumes a sealing function at the ampoule rear end, and to this end is preferably made from a rubber-like material. In situations where this stopper or plunger is driven forward in a purely linear sliding action, a change between static friction and sliding friction repeatedly occurs between the latter and the ampoule internal wall. However, this to a certain extent causes delayed and jerky forward driving movements of the plunger, as a result of which uniform dispensing of the fluid from the ampoule is not always guaranteed.

This is particularly problematic if several or a number of extremely small quantities are to be dispensed from an ampoule in succession, i.e. a preferably defined, pre-settable interval of time. If, during such dispensing, the plunger is held back due to static friction, the amount dispensed may be too small, in spite of the

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linear forward movement of the plunger rod. During the next dispensing operation, the holding back of the plunger due to static friction is overcome, causing the plunger as a whole to travel a greater distance than that intended, as a result of which the dose dispensed this time is too high. Consequently, the patient or user may be administered less or more of the fluid substance if administering small quantities until the ampoule is completely empty. This problem is obviously magnified, the smaller the quantity of fluid to be administered with each application and, in the extreme situation, this can lead to a switch between a dispensed quantity of zero (if the plunger is completely held back by static friction), whereas twice the intended quantity is dispensed in the next step.

Document US 2003/0167093 A1 describes a pump for dispensing a fluid from a reservoir. The pump comprises a first part for accommodating the reservoir incorporating a plunger unit, for example an ampoule, and a second part for accommodating the motor and the plunger forward drive mechanism. The two parts are disposed adjacent to one another, thereby reducing the length of the pump. A plate fixedly connected to a nut seated on a threaded rod driven in rotation and connected to a motor acts on the rear end of the plunger unit. When the motor rotates, the nut moves in the forward drive direction and pushes the plunger unit via the plate in a linear motion in the direction in which the fluid is dispensed. Alternatively, the threaded rod may be directly connected to the plunger rod via a gear. The plunger rod sits in a thread connection with the plunger and moves it linearly in the forward drive direction.

Patent specification EP 1 752 172 A1 discloses a drive mechanism for an infusion pump. As described in paragraph 0030, Figure 4 illustrates an ampoule with an internal thread in which a plunger with an external thread locates, which is thus screwed into the ampoule in a rotating motion about its rotation axis and dispenses the fluid contained in the ampoule as a result. In order to be able to empty the ampoule described in EP 1 752 172 completely, the internal thread must extend across the entire internal length of the ampoule.

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The objective of the invention is to propose an ampoule unit for administering devices which ensures that when repeatedly dispensing an identical small quantity from an ampoule, the quantity dispensed is always identical every time.

This objective is achieved by the invention on the basis of both an ampoule unit as claimed in claim 1 and an ampoule unit as defined in claim 2.

The ampoule unit proposed by the invention and defined in claim 1 comprises an ampoule for an administering device, with a proximal and a distal end. In this respect, what is referred to as the proximal end of the ampoule is that of the administering device which is disposed away from the dispensing end when the ampoule is being used, which is or can be connected to an injection needle or injection nozzle via which the fluid contained in the ampoule can be administered to a human's or animal's body. Accordingly, the distal end of the ampoule is the end lying opposite the proximal end, which can be connected to a needle holder, a needle or a nozzle in order to use the ampoule or is supplied already connected to one of these elements.

The ampoule may be supplied as an empty unit which is not filled with the fluid until shortly before use but it may also be supplied to the user already filled, which is the preferred option, especially if dispensing is to be effected by a self-administrator.

As proposed by the invention, the ampoule unit comprises an ampoule which has a thread at least at its proximal end, i.e. at least the proximal end of the ampoule is provided with a thread. This thread is preferably formed directly during the process of manufacturing the ampoule, for example in a casting or pressing mould, and is usually made from the same material as the ampoule, for example glass, metal, porcelain, ceramic or plastic. However, the part incorporating the thread may also be made from a different material from the rest of the ampoule. If these different

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materials are used together in the manufacturing process already, as is the preferred situation, namely simultaneously in a single manufacturing process, these materials must have similar physical properties, such as E-modulus or coefficient of expansion, for example.

The invention further relates to an ampoule unit comprising an ampoule and an adapter which can be connected to it so as to be locked in rotation and translation, which extends beyond the ampoule at least in the proximal direction. Standard, commercially available ampoules may be used with such an ampoule unit by preference. The adapter has a thread and is manufactured separately and then subsequently assembled with the standard ampoule to produce the ampoule unit proposed by the invention, for example by bonding or welding. One problem which might occur with bonding is that bits of the adhesive used could dissolve in the fluid contained in the ampoule over time, which might be problematic in terms of supplying filled ampoules over longer periods of time. One advantage of manufacturing the ampoule and adapter separately is that the ampoule body can be produced or bought in without a thread in large quantities, and the parts incorporating the thread can be produced in smaller quantities for different applications, for example with threads of differing pitch. The requisite second step of assembling the ampoule and threaded part could then take place immediately prior to filling the ampoules or, if supplying empty ampoules, immediately before their despatch.

The adapter has a thread, at least at its proximal end. In principle, a simple nut may be used as an adapter, which is or can be secured on the proximal end of the ampoule. In this case, the ampoule is preferably a standard, commercially available ampoule body. The adapter may also partially surround the ampoule or extend into the ampoule in the proximal region. Moreover, it may also totally surround the ampoule in the sense that the ampoule can be accommodated in the adapter. Finally, the adapter may also be fitted directly on the ampoule in a positive fit, for example shrink-fitted or injected on. Alternatively, the connection between the

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adapter and ampoule may also be releasable, in other words the ampoule can be inserted in the adapter subsequently and removed from the adapter after emptying. In any event, the important thing is that the adapter is not able to move relative to the ampoule and instead, the two parts are able to effect every linear movement and every rotating movement but only as a unit. However, the adapter may be separate from the ampoule. For example, it may be provided in the form of an internal thread on the internal face of the housing of the administering device or may be a separate threaded part fixedly connected to the housing which forms the adapter proposed by the invention.

Preferred embodiments of the ampoule units defined in claim 1 and claim 2 will be described below and, unless stated otherwise, all embodiments apply to both of the ampoule units proposed by the invention.

The ampoule unit may have a plunger unit for dispensing the fluid product. Pressure can then be applied to the fluid product via this plunger unit, for example in order to dispense it from the ampoule and enable it to be injected into tissue. To this end, the plunger unit, which comprises a plunger and a plunger rod for example, has a thread on the plunger or on the plunger rod, which forms a complementary thread to the thread of the ampoule unit. The two threads may be placed in a thread engagement, i.e. the plunger unit can be screwed into or onto the proximal end of the ampoule unit. To this end, the plunger is introduced into the proximal end of the ampoule and is moved in the forward drive direction by turning it further in the same direction so that it screws into the ampoule.

The plunger of the plunger unit may be made from a material which is sufficiently elastic to provide a seal for the ampoule in the proximal direction and simultaneously afford a slight sliding friction resistance to the material of the ampoule internal face. Alternatively or in addition, a seal may be attached to the distal plunger face. In order to reduce sliding friction resistance, the plunger may be of a concave shape at its circumference so that the contact region between the

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plunger and ampoule internal wall is limited to the leading and trailing ends of the plunger in the forward drive direction. However, the plunger may also be made from a hard cylindrical core onto which one, two or more sealing rings are injected. The material for the sealing rings may be selected with a view to obtaining the tight seal and low friction resistance. In order to reduce static and/or sliding friction resistance, the ampoule internal face and/or the plunger external face and the seals may be coated with a substance which reduces friction.

As far as the thread of the ampoule unit is concerned, it may be an internal thread or an external thread in principle. The thread is preferably disposed on the external wall of the ampoule unit. In this case, the plunger unit is shaped so that the complementary thread sits in the thread engagement with the thread disposed on the external face of the ampoule, whilst a central part of the plunger unit simultaneously causes the fluid product to be dispensed from the ampoule.

Less preferably, it may be an internal thread, in which case the plunger unit can be screwed into the ampoule unit from its proximal end. Since the thread proposed by the invention in this embodiment is disposed at the proximal end only, the ampoule is closed off by a seal element in the proximal direction, preferably a gasket, which lies in direct contact with a horizontal thread end of the thread portion projecting out vertically from the ampoule wall. The gasket preferably has an axial thickness and may be connected to the plunger unit by a positive join, for example, so that it turns with the plunger as it is screwed into the ampoule and also serves as a seal element. The gasket may also constitute the plunger of the plunger unit within the meaning of the invention.

As a rule, the thread and complementary thread have a thread pitch of 0 mm/U to 2 mm/U and it preferably lies between 0.5 mm/U and 2 mm/U. Less preferably, the thread pitch may also be in the range of ≤ 1 mm/U, and in individual instances more than 2 mm/U.

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The plunger unit, which preferably comprises a single piece, is screwed into the ampoule unit as the thread engagement is established between the plunger unit and ampoule unit in order to dispense the fluid product. In other words, the part of the plunger unit effecting the dispensing operation, namely its front end or, in the case of the external thread solution, the part guided in the ampoule, is screwed about its longitudinal axis into the ampoule unit, which is secured to prevent it from rotating as well. This combined rotating and linear movement of the plunger unit causes the front end of the plunger unit effecting the dispensing action to travel along a spiral-shaped path which is longer than the distance of a purely linear motion, used as standard in the prior art. However, a longer distance enables the static friction between the ampoule internal face and plunger unit external face to be overcome more readily and switch to a sliding friction.

Due to the fact that the plunger unit is able to move in the ampoule in a manner that is not exclusively linear, a free-flow can be more efficiently prevented whilst simultaneously minimising slip-stick. In order to effect the screwing movement of the plunger unit, it is sufficient for the plunger unit to be simply driven in rotation. The thread engagement between the ampoule and plunger unit shortens the chain of strain in the system compared with conventional solutions, results in a better defined plunger position in the ampoule and also reduces the accumulating bolus volume and delay times when dispensing. Especially in the case of repeated dispensing of small or extremely small fluid quantities, this offers greater reliability that the same quantity of fluid will always be dispensed from the ampoule. As a result, the same quantity of fluid, for example a medicament, is administered to a user in a reliably reproducible way with each use, which enables the quantity to be dispensed per dispensing operation to be limited to the necessary minimum.

As described, the ampoule unit is provided with a thread at least at the proximal end. However, provision of the thread is not limited to the proximal end,

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especially in the case of a solution based on an external thread, and instead, the ampoule unit external face as a whole may be formed as a thread.

The plunger unit may be provided in the form of a plunger solely or as a combination of a plunger and plunger rod. If the plunger unit comprises the plunger and plunger rod, the complementary thread which can be placed in a thread engagement with the thread of the ampoule unit may be provided either on the plunger or on the plunger rod. The plunger and plunger rod may comprise a single piece. This being the case, they may be made from plastic for example and manufactured by an injection casting process, for example two-component injection casting. Alternatively, however, the plunger and plunger rod may also be separate parts, which are non-releasably connected to one another, for example by means of a bonded or welded connection. Finally, the plunger may also be releasably connected to the plunger rod, in which case the connection may be a screw or plug-in connection. In this case, however, it is necessary to guarantee that the plunger and plunger rod always rotate jointly about their rotation axis when the plunger unit is being screwed into the ampoule unit. In other words, the plunger must not be able to move relative to the plunger rod in the connected state when the unit comprising the plunger and plunger rod is being screwed into the ampoule unit. The front end of the plunger may form a seal which is formed on the plunger during the manufacturing process or is connected to the plunger so that it is prevented from rotating, for example welded.

However, the plunger unit may also comprise the plunger, a sleeve incorporating the thread fixedly connected to the plunger and a drive element. The sleeve has a cut-out in the longitudinal direction, for example a square blind bore, in which the drive element positively engages, in this instance an appropriately designed square bar. When the drive element is driven in rotation, for example via a gear connected to its proximal end, the sleeve and the plunger rotate automatically and are screwed in the dispensing direction due to the thread connection between the sleeve and ampoule unit.

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The ampoule unit may be a disposable unit which is disposed of once it is completely empty. This being the case, it is of advantage for the recycling process if, in the case of the ampoule unit with the fixedly connected thread part defined in claim 1, the ampoule and the thread part are made from the same material. In the case where the adapter solution is used, it is of advantage if the adapter can be released from the ampoule for disposal purposes and the two parts can be disposed of and recycled separately from one another.

The ampoule units described above may be used in both stationary and mobile administering devices.

An example of an embodiment of the invention will be explained with reference to the appended drawings. Features which become apparent from the description of the embodiment constitute the subject matter of the claims, each individually and in every combination of features, and advantageously also complement the designs described above. Of the drawings:

Figure 1: shows an ampoule unit as defined in claim 1,

Figure 2: shows an ampoule unit with a nut as an adapter,

Figure 3: shows an ampoule unit with adapter, external thread,

Figure 4: shows an ampoule unit, adapter as part of the housing.

Figure 1 illustrates an ampoule unit 1, which is connected to a plunger unit 2. The ampoule unit 1 comprises an ampoule 1 with a distal opening 10 for dispensing the ampoule contents from the fluid chamber 6 and a proximal opening for accommodating and guiding a displacement unit, in this instance the plunger unit 2. The proximal end of the ampoule 1 has a thread portion formed on the external face. In the embodiment illustrated as an example, the thread portion is disposed at the most proximal end of the ampoule but it may be disposed at a different point of the ampoule, for example shifted farther in the distal direction.

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In order to dispense the contents of the fluid chamber 6, a plunger unit 2 illustrated in Figure 1 co-operates with the ampoule 1. This plunger unit 2 comprises a central plunger 2b with an external diameter which essentially corresponds to the internal diameter of the ampoule 1. At its foremost distal end, the central plunger has a seal 5, which prevents the contents of the ampoule 1 from escaping from the ampoule 1 at the rear during the dispensing operation. This seal 5 may be fixedly connected to the central plunger 2b but may also serve as the proximal seal of the ampoule 1 and may be fitted already at the time of manufacture of the ampoule 1, and is driven in the distal direction by the plunger unit 2 during the dispensing operation. In the latter case, the front end of the plunger 2 would also move the seal 5 from the supplied state in the forward drive direction V, preferably uniformly, in other words, by contrast with the system illustrated in Figure 1, the front face of the plunger 2 would extend parallel with the seal 5 and not at an angle. This being the case, the plunger 2 is connected to the seal 5 either by a positive fit or some other connection so that it is locked in rotation, i.e. the seal 5 would rotate with the plunger 2. The central plunger is surrounded by a plunger sleeve 2c and the central plunger 2b and plunger sleeve 2c jointly form the plunger unit 2 and are preferably manufactured together as a single piece, for example by an injection casting process.

Disposed between the central plunger 2b and the plunger sleeve 2c is a slot 2d. Whilst the external face of the central plunger 2b is smooth, the internal face of the plunger sleeve 2c is provided in the form of a plunger thread 2a and constitutes a complementary thread to the ampoule thread 1a. This means that the plunger unit 2 can be connected to the ampoule 1 by establishing a thread engagement between the plunger thread 2a and the ampoule thread 1a. In other words, the plunger unit 2a of the embodiment illustrated as an example may be screwed onto the ampoule 1. When the plunger unit 2 is screwed onto the ampoule, the central plunger 2b moves into the ampoule and as it moves in the distal direction is able to force the contents of the fluid chamber 6 through the opening 10 of the ampoule 1.

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The central plunger 2b is not only able to move linearly forwards in the ampoule. The central plunger 2b can only be screwed into the ampoule 1 by means of the thread 1a and the complementary thread 2a by a rotating movement of the plunger unit 2. In order to travel a distance x in the forward drive direction V corresponding to a dispensing quantity, the central plunger 2b must therefore travel a longer distance as it is screwed into the ampoule 1 than would be the case in the event of a purely linear movement. This advantageously ensures that a static friction between the ampoule internal wall and plunger external face is reliably switched to a sliding friction during the movement of the plunger. As a result, even if small or extremely small quantities of fluid are dispensed repeatedly, the pre-set dispensing quantity is always obtained to a high degree of reliability. Any distortion of the individual dispensed quantities due to slip-stick problems or a long chain of strain within the system is largely ruled out.

Figure 2 illustrates a first example of an embodiment of the ampoule unit defined in claim 2. Fixedly connected to the ampoule 1 is an adapter 4 in the form of a nut with an internal thread. The term fixedly in this context means that the nut or adapter 4 is not able to move relative to the ampoule 1, either linearly or in rotation. This may be achieved using an appropriate bonded or welded connection but could just as easily be achieved by appropriate shaping of the ampoule end, enabling the adapter 4 to be retained in a positive fit and secured to prevent any relative movement with respect to the ampoule unit 1.

In the embodiment illustrated as an example, the plunger 2 is of a concave shape at its external face and has a seal 5 extending around its top and bottom end respectively. It may be made as a separate part and already serve as a rearward seal in the state in which the ampoule 1 is supplied. In this case, it has connecting elements at its proximal end, namely that opposite the forward drive direction V, by means of which it can be connected to the plunger rod 3 so that it is locked in rotation. The expression locked in rotation is intended to mean that in the state

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connected to the plunger rod 3, the plunger 2 effects every rotating movement in unison with the plunger rod, at least every rotating movement by which the plunger is screwed into the ampoule in the distal direction and forces fluid out of the fluid chamber 6 through the opening 6.

The plunger rod 3 has an external thread 3a, which is a complementary thread to the internal thread of the adapter 4. Accordingly, the plunger rod 3 is able to turn with its thread 3a in the thread 4a of the adapter 4 and is thus screwed in the forward drive direction V into the ampoule 1. The plunger rod 3 may be connected to a gear 8 directly or via a stub, not illustrated, via a drive element 7, which is driven by a motor or manually and thus screws the plunger 2 in the forward drive direction V.

A second example of an embodiment based on claim 2 is illustrated in Figure 3. In this instance, the ampoule 1 is retained in an adapter 4 which partially surrounds it so that the adapter 4 is not able to move relative to the ampoule 1, either linearly or in rotation. To this end, the adapter 4 may be positively connected to the ampoule 1, for example adhered, welded or shrink-fitted. The one and only important aspect is the rigid connection of the two parts which does not allow any relative movement between the ampoule 1 and adapter 4.

In its rear proximal region, the adapter has an external thread. Disposed in a thread engagement with it is a plunger unit, which is a plunger unit of the type illustrated in Figure 1 and the associated description applies here. In other words, the plunger 2 is connected to the central plunger 2b so as to rotate in unison with it and the latter is in turn connected to the plunger sleeve 2c so as to rotate in unison with it. This being the case, at least the central plunger 2b and the plunger sleeve 2c are manufactured as a single piece, for example as an injection cast part. When the plunger sleeve 2c is turned so that the plunger sleeve 2c is screwed onto the adapter thread 4a by means of the plunger thread 2a, the central plunger 2b rotates at the same speed and in the same direction as the plunger sleeve 2c. In this

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respect, the plunger 2 may either be the front end of the central plunger 2b, a separate part which is fixedly connected to the central plunger or the plunger 2 may form the termination of the filled ampoule, in which case it is only when the plunger unit 2a, 2b, 2c has been fitted on the adapter 4 with the plunger unit 2a, 2b, 2c that it always effects the rotations of the central plunger 2b as the plunger unit 2a, 2b, 2c is being screwed onto the ampoule 4. The plunger 2 may have seal elements 5, which prevent the fluid from escaping from the ampoule via the plunger 2.

Finally, Figure 4 illustrates another example of an embodiment of the invention based on claim 2. The adapter proposed by the invention is provided in the form of a housing 9. This housing 9 may be the housing of the administering device for example, or the housing of a sub-unit of the administering device which is inserted in the administering device as a unit. The thread 9a formed on the internal face of the housing wall lies above an ampoule 1 inserted in the housing. The ampoule 1 is retained in the housing 9 so that it is not able to move in rotation or translation. A thread engagement is established between the internal thread 9a of the housing 9 and the external thread 2a of a plunger unit 2. When the plunger unit 2 is rotated about its rotation axis, the plunger unit 2 is screwed in the forward drive direction V into the ampoule and causes a dispensing operation from the fluid chamber 6 through the opening 10. Reference may be made to Figure 2 for a more detailed description. The description given of how the adapter 4 and plunger rod 3 cooperate also applies to the embodiment illustrated as an example in Figure 4.

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List of reference numbers

1	Ampoule
1a	Ampoule thread
2	Plunger / plunger unit
2a	Plunger thread
2b	Central plunger
2c	Plunger sleeve
2d	Slot
3	Plunger rod
3a	Plunger rod thread
4	Adapter
4a	Adapter thread
5	Seal
6	Fluid chamber
7	Drive element
0	
8	Gear
9	Gear Housing

Forward drive direction

V

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Claims

1. Ampoule unit for an administering device, comprising an ampoule (1) with

- a) a distal end with an opening (10) for dispensing a product and
- b) a proximal end with an opening for accommodating a displacement unit,

characterised in that

- c) the proximal end of the ampoule (1) has a thread (1a) which can be placed in a thread engagement with a complementary thread which is part of the displacement unit.
- 2. Ampoule unit for an administering device, comprising
 - a) an ampoule with a distal end with an opening (10) for dispensing a product and a proximal end with an opening for accommodating a displacement unit and
 - b) an adapter (4) which can be or is connected to the ampoule (1) so that is not able to move in rotation or translation,

characterised in that

- c) the adapter (4) is provided with a thread (4a) which can be placed in a thread engagement with a complementary thread which is part of the displacement body or a displacement body unit.
- 3. Ampoule unit as claimed in claim 1 or 2, further comprising a plunger unit (2, 3), which plunger unit (2, 3) constitutes the displacement body unit, and a complementary thread (2a; 3a) to the thread (1a; 4a) of the ampoule (1) or adapter (4) is at least partially formed on the plunger unit (2, 3) which can be placed in a thread engagement with it.
- 4. Ampoule unit as claimed in one of the preceding claims in which the thread pitch of the thread (1a; 4a) and complementary thread (2a; 3a) is ≤ 2 mm/U.

5. Ampoule unit as claimed in one of the preceding claims, in which the thread pitch is in the range of $0.5 \text{ mm/U} \le 2 \text{ mm/U}$.

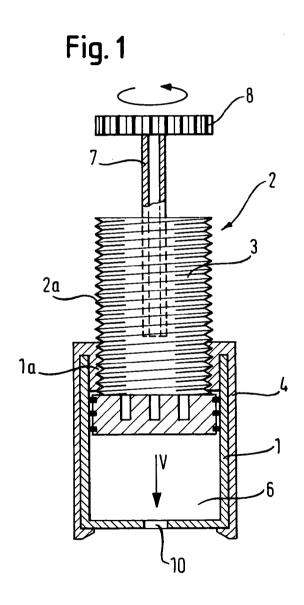
- 6. Ampoule unit as claimed in one of the preceding claims, in which the thread (1a; 4a) is an internal thread and the complementary thread (2a; 3a) is an external thread or vice versa.
- 7. Ampoule unit as claimed in one of claims 2 to 6, in which a nut fixedly connected to the proximal end of the ampoule (1) constitutes the adapter (4).
- 8. Ampoule unit as claimed in one of claims 2 to 6, in which the adapter (4) at least partially surrounds the ampoule (1) and is releasably connected to the ampoule (1).
- 9. Ampoule unit as claimed in one of claims 2 to 6, in which the adapter (4) at least partially surrounds the ampoule (1) and is non-releasably connected to the ampoule (1).
- 10. Ampoule unit as claimed in the preceding claim, in which the adapter (4) is injected or shrink-fitted onto the ampoule (1).
- 11. Ampoule unit as claimed in one of claims 2 to 6, in which the adapter (4) is a part of a housing (9), for example a part of the housing of the administering device.
- 12. Ampoule unit as claimed in one of claims 3 to 11, in which a plunger (2) constitutes the plunger unit.
- 13. Ampoule unit as claimed in one of claims 3 to 11, in which the plunger unit (2, 3) comprises a plunger (2) and a plunger rod (3) and the complementary

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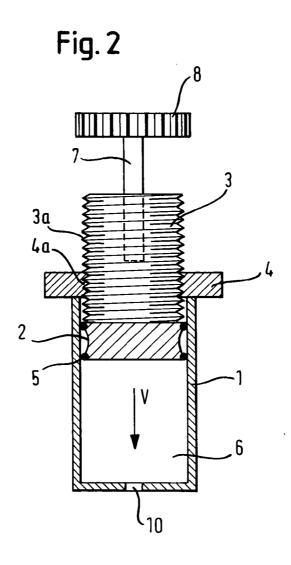
thread (2a; 3a) is disposed on the plunger (2) and/or the plunger rod (3).

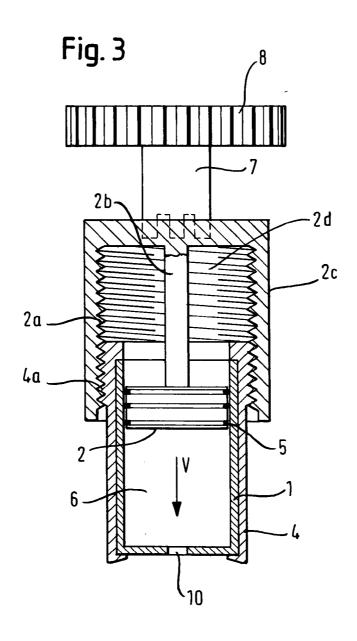
- 14. Ampoule unit as claimed in the preceding claim, in which the plunger (2) is releasably connected to the plunger rod (3), for example by means of a screw or plug-in connection.
- 15. Ampoule unit as claimed in claim 13, in which the plunger (2) is non-releasably connected to the plunger rod (3).
- 16. Ampoule unit as claimed in the preceding claim, in which the plunger (2) and the plunger rod (3) are made as a single piece, preferably from plastic.
- 17. Ampoule unit as claimed in one of claims 3 to 16, in which the plunger (2) or the plunger rod (3) can be connected to a drive which drives the plunger (2) and the plunger rod (3) in rotation.
- 18. Ampoule unit as claimed in one of the preceding claims, which ampoule unit is a disposable device.
- 19. Ampoule unit as claimed in one of the preceding claims, in which the plunger unit (2, 3) rotates about a rotation axis relative to the ampoule (1) due to the thread engagement and is thus moved in the ampoule (1) in a screwing action in the distal direction.

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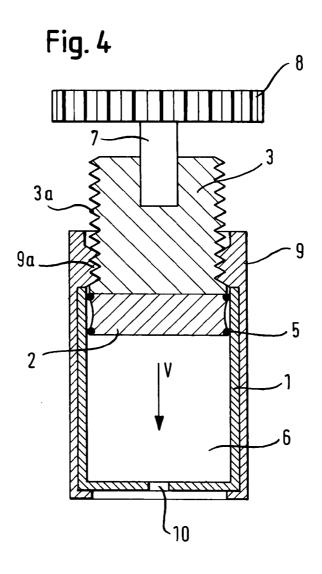


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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/008677

		PCT/EP2008/008677	
A. CLASSI INV.	FICATION OF SUBJECT MATTER A61M5/24		
According to	b International Patent Classification (IPC) or to both national classific	ation and IPC	
B. FIELDS	SEARCHED		
Minimum do A61M	cumentation searched (classification system followed by classification	on symbols)	
Documental	ion searched other than minimum documentation to the extent that s	such documents are inclu	uded in the fields searched
	ata base consulted during the international search (name of data ba	se and, where practical,	, search terms used)
FAO-TU	ternal, WPI Data		•
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the rel	evant passages	Relevant to claim No.
X	US 4 189 065 A (HEROLD WOLF-DIETE 19 February 1980 (1980-02-19)	RICH [DE])	1-3, 6-10, 12-16,
Α	figures 1-7		18,19 4,5,11,
	column 3, line 28 - column 5, lir	ne 23	
X	WO 2004/016303 A (MICRO THERAPEUT [US]; STRAUSS BRIAN M [US]; SMITH [US];) 26 February 2004 (2004-02-	I BROCK H	1-3, 6-10, 12-16,
Α .	figures 1-10	•	18,19 4,5,11,
	paragraph [0029] - paragraph [004	15]	•
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<u> </u>	ner documents are listed in the continuation of Box C.	X See patent fam	nily annex.
"A" docume	ategories of cited documents : ent defining the general state of the art which is not ered to be of particular relevance document but published on or after the international	or priority date and cited to understand invention	lished after the international filing date d not in conflict with the application but d the principle or theory underlying the
filing d "L" docume which		cannot be conside involve an inventive an inventive and invention "Y" document of particular to the consideration of the consideration	ular relevance; the claimed invention red novel or cannot be considered to ye step when the document is taken alone ular relevance; the claimed invention tred to involve an inventive step when the
other r	ent referring to an oral disclosure, use, exhibition or neans ent published prior to the international filing date but	document is comb	oined with one or more other such docu- pination being obvious to a person skilled
later th	an the priority date claimed actual completion of the international search		of the same patent family he international search report
	0 January 2009	06/02/2	·
	nailing address of the ISA/	Authorized officer	
	European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Reinbol	d, Sylvie

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/008677

HOD) DOCUMENTS CONSIDERED TO BE RELEVANT	PCT/EP200	8/008677
Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
US 2002/113088 A1 (PIERSON PAUL R [DE] ET AL PIERSON PAUL R [US] ET AL) 22 August 2002 (2002-08-22) figures 1-3 paragraph [0014] - paragraph [0025] paragraph [0016] - paragraph [0026]		1-3,6-8, 12-16, 18,19
US 5 618 273 A (FISCHER DAVID V [US]) 8 April 1997 (1997-04-08) figures 1-8 column 4, line 8 - column 8, line 9		1-3,6-8, 12-16, 18,19
GB 2 058 228 A (VEEN R F LE; VEEN H H LE) 8 April 1981 (1981-04-08) figures 1-4 page 1, line 109 - page 2, line 78		1,2
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		•
	US 2002/113088 A1 (PIERSON PAUL R [DE] ET AL PIERSON PAUL R [US] ET AL) 22 August 2002 (2002-08-22) figures 1-3 paragraph [0014] - paragraph [0025] paragraph [0016] - paragraph [0026] US 5 618 273 A (FISCHER DAVID V [US]) 8 April 1997 (1997-04-08) figures 1-8 column 4, line 8 - column 8, line 9 GB 2 058 228 A (VEEN R F LE; VEEN H H LE) 8 April 1981 (1981-04-08) figures 1-4	US 2002/113088 A1 (PIERSON PAUL R [DE] ET AL PIERSON PAUL R [US] ET AL) 22 August 2002 (2002-08-22) figures 1-3 paragraph [0014] - paragraph [0025] paragraph [0016] - paragraph [0026] US 5 618 273 A (FISCHER DAVID V [US]) 8 April 1997 (1997-04-08) figures 1-8 column 4, line 8 - column 8, line 9 GB 2 058 228 A (VEEN R F LE; VEEN H H LE) 8 April 1981 (1981-04-08) figures 1-4

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/008677

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 4189065	Α	19-02-1980	DE	7603096 U1	19-08-1976
WO 2004016303	Α	26-02-2004	AU CA EP JP	2003263891 A1 2494580 A1 1551478 A1 2005535415 T	03-03-2004 26-02-2004 13-07-2005 24-11-2005
US 2002113088	A1	22-08-2002	NONE		
US 5618273	À	08-04-1997	NONE		
GB 2058228	Α	08-04-1981	AU DE FR JP US ZA	6042480 A 3028354 A1 2462170 A1 56028770 A 4312343 A 8004243 A	05-02-1981 26-02-1981 13-02-1981 20-03-1981 26-01-1982 29-07-1981