RE-USABLE AUTO-INJECTOR WITH FILLING MEANS

Field of the Invention

This invention relates to an injection device, for example, a re-useable auto-injector into which a drug may be transferred from a vial prior to subcutaneous injection into a patient.

Background of the Invention

The use of automatic injection devices (commonly known as auto-injectors) to deliver a medicament to a patient has provided many benefits over manual syringes. In particular, auto-injectors have helped to relieve the burden on hospital staff to deliver a drug to a patient because patients are able to use the devices on themselves reliably and safely and in their own home.

Known auto-injectors are described in WO 95/35126 and EP-A-0 516 473. These and similar auto-injectors are typically provided primed (i.e. pre-sprung) and ready to be used for injecting a patient. For these reasons, it is difficult to insert a drug into the auto-injector and, as a consequence, manufacturers of such auto-injectors have typically provided a pre-filled syringe for use in the auto-injector, or a complete auto-injector unit which is pre-filled with a particular drug.

This requires a more complicated and expensive manufacturing process than would be otherwise required for an auto-injector because manufacturers must also obtain and provide the drugs and maintain the facilities for storing and handling them. Furthermore, the manufacturer must operate separate production lines for each drug which is required.

Drugs for medical use are often manufactured and distributed in standard vials. In this way, drugs may be supplied in bulk conveniently and relatively cheaply, regardless of the way in which the drug is finally used.

A significant cost-saving could be made in providing an auto-injector device which is capable of drawing a drug from a standard vial rather than relying on a pre-filled syringe. Not only would such a device benefit the manufacturers, who would no longer have to provide bespoke drug-filled devices, but also hospitals, which would enjoy a simplified inventory system and could make use of the standard vials which are used on a regular basis, and patients, who could be provided with a supply of vials for self administration.

In addition, the use of vials permits the possibility of reusing a greater proportion of an auto-injector device. Typically, auto-injectors are provided in two subassemblies. The first subassembly comprises the operating mechanisms and all other reusable components and the second subassembly contains the injection components that must be replaced each time the device is used.

A major factor in the cost of the second subassembly is the provision of a chamber which is pre-filled with a drug to be injected. As explained above, providing a range of syringes is an expensive and time-consuming aspect of the manufacturing process of an auto-injector. The use of standard vials would enable this cost to be reduced.

Summary of the Invention

The present invention aims to solve the aforementioned problems. Accordingly, an injection device comprises a housing; a chamber disposed within the housing, the chamber having proximal and distal ends, an inner surface and an exit aperture; a stopper movably disposed within the chamber, and having an outer surface substantially in contact with the inner surface about its perimeter; and a port adapted to receive a container containing a fluid. The stopper is fixed with respect to the housing and movement of the port causes movement of the exit aperture in relation to the stopper.

Providing an injection device, such as an auto-injector, having a chamber into which a fluid may be transferred from a separate container provides at least two benefits over the prior art. Firstly, manufacturers of auto-injector devices need no longer manufacture a range of pre-filled syringes to be inserted into a reusable sub-assembly. Rather, the

manufacturer may provide instead a single type of sub-assembly in accordance with the present invention into which any variety of drug may be transferred immediately prior to injection. The single type of sub-assembly may be manufactured in bulk, thereby reducing the manufacturing costs.

This advantage leads on to a second benefit whereby the invention may be used in conjunction with any type of container from which a drug may be transferred into the chamber. In particular the invention may be used with standard vials.

Furthermore, the invention allows a greater proportion of the needle assembly to be reused. Whereas known auto-injector systems require pre-filled syringes, the capability of transferring fluid into a chamber within the needle device permits greater scope for reusability.

The volume of the chamber into which the fluid is transferred is defined by the space between the stopper and the exit aperture. Consequently, the volume is decreased as the stopper is moved toward the exit aperture and increased as the stopper is moved away from the exit aperture. An increase in volume causes an initial decrease in pressure in the chamber which thereby draws the fluid into the chamber.

The port may be configured to bring the container into fluid engagement with the exit aperture when the exit aperture is adjacent the stopper. In this position, the volume of the chamber is at or substantially at its lowest. Preferably, engagement between the container and the exit aperture forms a fluid conduit for transferring fluid from the container to the chamber. In accordance with this embodiment, as the volume of the chamber is increased (for example, by moving the exit aperture away from the stopper) fluid from the container is transferred into the chamber.

In some embodiments, a biasing element is coupled to the port and configured to bias the port such that the exit aperture is biased away from the stopper. Starting from the position mentioned above (i.e. wherein the exit aperture is adjacent the stopper and the container is in fluid engagement with the exit aperture), the action of the biasing element

will cause the fluid to be transferred into the chamber without the need for external intervention. Optionally the biasing element is a spring, but other elements which perform a similar function are also envisaged.

In other embodiments, the injection device comprises a discharge nozzle in fluid communication with the exit aperture. Typically, containers suitable for use with the device comprise a cap made from rubber or foil, for example. In such cases, the discharge nozzle may be configured to pierce the cap to form a fluid conduit for transferring fluid from the container to the chamber.

Brief Description of the Drawings

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a side view of a first sub-assembly of an injection device;

Figure 2 is a side view of the first sub-assembly wherein the cap has been removed;

Figure 3 is a side view of a container being engaged with the first sub-assembly;

Figure 4 is a side view of the first sub-assembly in the fully retracted position;

Figure 5 is a side view of the first sub-assembly in the fully extended position;

Figure 6 is a side view of the container being removed from the first sub-assembly;

Figure 7 is a side view of the first sub-assembly being engaged with a second sub-assembly; and

Figure 8 is a side view of an injection device comprised of the first and second sub-assemblies.

Detailed Description of the Drawings

Figures 1 to 4 illustrate a first sub-assembly 110 suitable for use in an auto-injector according to the present invention.

The first sub-assembly 110 comprises a housing 111 and a chamber 112 disposed within the housing. The housing 111 has proximal 111a and distal 111b ends. The chamber 112 has proximal and distal ends, corresponding to the proximal and distal ends of the housing, and an inner surface. Adjacent the proximal end of the chamber there is provided a stopper 113. The stopper 113 is moveably disposed within the chamber 112 and has an outer surface. The outer surface of the stopper 113 is substantially in contact with the inner surface of the chamber 112 about its perimeter.

At the distal end of the chamber 112 there is provided an exit aperture 114. An injection needle 115 is provided in fluid connection with the exit aperture 114. The injection needle 115 is suitable for piercing the skin of a patient and delivering a drug subcutaneously. The needle 115 is also suitable for piercing a foil or rubber cap as might be provided on a vial.

The first sub-assembly 110 comprises a removable cap 116 including a sheath 117 disposed over the needle 115. The sheath 117 protects the needle and provides a substantially fluid tight seal over the tip of the needle, to prevent unwanted fluid ingress or egress.

Figure 2 illustrates the first sub-assembly of Figure 1 wherein the cap 116 has been removed from the first sub-assembly 110. In removing the cap 116, the sheath 117 has been removed from the needle 115. As can be seen in this figure, the first sub-assembly comprises a port 118 (or sleeve). In this configuration, the port 118 surrounds the needle to prevent damage to the needle or accidental contact between the needle and the user.

The port 118 is moveable in relation to the housing 111 but is coupled to the chamber 112 such that movement of the port 118 causes a corresponding movement of the

chamber 112 and the exit aperture 114, relative to the housing 111. In Figure 2, the port 118, and hence the chamber 112, are in a fully extended position.

The sub-assembly 110 comprises a biasing element 121 which acts on the port 118 to bias it away from the housing 111. In so doing, the biasing element 121 biases the exit aperture 114 of the chamber 112, which is moveable in relation to the housing 111, away from the stopper 113 which, at this point in the operation of the auto-injector (i.e. prior to activation of the auto-injector; specifically prior to advancement of the needle assembly out of the housing) is fixed in relation to the housing. As shown in Figure 2, the stopper 113 is coupled to a support rod 124 via a support block 126. The support rod is attached to the housing 111. The stopper 113 abuts the support block 126 and remains stationary with respect to the support rod 124 when the port 118 and the chamber 112 are advanced toward the proximal end 111a of the housing (described in detail below). The chamber is configured to slide over the support rod 124 and support block 126.

At its distal end 111a, the housing 111 comprising a first detent 122a. A second detent 122b, provided on the port 118, interfaces with the first detent 122a when the port 118 and the chamber 112 are in a fully extended position. The detents 122 prevent the port 118 from being extended beyond this position by action of the biasing element 121.

As shown in Figure 3, the port 118 is adapted to receive a container 119 containing a fluid, for example a pharmaceutical product. Figure 3 depicts a vial, but other containers may be used. The container 119 includes a cap 120 at one end. As illustrated, the end of the container having the cap 120 is inserted into the port 118 whilst the port is in an extended position. The port 118 is sized and shaped to accept the container 119 and hold it within the port 118 without the need for any additional locking mechanism. Of course, locking means may be provided to give better securement.

The available volume of the chamber 112 into which a fluid may be transferred depends on the distance between the stopper 113 and the exit aperture 114. In Figures 1 to 3, the available volume of the chamber 112 is substantially at its greatest. However, in this state, prior to the engagement of the container 119, the chamber 112 is empty. The

process of transferring fluid from the container 119 to the chamber 112 will be described with reference to Figures 4 and 5.

As a user inserts the container 119 into the port 118, the container is retained inside the port by a flange (not shown) provided around the inner surface of the port 118. The flange occupies a recess in the container 119, thereby securing the container within the port 118.

As the container 119 is advanced further, the port 118 and the chamber 112 are driven towards the proximal end 111a of the housing 111. As the chamber 112 is moved towards the proximal end 111a of the housing, the exit aperture 114 is moved toward the stopper 113. The available volume of the chamber 112 decreases accordingly.

Figure 4 shows the first sub-assembly 110 when the port 118 and the chamber 112 are in a fully retracted position. As illustrated, in the fully retracted position, the stopper 113 is immediately adjacent the exit aperture 114. In this configuration, the available volume of the chamber 112 is substantially at its lowest.

As the user engages the container 119 with the port 118, the injection needle 115 pierces the cap 120 and provides a fluid conduit between the container 119 and the chamber 112. The fluid conduit begins at the container 119, passes through the injection needle 115 and the exit aperture 114 and ends at the chamber 112.

In Figure 4, the fluid is contained within the container 119. As the user releases the container 119, the biasing element 121 forces the port 118 away from the housing 111 and, accordingly, forces the exit aperture 114 away from the stopper 113. The container 119 remains secured within the port 118 and engaged with the needle 115 which is moved along with the exit aperture 114. Thus, the fluid conduit is preserved.

As the exit aperture 114 moves away from the stopper 113, the available volume of the chamber 112 increases. The increase in volume of the chamber 112 causes a reduction in chamber pressure and the pressure difference between the vial and the chamber causes

fluid to be drawn from the container 119 along the fluid conduit into the chamber 112. The further the exit aperture 114 moves away from the stopper 113, the more fluid is drawn into the chamber 112.

Figure 5 illustrates the sub-assembly 110 after the biasing element 121 has forced the port 118 and the chamber 112 into the fully extended position. As before, the detents 122a,b on the housing 111 and the port 118 prevent the port 118 from being over extended. As shown, the fluid has been completely transferred from the container 119 to the chamber 112. The available volume of the chamber 112, between the stopper 113 and the exit aperture 114, is now filled with the fluid.

As it is now spent, the empty container 119 may be removed from the first sub-assembly 110 and discarded. Figure 6 illustrates the first sub-assembly 110 which has been primed (i.e. filled with the fluid) and is ready to be used.

To administer the fluid, the first sub-assembly 110 is engaged with a second sub-assembly 210. As illustrated in Figure 7, the second sub-assembly comprises a housing 211 and a drive mechanism 212. The housing has proximal 211a and distal 211b ends and a cap 213 located at the proximal end 211b. The cap includes a lip 215 which is engageable with the housing 111 of the first sub-assembly 110. A slot 214 is provided in the second sub-assembly 210.

Once the first sub-assembly 110 has been primed, the distal end 211b of the housing 211 of the second sub-assembly 210 is inserted into the proximal end 111a of the housing 111 of the first sub-assembly 110. The chamber 112 fits within the slot 214 and is coupled to the driving mechanism 212. The second sub-assembly 210 is secured to the first sub-assembly 110 by rotating the cap 213 which engages the lip 215 with the housing 111 of the first sub-assembly 110.

Figure 8 illustrates an injection device 300 which has been primed and is ready to use. Activation of a firing mechanism of the injection device 300 actuates the driving mechanism 212 which exposes the needle 115 outside of the injection device 300 to

pierce the skin of a patient and drives the stopper 113 through the chamber 112 to inject the patient with the fluid. The drive mechanism 212 subsequently retracts the needle 115 so that it is wholly within the injection device 300.

Once the fluid has been injected, the second sub-assembly 210 may be disassembled from the first sub-assembly 110 and reused. The first sub-assembly 110 may be discarded and a new first sub-assembly provided for subsequent injections, or may be sterilised for reuse.

It will be appreciated that modifications may be made to the embodiment described without departing from the scope of the invention, as defined in the appended claims.

Claims

1. An auto-injector having a first sub-assembly, the first sub-assembly comprising:

a housing;

a chamber disposed within the housing and having proximal and distal ends, an inner surface and an exit aperture;

a stopper movably disposed within the chamber and having an outer surface substantially in contact with the inner surface about its perimeter; and

a port movable in relation to the housing and coupled to the chamber such that movement of the port causes a corresponding movement of the chamber and the exit aperture, relative to the housing, the port adapted to receive a container containing a fluid and configured to bring the container into fluid engagement with the exit aperture;

wherein when the port and the chamber are moved in relation to the housing, the stopper remains stationary with respect to the housing such that movement of the port causes movement of the exit aperture in relation to the stopper.

2. The auto-injector of claim 1, wherein the port is configured to bring said container into fluid engagement with the exit aperture when the exit aperture is adjacent the stopper.

3. The auto-injector of claim 1 or claim 2, further comprising:

a biasing element coupled to the port and configured to bias the port such that the exit aperture is biased away from the stopper.

4. The auto-injector of claim 2 or claim 3, wherein engagement between the container and the exit aperture forms a fluid conduit for transferring fluid from the container to the chamber.

5. The auto-injector of any preceding claim, further comprising an injection needle in fluid communication with the exit aperture.

6. The auto-injector of claim 5, wherein the container comprises a cap, and wherein the injection needle is configured to pierce the cap to form a fluid conduit for transferring fluid from the container to the chamber.

7. The auto-injector of any preceding claim, further comprising a second sub-assembly, the second sub-assembly comprising:

a releasable drive mechanism configured to be driven against the stopper upon activation of the drive mechanism.

8. The auto-injector of claim 7, when dependent on claim 5 or claim 6, wherein the releasable drive mechanism is, upon activation, adapted to:

(a) move the chamber and the injection needle from a retracted position in which the needle is wholly inside the housing to an extended position in which the needle is at least partially outside the housing; and

(b) subsequently move the stopper within the chamber toward the exit aperture to expel fluid out of the injection needle.

9. The auto-injector of claim 8, further comprising a retraction mechanism adapted to retract the injection needle into the housing after the fluid has been expelled.

10. The auto-injector of any one of claims 7 to 9, wherein:

the first sub-assembly is detachable from the second sub-assembly; and

the second sub-assembly is reusable.

11. A method of priming an auto-injector having a first sub-assembly comprising housing, the method comprising the steps of:

inserting a container into a port on the injection device, the port being moveable with respect to the housing, first sub-assembly comprising a chamber having an exit aperture and a stopper movably disposed within the chamber, the port being configured to bring the container into fluid engagement with the exit aperture, the chamber being coupled to the port such that movement of the port causes a corresponding movement of the chamber and the exit aperture, relative to the housing, wherein when the port and the chamber are moved in relation to the housing, the stopper remains stationary with

respect to the housing such that movement of the port causes movement of the exit aperture relative to the stopper;

moving the port into the housing; and

moving the port out of the housing such that fluid is drawn into the chamber from the container.