A needle-less injector system having an ampule with an elongated hollow body. The elongated hollow body includes a nozzle and an aperture for receiving a plunger. The aperture extends from the second end of the body towards the first end and is in fluid communication with the nozzle. The ampule cooperates with a plunger that has a concave rib that extends about the perimeter of the plunger and towards the first end of the plunger. As the plunger moves through the aperture the concave rib sealingly engages the sidewalls of the aperture.
NEEDLELESS INJECTOR AND AMPULE SYSTEM

RELATED APPLICATION


BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to a system for the subcutaneous delivery of medicaments, and more particularly to a handheld actuator, and a plunger and ampule or vial used to deliver a stream of medication.

[0004] 2. Description of Related Art

[0005] The need for a needle-less injection device that can be used to deliver a fine, high-pressure stream of medication through the skin has been recognized for some time. However, the problems associated with creating high-pressure streams, particularly within a self-contained, handheld device, has proven to be a greater challenge than expected. The typical approach at creating these streams has been to use a piston that is driven by a CO2 cartridge, compressed air, or a spring. The piston is then used to drive the medicament from a reservoir through a small nozzle that is used to create the fine stream that is to penetrate the skin. The size and energy of the stream allows the stream to penetrate the skin to a depth where it can then be absorbed by the body.

[0006] One important problem is that in order to create such a stream it is difficult to produce a nozzle that provides a tight, uniform stream, and not a spray of the medicament.

[0007] Another important problem associated with the design of a needle-less injection system involves the efficient delivery of the dose of medicament held within the reservoir. In other words, it is important that the system does not allow medicament to escape between the piston and the reservoir or cylinder through which the medicament is being delivered. The problem of loss of medicament is typically caused by the escape of medicament under the pressure required to adequately deliver the medicament through the nozzle.

[0008] Still another important problem associated with needle-less injection devices, and particularly with handheld devices of this type, is the provision of sufficient power to create and deliver a stream with sufficient energy so that the stream can penetrate the body to a depth where the medicament can be absorbed.

[0009] Yet another problem associated with needle-less devices is maintenance of a required amount of pressure during the delivery of the medicament from the reservoir, through the nozzle.

SUMMARY OF THE INVENTION

[0010] One object of the present invention is to provide a needleless injection device that delivers a fine, high pressure stream of medicament through a surface.

[0011] Another object of the present invention is to provide a needleless injection system that delivers the medicament without any loss of quantity thereof.

[0012] In accomplishing these and other objects of the present invention, there is provided a needleless injection device including an ampule. The ampule includes an elongated hollow body, the elongated hollow body having a first end and a second end. The first end of the hollow body includes a nozzle, and the second end of the hollow body including an aperture for accepting a plunger. The aperture extends from the second end towards the first end and is in fluid communication with the nozzle. The generally cylindrical plunger, includes a first end and a second end. The plunger also includes a concave rib extending about the perimeter of the plunger and extending towards the first end.

[0013] According to one example of the invention, the body of the plunger is centered about an axis and the first end of the plunger includes a generally conical end that is centered about the axis. Additionally, the conical end will extend from the concave portion of the concave rib. Still further, it is contemplated that the plunger will include a second rib, the second rib being between the concave rib and the second end of the plunger.

[0014] The plunger is received by the aperture in the ampule, with the concave rib sealingly engaging the sidewalls of the aperture in the body of the ampule. The second rib will also cooperate with the sidewalls of the aperture of the ampule and may provide some sealing function, but will primarily serve to stabilize or align the plunger as it is forced through the ampule.

[0015] The ampule connects to an actuator that will provide the power to push the plunger through the ampule and drive the medicament from the ampule through the nozzle. In an illustrated example of the actuator, the actuator includes a casing that holds a spring that is used to drive a rod. The rod in-turn pushes against the plunger, which then pushes the medicament through the ampule.

[0016] The release of the spring in the actuator is accomplished by providing a hammer that includes a forward end that is adapted for cooperating with the rod and the trigger mechanism, and an aft end that is adapted for cooperating with the spring. The trigger mechanism is used to retain the spring in a loaded or compressed position, and then release the spring to drive the plunger through the ampule.

[0017] These and other objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description of the preferred embodiment relative to the accompanied drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] FIG. 1 is a cross-sectional plan view of the system of the present invention in a cocked position.

[0019] FIG. 2 is a cross-sectional view of the system of the present invention in a fired position.

[0020] FIG. 3 is a partial cross-sectional view of the device of the present invention illustrating the cooperation of the hammer, push-rod, vial or ampule, and seal.

[0021] FIG. 4 is an enlarged cross-sectional view of the components of FIG. 3.
FIG. 5 is an enlarged cross-sectional view of the seal or plunger of the device of the present invention as it is driven through the vial or ampule.

FIG. 6 is a cross-sectional view illustrating the cooperation of the plunger and ampule of the present invention at the end of the stroke or delivery cycle.

FIG. 7 is a side view of the hammer of the device of the present invention mounted between the spring and the push-rod.

FIG. 8 is an end view of the hammer of FIG. 7.

FIG. 9 is a cross-sectional view taken along line 9-9 of FIG. 7.

FIG. 10 is an end view of an embodiment of the plunger of the device of the present invention.

FIG. 11 is a cross-sectional view of the plunger.

FIG. 12 is a perspective view of the plunger of the device of the present invention.

FIG. 13 is a cross-sectional view of the vial or ampule of the device of the present invention.

FIG. 14 is an end view of the vial or ampule of the device of the present invention.

DETAILS DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG. 1, a needle-less injection system 10 is shown in a cocked position with the cover of the actuator removed along with sections of the internal sleeve, so that the internal components may be observed. It should be understood that it is contemplated that the system of the present invention may be used with a hand held actuator 12 or other actuator, for example, using a pneumatic piston or combustion driven piston. Actuator 12 includes a hammer 14 that slides along a sleeve 16. The hammer 14 is powered by a spring 18 that is held within the sleeve 16. The power or driving force provided by the spring 18 may be fixed by creating a device that will allow the spring 18 to be compressed a set distance or by providing a spring compression adjustment mechanism 20, such as a threaded plug 22 that is mounted on an end of the sleeve 16.

As shown in FIGS. 1 and 2, energy is stored in the spring 18 by compressing the spring 18 to the "cocked position" illustrated in FIG. 1. This energy is then released to the hammer 14, which drives a rod 24 that extends between the hammer 14 and a plunger 26. The plunger 26 fits into and seals an aperture 28 in an ampule 30. The ampule 30 is attached to the actuator 12 by way of a bayonet connector 32 (FIG. 6), or a threaded or any other suitable connector.

Referring to FIGS. 2-6, it will be understood that the disclosed system will deliver medicament through the skin by creating a very thin, high energy or velocity, jet of medicament 34 through the ampule 30. The jet of medicament 34 is produced by driving the plunger 26 through the aperture 28 or open end 48 to pressurize the fluid medicament 36 in the ampule 30, which pushes the medicament 36 through a nozzle 38 located on second end 50 of the ampule 30.

It should be appreciated that the ampule 30 will be made from a readily moldable material, such as a pharmaceutical grade polypropylene material that is suitable for injection molding or any other polymer that is suitable for injection molding. An important drawback to the use of polymers as the material for the ampule 30 is that the mechanical properties of these materials allow the materials to deflect under the pressures needed for creating the jet of medicament 34 through the nozzle 38. Additionally, fabrication of the ampule 30 from stiffer materials results in a device that is too brittle or a device that cannot be manufactured through the use of high production rate methods, such as injection molding. Therefore, the machining of the ampules from stainless steel would be a prohibitively expensive approach at manufacturing the device. Furthermore, an opaque material will not allow the user of the device to ascertain whether the plunger 26 has traveled through the desired length of the ampule 30, and delivered the adequate dosage of medicament.

FIGS. 3-6 illustrate the entire travel of the plunger 26 as driven by the spring 18 and hammer 14. Importantly, FIGS. 4 and 5 illustrate the deflection of the sidewalls of the vial or ampule while the plunger or seal is driven towards the nozzle to force the medicament from the ampule. The deflection 42 of the ampule 30 that has been produced by the pressurization of the ampule 30 during travel of the plunger 26 through the ampule 30 is shown by dashed line. In known devices, this deflection 42 causes a loss of pressure in the ampule 30, which results in an inadequate transfer of energy to the jet of medicament 34. However, plunger 26 of the present invention includes a concave rib 44 that is designed to open towards the nozzle 38. The concave rib 44 should be made of a flexible, yet strong material, such as polypropylene, rubber or other polymer. As shown in FIG. 5, the plunger deflects to compensate for the dimensional changes in the ampule.

In operation, as illustrated in FIGS. 3-6, the plunger 26 is driven through the aperture 28 by the force of the spring 18 pushing against the hammer 14. As the plunger 26 is driven through the elongated hollow body 46 of the ampule 30, the plunger 26 pushes the medicament 36 from the ampule 30 and through the nozzle 38. The elongated hollow body 46 of the ampule 30 include a first end 40 and a second end 50. Thus, the plunger 26 is pushed through the aperture 28, from the first end 40 towards the second end 50 of the ampule 30. The pressure within the aperture 28 of the ampule 30 increase as the plunger 26 is pressed against the medicament 36, causing the deflection 42 of the ampule 30. In order to maintain the pressure, and hence the required energy transfer to produce the jet of medicament 34, the concave rib 44 also expands under the pressure, as indicated by the arrows 52 in FIG. 5. The expansion or flaring out of the concave rib 44 takes up or seals any fluid passages or bypasses that may be otherwise formed due to the expansion of the ampule 30.

Thus, from the accompanying illustrations, it will be understood that the plunger 26 extends about an axis 54 and may also include a first end 56 (FIG. 11) that terminates in a generally conical surface 58. Additionally, the plunger 26 includes a second end 60 and a mid-section 61, located between the first end 56 and the second end 60. Plunger 26 also includes an external surface 62 that may be cylindrical or of any other suitable cross-section. The concave rib 44
extends about the axis 54, and expands towards the first end 56 of the plunger 26. In the illustrated example, the concave rib 44 extends over the conical surface 58 of the plunger and towards the first end 56 of the plunger 26. Still further, in the illustrated example, the concave rib 44 extends over a portion of the conical surface 58. The conical surface 58 cooperates with the nozzle 38 to push any remaining medications from ampule 30.

[0039] Referring to FIGS. 10-12, it will be understood that plunger 26 may also include a second rib 64. The second rib 64 is positioned between the concave rib 44 and the second end 60 of the plunger 26. The second rib 64 cooperates with the concave rib 44 to stabilize the plunger 26 as it is driven through the ampule 30. The design of the concave rib 44 has been illustrated as being approximately conical in shape. This conical shape provides flexibility that allows the second rib 64 to accommodate the shape of the sidewalls 66 of the aperture 28. However, it is contemplated that the shape or cross-section of the second rib 64 may be one of many different shapes, and may not act as a seal, meaning that the rib is not continuous about the exterior surface of the body of the plunger 26.

[0040] FIGS. 13 and 14 provide greater detail of the ampule 30, and illustrate that it is contemplated that the nozzle 38 can be located within a raised annular portion 68, which in turn is located within a recessed annular portion 70. The recessed annular portion 70 cooperates with the raised annular portion 68 to pull the skin tight, and retain this tightness, around the nozzle opening 72, so that the nozzle opening 72 is at a distance from the skin and the skin that is to be injected is pulled taut so as to avoid energy losses in the jet of medication as the jet of medication impacts the skin. In other words, by pulling the skin taut, one minimizes energy losses due to deflection of the skin. Still further, the bayonet connectors 32 are clearly visible from these figures, together with radially positioned stiffeners 74.

[0041] Although the present invention has been described in relation to particular embodiments thereof, many other variations and other uses will become apparent to those skilled in the art. It is preferred therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

1-15. (canceled)

16. A needleless injector system for holding a fluid and delivering a stream of fluid through an area, the system comprising:

a plunger extending about an axis and having opposed first and second ends and an external surface, said plunger including at least one concave rib extending about the axis, wherein said at least one concave rib has an outer diameter extending away from and greater than an outer diameter of the external surface; and

an ampule including an elongated hollow body having a first and second end, the first end of the elongated hollow body including a nozzle, and the second end of the hollow body including an aperture for receiving the plunger, said aperture being in fluid communication with the nozzle, wherein the outer diameter of said at least one concave rib sealingly engages the hollow body to expand and seal the aperture in response to a deflection in the hollow body, wherein deflections in the hollow body caused by a pressure force created as the fluid is driven from the hollow body by the plunger is sealed by the at least one concave rib.

17. The system of claim 16, wherein said plunger includes a second rib, the second rib being disposed at the second end of the plunger.

18. The system of claim 16, wherein said first end of said plunger has a conical shape.

19. The system of claim 18, wherein said plunger includes a second rib, the second rib being located at the second end of plunger.

20. The system of claim 16, wherein the ampule is made from a polypropylene material.

21. A needleless injector system for holding a fluid and delivering a stream of fluid through an area, the system comprising:

a plunger having opposed first and second ends and an external surface, said plunger including at least one concave rib extending from the external surface of the plunger, said at least one concave rib having an outer diameter extending away from and greater than an outer diameter of the external surface; and

an ampule having an elongated hollow body for receiving the fluid, the hollow body having first and second opposed ends, the first end of the elongated hollow body including a nozzle, the second end of the hollow body being open to receive the plunger, wherein the outer diameter of said at least one concave rib sealingly engages an inner diameter of the hollow body to form a sealing fit therewith to expand and seal the hollow body in response to deflections in the hollow body caused by a pressure force created as the fluid is driven from the hollow body by the plunger.

22. The system of claim 21, wherein said plunger includes a second rib disposed at the second end of the plunger.

23. The system of claim 21, wherein said concave rib is approximately conical in shape.

24. The system of claim 23, wherein said plunger includes a second rib extending from said external surface, said second rib having a generally conical shape and being located at the second end of the plunger.

25. The system of claim 21, wherein the ampule is made of a polypropylene material.

26. The system of claim 21, wherein the plunger is made of a polypropylene material.

27. A method for preventing pressure losses in a needleless injector system while delivering a stream of fluid, the method comprising the steps of:

providing a plunger, the plunger having opposed first and second ends and an external surface, said plunger including at least one concave rib having an outer diameter that extends away from and is greater than an outer diameter of the external surface; and

providing an ampule, the ampule having an elongated hollow body, the hollow body having a first end and a second end, the first end of the elongated hollow body including a nozzle, the second end of the hollow body being open to receive the plunger, wherein the outer diameter of said at least one concave rib sealingly engages an inner diameter of the hollow body to form a sealing fit therewith;
supplying the ampule with fluid and placing the plunger into the hollow body so that the fluid is held between the plunger and the nozzle; and

compressing the fluid by moving the plunger towards the nozzle, wherein the at least one concave rib expands against the inner diameter of hollow body to seal the hollow body in response to deflections in the hollow body caused by a pressure force created as the fluid is driven from the hollow body by the plunger.

28. The method of claim 27, further comprising the step of forming the plunger form a polypropylene material.

29. The method of claim 27, further comprising the step of forming the ampule from a polypropylene material.

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