DISPOSABLE NEEDLELESS INJECTOR

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References Cited

UNITED STATES PATENTS
2,559,091 7/1951 Reasenberg 141/19
2,645,223 7/1953 Lawshe et al. 128/173 H

ABSTRACT

A needleless hypodermic injector including a medicament containing ampule, a container of pressurized gas and a connection operatively coupling the gas to the ampule to pressurize the medicament for discharge. The ampule includes at least one rigid end wall which is provided with an opening therein which serves as a discharge orifice through which the pressurized medicament is discharged in the form of a high pressure injection stream. The opposite end of the ampule is configured to permit the medicament to be rapidly pressurized by the gas.

11 Claims, 3 Drawing Figures
DISPOSABLE NEEDLELESS INJECTOR

The present application is a continuation-in-part application of parent application U.S. Ser. No. 186,653, filed Oct. 5, 1971 and now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to hypodermic injection devices and more particularly to a needleless hypodermic injector of the type wherein medicament is expelled from an ampule through an orifice at a high velocity under pressure from a gas.

2. Description of the Prior Art

As evidenced by the U.S. Pat. Nos. to Smoot 2,547,099; Lawshe et al. 2,645,223; Morando 3,115,133; and Clark 3,527,212, the concept of needleless hypodermic injection has been known for many years. However, because of certain problems heretofore unsolved by the prior art, full implementation of this injection technique has not been accomplished. For example, some prior art needleless injectors require that the same discharge orifice be repeatedly used, in which case the orifice is subject to contamination and/or clogging. In those devices wherein the component including the discharge orifice is disposable, the complexity of the orifice forming structure is such as to make that component unduly expensive. In those prior art devices which utilize an elongated cannula to form the discharge orifice, a pressure drop occurs over the length of the cannula sufficient to limit the discharge velocity of the liquid and thus severely limit the depth of penetration. Another disadvantage common in many of the prior art devices is that the means of coupling the medicament containing ampule and the pressurizing source includes a relatively large initially unpressurized volume which, during the initial pressurization period, causes a substantial amount of liquid to be discharged at low pressure before the coupling volume is raised to the required high pressure.

SUMMARY OF THE PRESENT INVENTION

It is therefore an object of the present invention to provide a needleless injection device which is efficient, simple in structure, inexpensive and disposable.

Another object of the present invention is to provide a disposable medicament ampule for use in a needleless injection which has a discharge orifice that is not subject to a substantial loss of liquid pressure over its effective flow length.

Briefly, the present invention relates to a needleless hypodermic injector including, a medicament containing ampule, a container of pressurized gas, and a means for operatively coupling the pressurized gas to the ampule in such a manner that the medicament is discharged from the ampule in a high pressure stream. The ampule forms a medicament container having at least one rigid end wall which is provided with an opening therethrough that is of extremely small diameter and flow length. This opening serves as the discharge orifice through which the medicament is forced to provide the high pressure injection stream. The opposite end of the ampule is configured so as to sealingly close the ampule, yet permit the fluid contained therein to be rapidly pressurized.

An important advantage of the present invention is that due to its mechanical simplicity, the injector may be made so inexpensively as to be entirely disposable. Alternatively, the support structure for the ampule and gas container may be retained for subsequent use with replacements for the expended ampule and/or gas container.

Another advantage of the present invention is that since the discharge orifice forms a part of the disposable ampule, there is no need to clean the injector between successive injections.

Another advantage of the present invention is simple and effective closure of the pressurizing orifice of the medicament which also performs the function of a high pressure seal when the high pressure gas is applied to the medicant chamber.

Still another advantage of the present invention is that the extremely short orifice flow length imposes very little pressure loss in the fluid passing there-through and therefore enables the high pressure injection stream to be developed using a lower gas pressure than has heretofore been possible.

Other objects and advantages of the present invention will no doubt become apparent to those of ordinary skill in the art after having read the following detailed description of certain preferred embodiments which are illustrated in the several figures of the drawing.

IN THE DRAWING

FIG. 1 is a schematic diagram showing a longitudinal section taken through a needleless injection device in accordance with the present invention.

FIG. 2 is a schematic diagram showing a longitudinal section taken through the embodiment illustrated in FIG. 1 during the injection operation.

FIG. 3 is a schematic diagram showing a longitudinal section taken through an alternative embodiment of the needleless injection device of this invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to Figs. 1 and 2 of the drawing, a simplified embodiment of a needleless injector is illustrated in the loaded configuration (FIG. 1), and in the injection configuration (FIG. 2). The hypodermic device 10 includes a generally cylindrical shaped body 12 having laterally extending fingerpiece hooks 14 affixed to the sides thereof, an ampule 16 contained within one portion of the body 12, a container 18 of high pressure gas disposed within another portion of body 12, and a cap 20 which is telescopically received over the end 22 of body 12. Although as illustrated, cap 20 is intended to telescopically slide over the outer surface of body 12, it will be appreciated that end 22 and cap 20 could be threaded so that cap 20 could be advanced onto body 12 by rotation, rather than by the application of a compressive force F as indicated in FIG. 2. With cap 20 removed, device 10 is loaded by first inserting ampule 16 into body 12, and then inserting container 18 therebehind. Cap 20 is then replaced over end 22, and device 10 is fully loaded and ready to provide an injection.

Ampule 16, in this embodiment, includes a rigid outer casing 24, preferably of stainless steel or some other suitable material which is inert with respect to the medicament 26 contained therein. At the discharge end of ampule 16, a discharge orifice or opening 28 is provided. At the opposite or charge end of ampule 16,
a cannula 32 is affixed having a sharply pointed end 34 for puncturingly engaging a weakened plug 44, or soft material portion of container 18, and hence providing a flow passage 36 through which the high-pressure gases from container 18 may enter ampule 16 to pressurize the liquid medicament contained therein.

In a preferred embodiment discharge orifice 28 is formed by a bore dimensioned to provide subcutaneous-intramuscular injection for a particular medicament at a particular pressure. Tests conducted have shown that an opening having a diameter of approximately 0.008 inches provides good results as long as the length of the opening is maintained sufficiently short to prevent too great a pressure drop therealong and thereby lowers the pressure of the pressurized medicament to a value at which needless injection becomes ineffective. Tests have also shown that a length of less than about 0.024 inches is eminently suitable and that the effectiveness of the needleless injection increases with decrease in the bore length because of the greater retained pressure of the medicament. The term “dimensioned for needleless injection,” as used in the appended claims in connection with the discharge orifice 28, means a bore having a diameter and a length combination which provides an acceptable subcutaneous-intramuscular injection of the particular medicament contained in capsule 16 when pressurized by the gas in container 18.

It has also been found that satisfactory subcutaneous-intramuscular injection can be had with a somewhat different combination between opening diameter and opening length. The larger the opening diameter, the longer may be the opening length without suffering an unacceptably large pressure drop. The term “dimensioned for lack of medicament leakage” as used in the appended claims in connection with the discharge orifice 28, means a bore which is dimensioned for needleless injection, as this term has been defined above, and in which the diameter is further selected sufficiently small to prevent normal medicament leakage through the bore when the medicament is not pressurized. A bore diameter of 0.008 inches for a medicament having an average viscosity has been found to meet this criterion.

Selection of gas pressure for pressurizing the medicament depends on the desired depth of the subcutaneous-intramuscular injection. For example, medicaments pressurized to 800–1100 psi usually provide intradermal penetration and medicaments pressurized to 1,700 psi or above usually provide intramuscular penetration. Medicants pressurized between 1,100 and 1,700 psi provide subcutaneous penetration.

Because of the extremely small size of orifice 28 no seal is normally required to prevent leakage of the medicament therethrough within the usual range of medicaments. However, when the injection of liquid of extremely low viscosity is to be contained within ampule 16, it may be advisable to provide a thin plastic or wax coating over the end 30 to prevent leakage, such coating being easily pierced by the liquid medicament as it is pressurized during the injection operation.

To prevent leakage of the medicament through cannula 32, a cap 48 is provided which caps the cannula. Cap 48 may be simply a cylindrical plug made out of rubber or some other resilient material which allows itself to be impaled upon the sharp tip of the cannula to plug the cannular passage 36 and provides an efficacious seal. It should also be noted that cap 48 also provides a high pressure seal between the outer shoulder of cartridge 18 facing the cannula and ampule 16 as the pressurized cartridge is moved against the ampule for pressurizing the medicament.

In operation, the device is held in one hand with two fingers hooked about the fingerhoods 14. As cap 20 is squeezed into the heel of the hand, cap 20 moves telescopically over end 22 of body 12, thereby moving container 18 leftwardly into engagement with cannula 32. As cannula 32 pierces the weakened plug 44 and extends into container 18, the high-pressure gases rushing through passageway 36 to begin the initial pressurization of fluid 26. The pressure causes the liquid 26 at the right-most end of ampule 16 to be forced with the result being that liquid 26 is more or less uniformly pressurized and moved in a column, as indicated at 46 in FIG. 2, for discharge through opening 28. Cap 48, moved inwardly along the cannula by the shoulder of container 18 also provides a seal for preventing excess leakage of gases around cannula 32.

Once the injection is complete, the entire device may be disposed of, or ampule 16 and container 18 may be removed from body 12 and replaced with fully charged elements so that the body 12 and cap 20 can be reused. Since the forces exerted on body 12 are of relatively small magnitude, it is contemplated that by using inexpensive plastic or nylon materials, the entire hypodermic device may be economically made disposable.

Turning now to FIG. 3 of the drawing, an alternative embodiment of a needleless hypodermic injector is illustrated at 130. This embodiment includes a medicament containing unit 132, a high pressure gas source 134, and a valve body 136 for selectively coupling unit 132 to source 134. Ampule 132 may be configured in a manner similar to the previously described ampules, except that in this embodiment it has threads to facilitate its attachment to valve body 136.

Valve body 136 is configured to include a threaded coupling 152 for mating with the threaded end of unit 132, a threaded coupling 154 for mating with the threaded discharge end 156 of gas source 134, an opening 158 for receiving the initially capped cannula of ampule 132 in which cap 48 is pushed inwardly to provide a seal against unit 130, a cannula 160 for piercing the discharge end 162 of gas source 134, and a rotatable valve member 166 having a passage 168 extending more or less transversely therethrough. A handle 169 is affixed to one end of member 166.

Note that passage 168 is enlarged at the end 170 so that as member 166 is rotated clockwise from the loading position to the injection position, the end 170 of passage 166 communicates with source 134 slightly before the end 172 communicates with opening 158. This allows the transiitional pressurization of passage 168 to occur before ampule 132 is subjected to pressurization, Thus, the slow pressurization disadvantages of the prior art mentioned above are circumvented.

In operation, with source 134 screwed into the operative position illustrated in FIG. 3, the medicament containing unit 132 is screwed into place as indicated. End 144 is then pressed against the surface to be injected and handle 167 is rotated clockwise into the injection position illustrated in FIG. 3 and left in that position until all of the medicament is discharged from the ampule 132. When the injection is completed, actuator
3,853,125

168 is rotated counterclockwise back into the loading position. Even though source 134 may only contain sufficient pressurizing gas for one injection, it is to be understood that a larger source can likewise be utilized together with a valve which provides a measured amount of pressurizing gas to the medicament chamber. In this manner, several disposable ampules 132 may be used with a single pressurization source. It is to be noted that in each of the above described embodiments, the discharge orifice forms a part of the disposable component, thus obviating one of the most troublesome problems associated with the prior art devices; namely that of cleaning and maintaining the discharge orifice clear of obstruction. Furthermore, since the discharge orifice is formed in a thin wall of the disposable ampule, its length can be made much shorter than would be possible in the case of a device having a re-useable orifice, and thus the pressure drop suffered by the liquid in passing through the discharge orifice is kept to a minimal loss. Note also that in the case of each of the above disclosed embodiments, the initially unpressurized volume coupling the gas source to the ampule is held to an absolute minimum so that maximum pressurization of the ampule is obtained almost instantaneously, thereby insuring that a full dosage of medicament is injected.

Whereas the invention has been described above in terms of several simplified preferred embodiments, it is to be understood that the disclosure is intended to be illustrative only, and is in no way to be taken as limiting. Accordingly, it is intended that the claims be interpreted as covering all modifications of the invention which fall within the true spirit and scope of the invention.

What is claimed is:

1. A needleless hypodermic injector, comprising: an ampule filled with a liquid medicant to be injected and including, a pressurizing end portion for receiving a charge of pressurizing gas, and a rigid discharge end portion for placing directly into contact with the skin where the injection is to be made which has a substantially uniform diameter bore extending therethrough which is dimensioned for needleless injection; a container of pressurized gas; and means for pressurizing said medicant directly with a charge of said pressurizing gas to form a medicant-gas mixture which is expelled through said bore for needleless injection.

2. A needleless hypodermic injector in accordance with claim 1 in which said container of pressurized gas includes a puncturable membrane and said pressurizing end portion of said ampule includes a puncturing means for puncturing said membrane.

3. A needleless hypodermic injector in accordance with claim 2 which further includes a resilient capping means disposed upon said puncturing means for sealing the pressurizing end portion of said ampule.

4. A needleless hypodermic injector in accordance with claim 3 in which said capping means is configured for engagement by the area of said container immediately surrounding the opening generated upon puncture of said membrane by said puncturing means, said capping means including a puncturable end portion for puncturing by said puncturing means.

5. A needleless hypodermic injector in accordance with claim 4 in which said capping means is slidable along said puncturing means and forms a sealing contact between said ampule and container during pressurization of said medicant.

6. A needleless hypodermic injector as recited in claim 1 which further includes an elongated casing forming a chamber having openings at both ends, said ampule being disposed within said chamber with said discharge end portion extending through one of said openings, and said container being slidably disposed within said chamber opposite said pressurizing end portion, and said means for pressurizing said medicant having a cannula affixed to said pressurizing end portion for puncturing said container.

7. A needleless hypodermic injector in accordance with claim 6 further including a casing cap slidingly disposed over the other of said openings of said casing and in contact with said container.

8. A needleless hypodermic injector in accordance with claim 7 further including finger hold means integral connected to said casing whereby squeezing the casing cap with the heel of the hand against said casing with fingers engaging said finger hold means pressurizes said medicant.

9. A needleless hypodermic injector as recited in claim 1 in which said means for pressurizing includes a valve having a valve element movable between an open and a closed position.

10. A needleless hypodermic injector in accordance with claim 6 which further includes a capping means engaging the tip of said cannula for sealing the pressurizing end portion of said ampule.

11. A needleless hypodermic injector in accordance with claim 10 in which said capping means is configured for sliding engagement along the outer surface of said cannula and includes a puncturable end portion for puncturing by the tip of said cannula when said container is moved towards said ampule for pressurizing said medicant.

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