

### [54] HYPODERMIC DEVICES

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[58] Field of Search .....128/215, 216, 218 R,  
128/218 D, 218 DA, 218 N, 218 F, 220, 272

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Primary Examiner—Richard A. Gaudet

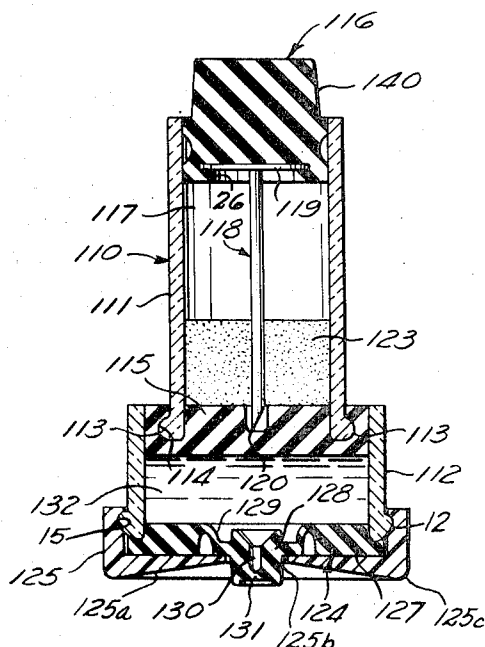
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### [57] ABSTRACT

Hypodermic ampoules of the contained-needle type, a method of assembling and filing such ampoules, and combinations of such ampoules with so-called "applicators" for actuating the ampoules to make injections are disclosed. Each of several ampoule forms has a plurality of cylindrical, medicament-containing chambers and a plunger closing one end of one of the chambers. A hollow needle is fixed to the plunger and is initially contained within such a chamber. The other end of the ampoule is sealed by a diaphragm which is pressed against a beaded end portion of a cylinder and is sealed thereto by a cup-shaped clip which snaps over the beaded end portion to thereby compress the diaphragm against the end portion. The clip has a peripheral rim about a recessed bottom end which stretches the patient's skin to facilitate the injection. According to the invention, the ampoule includes multiple chambers for premixing a medicament with at least one other medicament and dispensing the mixture by, for example, injecting it either subcutaneously or intramuscularly.

5 Claims, 14 Drawing Figures



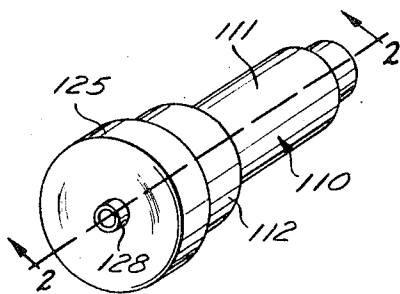


Fig. 1

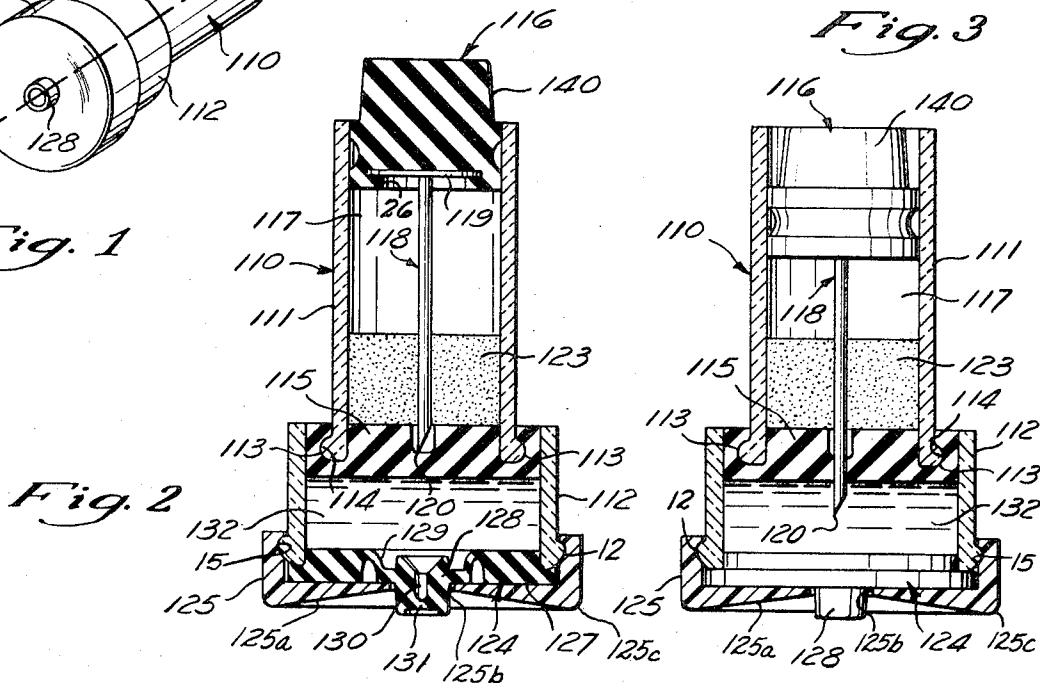


Fig. 2

Fig. 3

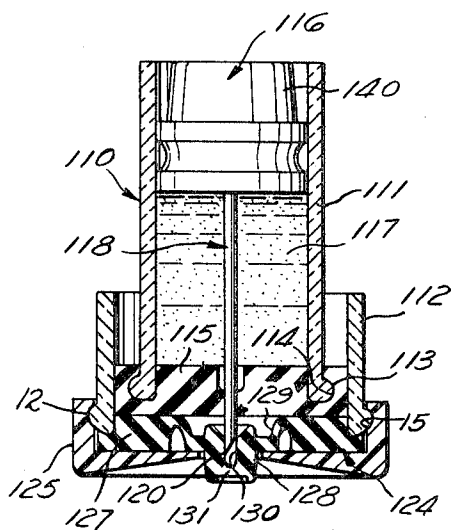


Fig. 4

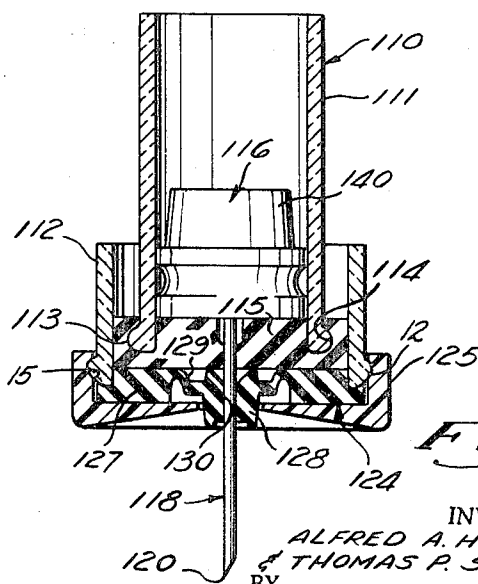
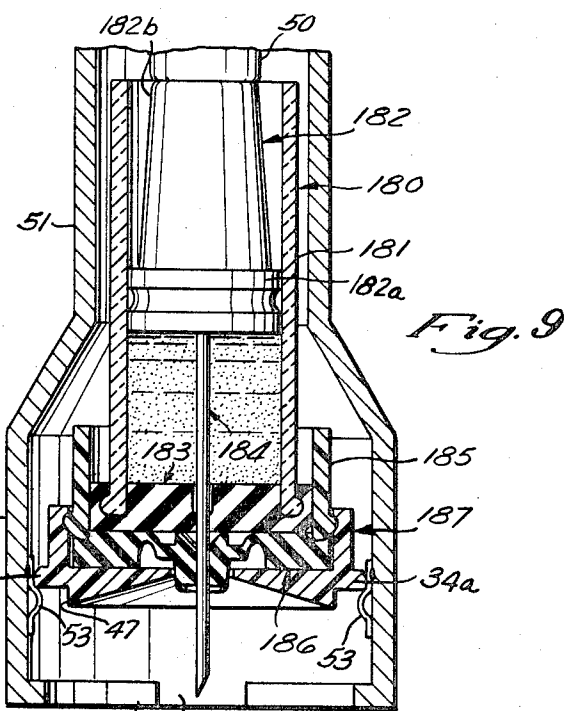
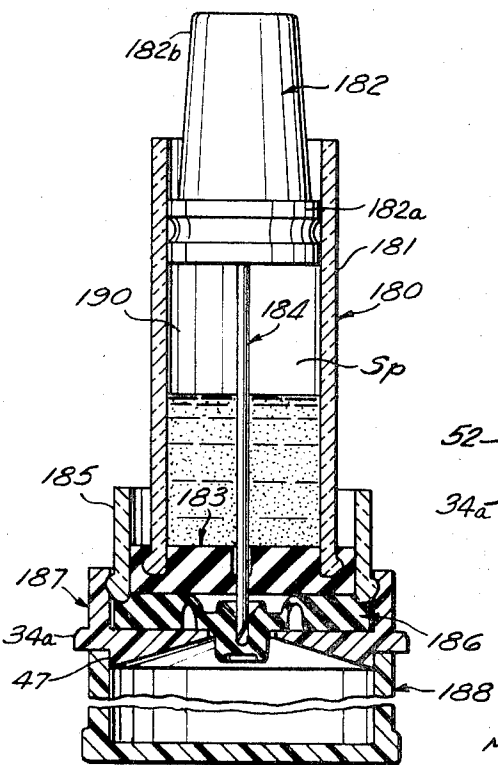
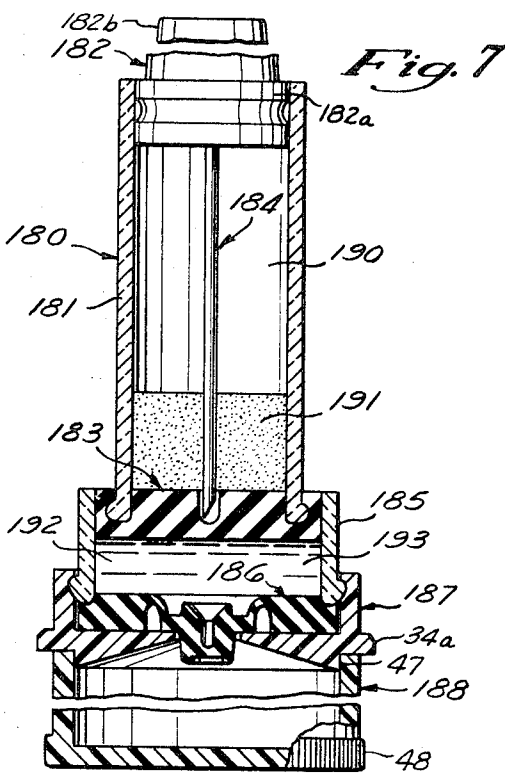
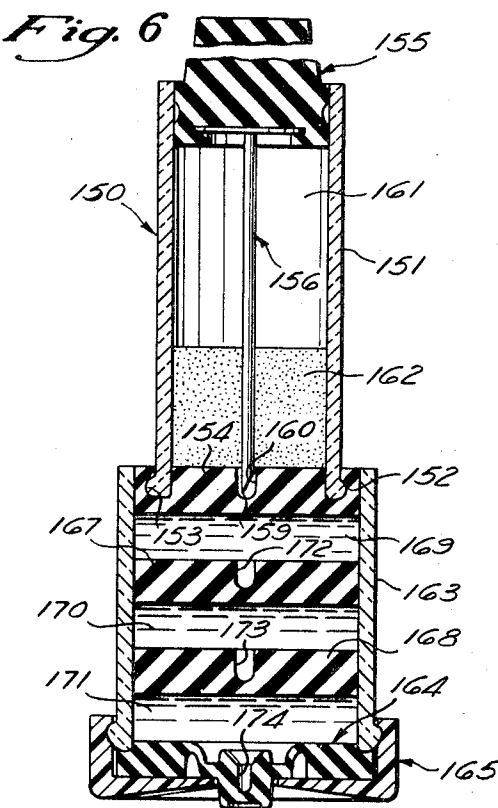


Fig. 5

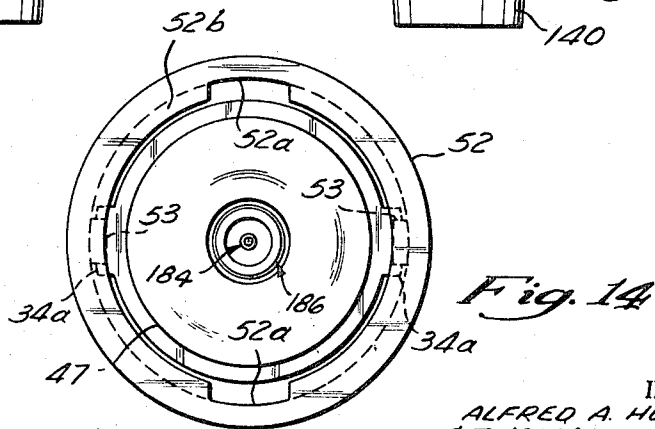
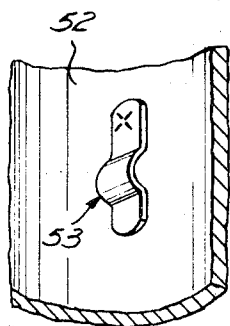
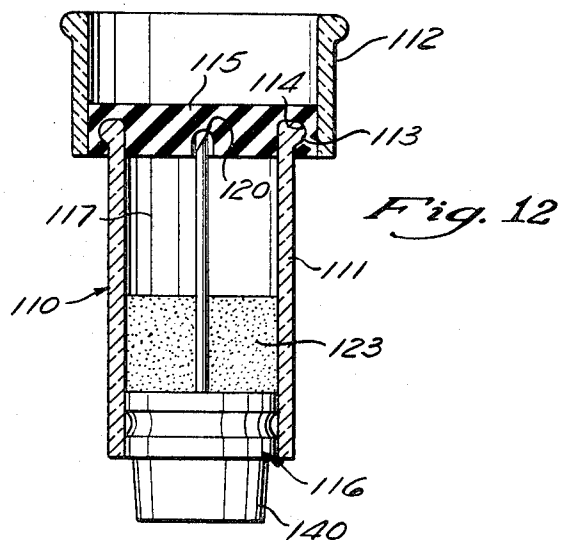
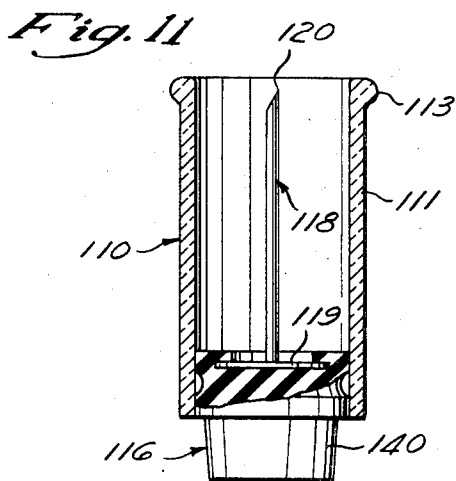
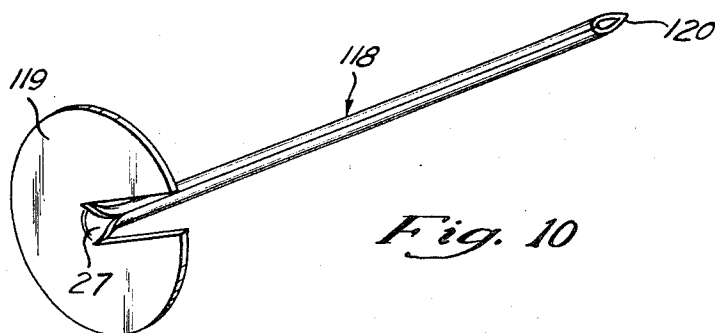
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## HYPODERMIC DEVICES

## BACKGROUND OF THE INVENTION

This invention relates to disposable hypodermic ampoules that provide a chamber containing both a medicament to be injected and the hypodermic needle through which the injection is made, the injection being performed by collapsing or otherwise actuating the device to project the pointed end of the needle through a puncturable wall of the ampoule and then into the patient while reducing the volume of the medicament-containing chamber to express the medicament through the needle and into the patient. Such ampoules are referred to herein by the generic designation, "contained-needle type."

A number of drug compounds, including some antibiotics, some vaccines, and several other injectable products, require that an active ingredient (usually in a powder form) be mixed with an injection vehicle (usually water) shortly before administration. One widely accepted procedure for mixing powder and liquid medicament components is to provide them in separate vials, each having its own rubber stopper closing its outlet opening. The liquid is withdrawn from its vial by a needle and syringe and is then injected into the vial containing the powder. The thus mixed liquid and powder in the latter vial, after shaking it where required, are withdrawn as a dispersion by the same needle and syringe, and the injection is effected therewith in a conventional manner.

Attempts have been made to provide a multicompartiment vial wherein liquid and solid components to be mixed prior to injection are separately contained in a manner that permits mixing them within the common vial. For example, U.S. Pat. No. 2,495,942 to W. A. Nosek provides an outer container having an inner container mounted therein. The outer container contains a liquid medicament and the inner container contains a solid medicament. The inner container is releasably sealed to a stopper which closes both containers. By depressing the stopper, the inner container is released so that its solid contents may mix with the liquid. The mixture is then withdrawn by piercing the stopper with the needle of a hypodermic syringe. Such an arrangement, however, is not readily applicable to the contained-needle type of hypodermic ampoules to which the present invention relates, apart from other objections thereto.

Another proposal for providing a multichamber container is set forth in U.S. Pat. No. 3,342,180 to Sandhage et al., dated Sept. 19, 1967. In that patent, the patentees provide a vial which is separated into two chambers by a plunger. Power is provided in a lower chamber and liquid is provided in the upper chamber. The plunger is provided with a one-way check valve so that, upon retraction of the plunger, the liquid is forced through the valve and into the compartment containing the powder. The vial is provided with an external needle at its lower end so that the mixed medicament may be injected into the patient. Again, apart from other objections thereto, such an arrangement is not readily applicable to the contained-needle type of hypodermic ampoules to which the present invention relates.

As a result of the foregoing problems, and numerous others, prior hypodermic ampoules of the contained-needle type, to which the present invention relates, have all been subject to severe limitations on their

practical utility, and their uses have been restricted accordingly. The present invention is directed to the provision of a basic ampoule design of the contained-needle type that is adaptable for making both subcutaneous and intramuscular injections of two or more separated medicament components that are mixed in the ampoule itself. A major objective is to achieve all of this

1. with a maximum utilization of basic parts of both the ampoules and applicators therefor,
2. with a minimum variation in the techniques of assembling, filling, and using the ampoules, and
3. while overcoming or avoiding the many problems that have heretofore prevented general use of the desirable, contained-needle type of injection device.

## SUMMARY OF THE INVENTION

This invention provides a multichamber, hypodermic device which includes first and second coaxially disposed cylinders. The cylinders respectively provide first and second, medicament-containing chambers, the adjacent ends of which are separated by a first, puncturable, piston-like diaphragm. This first diaphragm extends across and around the end of the first cylinder to close and seal the same and is slidably mounted in the adjacent end of the second cylinder to close and separately seal the same. These two seals are exposed to and separated by the ambient atmosphere so as to avoid liquid seepage from one chamber into the other. The other end of the first cylinder slidably carries a plunger. A hypodermic needle is mounted on the plunger with its pointed end extending axially toward a pierceable, central portion of the first diaphragm. The other end of the second cylinder is closed and sealed by a puncturable clip and diaphragm assembly having its pierceable portion also axially aligned with the pointed end of the needle.

The first chamber is partially filled with a first medicament, usually in powder form, and the excess space therein is preferably partially evacuated. The second chamber is filled with a second, liquid medicament or vehicle for the first medicament. These medicament components are mixed by partially depressing the plunger so that the pointed end of the needle cannula pierces the first diaphragm. The partial vacuum in the excess space in the first chamber facilitates the flow of liquid from the second chamber through the needle and into the first chamber as the first diaphragm moves toward and into engagement with the second diaphragm, thus mixing the two medicaments. When the second chamber is exhausted and its volume reduced essentially to zero in this manner, an injection may be effected by pressing the puncturable clip and diaphragm assembly against the skin of a patient and further depressing the plunger to the end of its stroke.

This invention also provides similar multichamber devices like the one last described but with the similar provision in the second cylinder of one or more additional, coaxially disposed chambers containing additional, liquid medicament components to be sequentially mixed in a like manner with the first two components prior to making the actual injection.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a multichamber hypodermic ampoule according to this invention.

FIG. 2 is a cross-sectional view of the ampoule of FIG. 1, the plane of the section being indicated by the line 2—2 in FIG. 1.

FIGS. 3, 4 and 5 are cross-sectional views similar to FIG. 10, but showing component parts of the ampoule in positions attained after initiating a mixing operation, completion of the mixing operation, and completion of an injection operation, respectively.

FIG. 6 is a cross-sectional view of a multichamber hypodermic ampoule according to a further aspect of this invention.

FIG. 7 is a cross-sectional view of a multichamber hypodermic ampoule according to a still further aspect of this invention.

FIGS. 8 and 9 are cross-sectional views illustrating the component parts of the ampoule of FIG. 7 in positions attained at the completion of a mixing operation and after further actuation to ready it for making an injection, respectively.

FIG. 10 is a perspective of a needle which may be employed in combination with devices according to this invention.

FIGS. 11 and 12 illustrate progressive filling and assembly operations to produce the ampoule illustrated in FIGS. 1 through 5.

FIG. 13 is a fragmentary perspective view of an ampoule retaining clip provided in the applicator illustrated in FIG. 9.

FIG. 14 is a bottom end view of an ampoule mounted in the applicator illustrated in FIG. 9.

#### DETAILED DESCRIPTION OF THE INVENTION

Referring now to the drawings, and particularly to FIGS. 1 through 5, a multichamber ampoule 110 is illustrated. The ampoule 110 is adapted to perform a subcutaneous injection and includes a first cylinder 111 and a second cylinder 112 of larger diameter, both being preferably made from glass tubing. One end of the first cylinder 111 has a radially extending annular bead 113 which is received within an annular groove 114 provided in a first diaphragm 115. The first diaphragm 115 is preferably made from rubber and is received with an interference fit within one end of the second cylinder 112. This radially compresses this diaphragm and causes it to more tightly embrace the cylinder bead 113.

The other end of the first cylinder 111 is closed by a rubber plunger 116 which, together with the first cylinder 111 and the first diaphragm 115, defines a first chamber 117. The plunger 116 is preferably made of rubber and has an interference fit in the first cylinder.

Entirely enclosed within the first chamber 117 is a hypodermic needle (FIG. 10) which is preferably of the type disclosed in U.S. Pat. No. 3,173,206 to Dunmire et al. The illustrated circular base 119 at the butt end of the needle 118 is mounted on the plunger 116 so that the needle is in substantial axial alignment with the cylinder 111 and has a pointed end 120 projecting downwardly and into the diaphragm 115 in position to be forced through the unpierced remainder thereof. Mounting of the needle base 119 on the plunger 116 is effected by snapping the peripheral edge of the needle base under an annular lip 26 that is an integral part of the plunger. Flow into the butt end of the needle occurs through an opening 27 in the cannula wall adjacent the base 119 of the needle.

As will be hereinafter explained in greater detail, the chamber 117 is at least partially filled with a powdered medicament 123 and is partially evacuated. A sliding interference fit between the diaphragm 115 and the inner sidewall of the cylinder 112 aids in sealing the bead 113 within the annular groove 114. Friction between the plunger 116 and wall of the cylinder 111 and resistance of the diaphragm 115 to penetration by the needle 118, of course, prevent the plunger 116 from prematurely moving toward the diaphragm 115.

The other end of the second cylinder 112 is closed by a second diaphragm 124 and a clip 125. The clip 125 is cup-shaped and has an inner annular groove 15 in its cylindrical sidewall which snaps over a radially extending annular bead 12 at one end of the second cylinder 112. The clip 125 also includes a bottom wall 125a having a central aperture 125b therethrough. The bottom wall 125a has a concave outside surface which includes an outer rim 125c and which tapers upwardly toward the aperture 125b.

The diaphragm is preferably molded from rubber and is shaped to function in accordance with the teachings of U.S. Pat. No. 3,094,988 to Dunmire. It includes an outer annular portion 127, a thick, elongated, centrally located, needle guiding and liquid sealing gland 128 and a relatively thin, flexible, corrugated, intermediate portion 129 connecting the gland and the outer portion to permit relative axial movement therebetween. The gland extends through the aperture 125b in the clip 125. An axial needle passage 130 may extend into the upper end of the gland from the inside and terminates short of the opposite, lower end of the gland to form a thin, easily puncturable wall 131 closing the bottom of the passage.

The first diaphragm 115, second diaphragm 124, and cylinder 112, together, define a second chamber 132. The second chamber 132 is filled with a liquid medicament in a manner which will hereinafter be explained.

The liquid medicament in the second chamber is mixed with the solid powder medicament in the first chamber prior to injection in a manner which will now be explained. The plunger 116 is pushed axially toward the first diaphragm 115 until the needle 118 pierces this diaphragm and provides communication through the needle between the second chamber 132 and the first chamber 117, as shown in FIG. 3. Once communication is established between these chambers, the liquid is drawn upwardly into the first chamber by downward movement of the cylinder 111 and first diaphragm 115, together, into engagement with the second diaphragm 124, as shown in FIG. 4. At this stage, the pointed end of the needle 118, which previously pierced the first diaphragm 115, has entered the gland 128 of the diaphragm 124.

To ensure that the pointed end of the needle will not be initially extended too far beyond the first diaphragm 115 after it pierces that diaphragm, the plunger 116 is provided with a centrally raised portion 140 which extends beyond the end of the cylinder 111 when the ampoule is initially assembled. The raised portion 140, therefore, extends beyond the end of the cylinder 111 for a distance which substantially corresponds to the thickness of the portion of the diaphragm 115 to be pierced plus the desired extension of the needle beyond the diaphragm 115 during the mixing operation. To perform the penetration operation, therefore, the raised portion 140 is depressed until its upper or outer

end is flush with the top mouth of the cylinder 111, as illustrated in FIGS. 3 and 4.

When the ampoule 110 is in the condition illustrated in FIG. 4 and the ampoule has been inverted several times or vigorously shaken as reliable mixing of the medicament components may require (generally not necessary), the ampoule is in a condition suitable for making a subcutaneous injection. To perform the injection, the diaphragm 124 is placed adjacent the patient's skin and the plunger is fully depressed until it assumes the position illustrated in FIG. 13. During the plunger depressing step, the needle penetrates the wall 131, and fluid is exhausted from the first chamber through the needle opening 27 (FIG. 10) adjacent the plunger 116 and through the opening in the end of the needle as the needle penetrates the skin and subcutaneous fat of the patient.

Referring now to FIG. 6, an ampoule 150 is illustrated. The ampoule 150 is suited for performing an injection requiring the premixing of two or more liquid medicaments with each other or with each other and with a solid medicament. The ampoule 150 includes a first cylinder 151 which is preferably made from glass and which has a beaded rim portion 152 at its lower end. The rim portion 152 is received within an annular groove 153 which is provided in a first diaphragm 154. The diaphragm 154 closes one end of the cylinder 151, and the other end of the cylinder 151 is closed by a plunger 155. A needle 156 similar to the needle 118 (except for cannula length) is mounted on the plunger 155 similarly to the arrangement of FIG. 2. A pointed end 159 of the needle 156 is received within a passage 160 in the first diaphragm 154. The plunger 155, cylinder 151, and the diaphragm 154, together, define a first chamber 161. As will be hereinafter explained in greater detail, the chamber 161 is partially evacuated during the assembly operation and is at least partially filled with a liquid or powdered medicament 162.

The first diaphragm 154 is slidably received within a second cylinder 163. The second cylinder 163 has its upper end closed by the first diaphragm 154 and has its lower end closed by a second diaphragm 164 and a clip 165 constructed and operating like the previously described similar diaphragm and clip of FIGS. 1-5.

Intermediate diaphragms 167 and 168 are provided in the cylinder 163. The intermediate diaphragms 167 and 168, the diaphragms 154 and 164, and the cylinder 163, together, define second, third, and fourth chambers 169, 170, and 171, respectively. The chambers 169, 170, and 171 are filled with different liquid medicaments.

The medicaments contained in the chambers 169-171 are mixed together, and that mixture is in turn mixed with the powder 162 in the following manner. The plunger 155 is pushed downwardly until the needle 156 pierces the first diaphragm 154 to provide fluid communication between the chamber 169 and the chamber 161. The fluid in the chamber 169 is drawn through the hollow needle 156 and into the chamber 161. After the liquid in the chamber 169 is exhausted in this manner, the diaphragm 154 contacts the diaphragm 167 and the pointed end 159 of the needle enters a passage 172 in the diaphragm 167. Further pressure on the plunger 155 causes the needle 156 to pierce the diaphragm 167 to thereby draw liquid from the chamber 170 into the chamber 161 and move the diaphragm 167 against the diaphragm 168. The pointed

end 159 of the needle 156 then enters a passage 173 in the diaphragm 168 and further pressure on the plunger 155 drives the needle 156 through the diaphragm 168 to thereby draw liquid from the chamber 171. After the liquid in the chamber 171 is exhausted, the diaphragm 168 contacts the diaphragm 164 and the pointed end of the needle is received within a passage 174 provided in the diaphragm 164.

After the several liquids are mixed with each other and with the material 162 in the chamber 161, the ampoule 150 is in a condition to perform an injection. This injection is performed by placing the diaphragm 164 against the skin of the patient and by depressing the plunger 155 until the plunger 155 contacts the diaphragm 154. It should be appreciated that any number of liquids may be mixed in this manner with or without a powdered medicament, after which the ampoule, with or without an applicator may be used to make a subcutaneous injection in the general manner previously described.

Referring now to FIGS. 7, 8, 9, an ampoule 180 is illustrated. The ampoule 180 may be employed to mix liquid and powdered medicaments prior to an injection, and may be employed to effect an intramuscular rather than subcutaneous injection. The ampoule 180 is generally similar to the ampoule 110 in that it includes a first cylinder 181 which is closed at one end by a rubber plunger 182 and is closed at the other end by a first diaphragm 183. The plunger 182 has an enlarged portion 182a which forms a sliding interference fit with the inner sidewall of the cylinder 181. The plunger 182 is provided with an axially extending reduced upper portion 182b which initially extends beyond the cylinder 181. A needle 184 is fixed to the plunger 182 in the same manner previously described, and the diaphragm 183 is slidably received in a second cylinder 185. The second cylinder 185 is closed at its lower end by a second diaphragm 186 and a clip 187 constructed and operating like the previously described similar diaphragm and clip of FIGS. 1-5. A needle guard 188 is removably fixed to the clip 187 and extends axially therefrom. The needle guard 188 is preferably of transparent plastic, is cup-shaped, and has an open mouth which forms an interference fit with an annular, axially projecting shoulder portion 47 of the clip 187. For purposes which will hereinafter become apparent, the guard 188 is provided with a knurled bottom rib 48.

The first cylinder 181, diaphragm 183, and plunger 182, together, form a first chamber 190 which is evacuated and partially filled with a powdered medicament 191. The second cylinder 185 and diaphragms 183 and 186, together, form a second chamber 192 which is filled with a liquid medicament 193.

The medicaments 191 and 193 are mixed in a manner similar to the mixing procedure set forth with regard to the ampoule 110 of FIGS. 1-5. The plunger 182 is pushed axially until the needle 184 pierces the diaphragm 183 and provides liquid communication between the chambers 190 and 192. When such communication is established, the diaphragm 183 moves into engagement with the diaphragm 186, and the parts of the ampoule 180 assume the positions illustrated in FIG. 8.

To ensure an intramuscular type injection, the needle 184 must pass through the skin and the surface layers of fat and enter the muscle prior to medicament flow through the needle. Therefore, the chamber 190 is de-

signed so that its volume is greater than the total volume of medicament to be contained therein. Thus, as is illustrated in FIG. 8, there is a space Sp between the liquid level and the plunger 182 when the diaphragms 183 and 186 are drawn together. Prior to effecting an injection, the plunger 182 is further depressed until the plunger 182 contacts the surface of the liquid in the chamber 190. This operation projects the needle 184 a predetermined distance beyond the diaphragm 186, which distance substantially corresponds to the normal maximum depth of the muscle beneath the skin of the patient, and air or gas in the chamber 190 is substantially fully expelled through the needle. This operation is most conveniently performed by placing the needle guard 188 on a flat surface and pressing the portion 182b downwardly until the top of the portion 182b is substantially flush with the top of the cylinder 181. If desired, the plunger may be depressed in this manner until the appearance of a drop of medicament at the point of the needle (visible through the transparent sidewall of the needle guard 188) indicates the elimination of substantially all air or gas from the chamber 190.

An injection may then be performed by removing the needle guard 188 and manually applying the ampoule 180 against the skin of the patient so that the needle 184 penetrates the skin and enters the muscle. After this operation, the plunger 182 is completely depressed to inject the medicament into the muscle. A preferred method of effecting an injection, however, is to employ an applicator. As fragmentarily shown herein, such an applicator includes a spring-biased plunger 50 mounted within a casing 51. An applicator adapted to perform an intramuscular injection includes an elongated, metal, bell-shaped mouth portion 52 which is provided with diametrically opposed inner spring clips 53 or the like (see FIG. 13) which are spot welded to the inner sidewall of the portion 52. The clips 53 retain the ampoule diaphragm clip 187 in the position illustrated in FIG. 9, so that the partially advanced needle 184 is initially recessed in the applicator. With the needle guard attached, the ampoule 180 is mounted within the applicator by inserting a pair of diametrically opposed lugs 34a provided on the clip 187 into a cooperating pair of slots 52a (FIG. 14) which extend axially through a radially inwardly extending flange 52b. This operation is performed by grasping the knurled bottom rib 48 on the needle guard 188. The ampoule is pushed upwardly into the casing 51 until the lugs 34a are above the level of the spring clips and is then rotated 90° until the lugs 34a rest on the clips 53 (see FIG. 9). It is desirable to remove the guard 188 after the ampoule 180 is mounted in the applicator to prevent contamination of the needle. The needle guard is removed by pulling one portion of the rib 48 downwardly while pushing a diametrically opposed portion of the rib upwardly since an axial force applied to the rib may disengage the lugs from their retaining spring clips. After the needle guard is removed, the mouth 52 of the applicator is placed against the skin of the patient and the plunger is fired. The applicator spring clips are designed so that they release the ampoule diaphragm clip 187 prior to movement of the plunger 182 relative to the ampoule cylinder 181. To this end, the springs are designed so that the force required to drive the lugs 34a from their retained position is less than the force required to move the plunger 182 relative to the cylinder 181. In this

manner, the needle 184 is driven into the muscle prior to injection of the medicament. After the needle 184 enters the muscle, the plunger 182 again moves toward the diaphragm 186 to perform the injection by expressing the medicament through the needle 184 as it is driven further into the muscle. The injection is complete when the plunger engages the diaphragm.

Referring now to FIGS. 11 and 12, the ampoule 110 is assembled and filled by first attaching the needle 118 to the plunger 116 and then inserting the plunger in one end of the cylinder 111, as shown in FIG. 11. With the open mouth of the cylinder 111 in an upright position, the cylinder 111 is at least partially filled with the powdered medicament 123 and is subjected to a vacuum during or at the conclusion of the introduction of powdered medicament. While subjected to the vacuum, the first diaphragm 115 is applied to the mouth of the cylinder. Thereafter, the second cylinder 112 is applied to the diaphragm 115, as illustrated in FIG. 12. The second cylinder 112 is then filled with a liquid medicament, and the remaining components are assembled to provide the ampoule shown in FIGS. 1 to 5.

The invention is not restricted to the slavish imitation of each and every detail set forth above. Obviously, hypodermic devices may be provided which change, eliminate or add certain specific details without departing from the scope of the invention.

What is claimed is:

1. A multichamber ampoule for mixing and discharging medicaments, comprising a first cylinder, a first diaphragm sealed to and closing one end of said first cylinder, a plunger slidably disposed in the other end of said first cylinder to provide a first chamber between said plunger and first diaphragm, a hollow needle disposed in said first chamber for movement with said plunger toward said first diaphragm and having an open end adjacent said plunger and an opposite pointed discharge end adjacent said first diaphragm, and a powder medicament in said first chamber; a second cylinder axially aligned with said first cylinder and having one end closed by insertion of said first diaphragm therein with a peripheral portion of the first diaphragm in axial sliding engagement with the inner surface thereof, a second diaphragm closing the other end of said second cylinder, said first and second diaphragms and second cylinder, together, defining a second chamber, and a fluid medicament in said second chamber; whereby said fluid and solid medicaments may be mixed preparatory to discharge thereof by first moving said plunger and needle sufficiently toward said first diaphragm to project the pointed end of the needle through said first diaphragm to establish communication between the two chambers and by then moving said first cylinder, first diaphragm, plunger, and needle as a unit toward said second diaphragm to progressively reduce the volume of said second chamber substantially to zero and thereby express said liquid medicament through the needle into the first chamber while bringing said first and second diaphragms substantially into engagement and disposing the pointed end of said needle in position to project the needle through said second diaphragm upon further movement of said plunger toward said first and second diaphragms.

2. A multichamber ampoule according to claim 1, wherein the outer diameter of said first cylinder is less than the inner diameter of said second cylinder.



3. A multichamber ampoule according to claim 1, wherein the volume of said first chamber is substantially equal to the volume of said second chamber.

4. A multichamber ampoule according to claim 1, wherein the volume of said first chamber sufficiently exceeds the volume of said second chamber so that the volume of the two medicaments in said first chamber after mixing the medicaments therein is substantially less than the remaining volume of said first chamber, whereby, prior to expelling the mixed contents of the first chamber, said plunger may be further advanced toward said first and second diaphragms to extend a portion of the length of said needle through and beyond said second diaphragm in an exposed condition for projection into a patient to the depth of muscle tissue to be injected, and said plunger may then be moved further toward said first and second diaphragms to progressively expel the mixed contents of said first cham-

ber through said needle and into said muscle tissue while further advancing said needle into said muscle tissue.

5. A multichamber ampoule according to claim 1, in which at least one additional diaphragm is disposed in said second chamber between said first and second diaphragms so as to divide said second chamber into a plurality of smaller chambers, and a corresponding plurality of different liquid medicaments respectively substantially fill said smaller chambers, whereby each of said liquid medicaments, one after another, may be caused to flow through said needle into said first chamber by progressive movement of said first diaphragm, first cylinder, plunger, and needle, as a unit, to bring all of said diaphragms substantially into engagement with one another.

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