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Hurschman

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[54] **MULTIPLE COMPARTMENT HYPODERMIC DEVICES**

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[*] Notice: The portion of the term of this patent subsequent to May 29, 1990, has been disclaimed.

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[51] **Int. Cl.**..... **A61m 5/28,** A61j 5/00

[58] **Field of Search**.... 128/215, 216, 218 R, 218 P, 128/218 NV, 218 F, 218 M, 218 D, 218 DF, 272, 220; 215/47, 52, 56; 206/63.2 R, 56 R, 47 A

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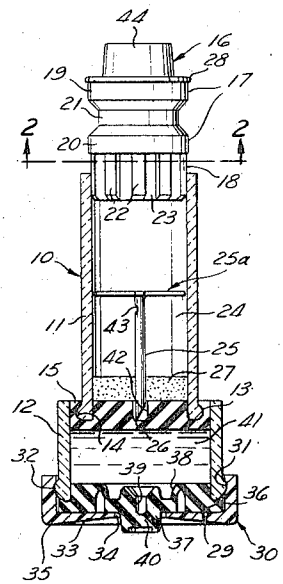
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[57] **ABSTRACT**

A multichamber hypodermic ampoule of the contained needle type and a method of assembling and filling such an ampoule are disclosed. The ampoule includes multiple chambers for premixing a powdered medicament with a diluent and injecting the mixture. One end of one chamber is closed by a plunger and the other end of that chamber is closed by a first pierceable diaphragm. A hollow needle is operatively associated with the plunger and is initially contained within that chamber. The first pierceable diaphragm is slidably mounted in one end of a second chamber which contains the diluent, and the other end of that chamber is closed by a second pierceable diaphragm. The plunger is provided with a first cylindrical portion having a plurality of axially extending and radially projecting ribs, and is provided with a second cylindrical portion which is adapted to form a seal with the chamber. The ampoule is assembled and filled by affixing the first diaphragm to one end of the first chamber, slidably mounting the first diaphragm in one end of the second chamber, filling the second chamber with a diluent, affixing the second diaphragm to the other end of the second chamber, staking the pointed end of a needle in said first diaphragm, partially filling the first chamber with a medicament to be lyophilized, and partially inserting the plunger in the first chamber so that passageways defined by the ribs permit vapor to be sublimed from the chamber during a lyophilization process. When lyophilization is complete and the medicament in the first chamber is in a powdered or freeze-dried condition, the plunger is fully inserted to seal the ampoule and to contact the head of the needle.

6 Claims, 7 Drawing Figures



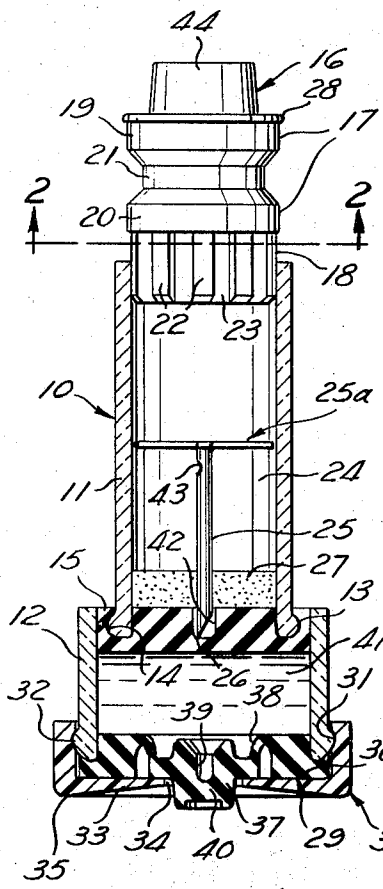


Fig. 1

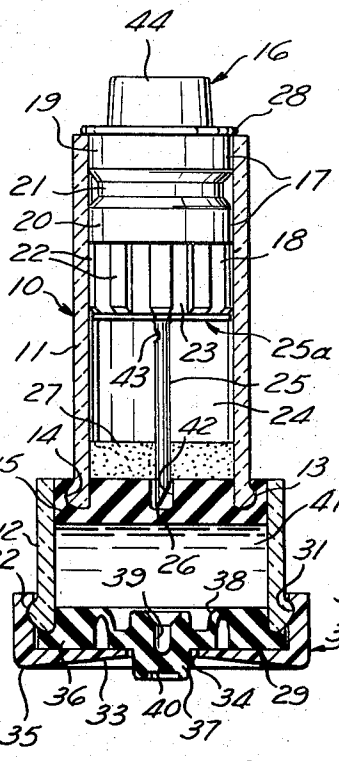


Fig. 3

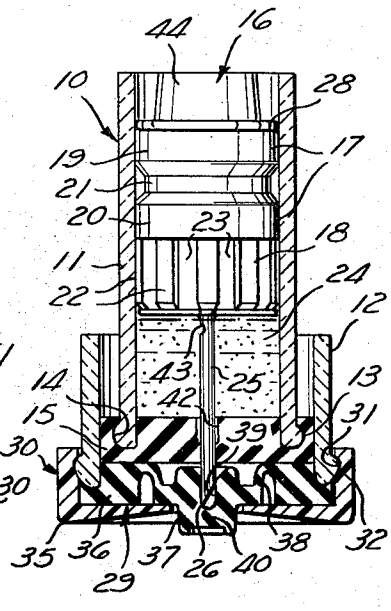


Fig. 4

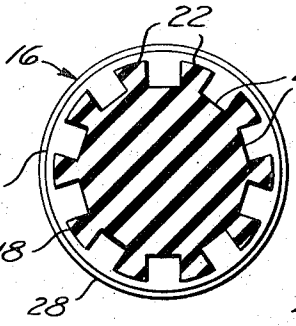


Fig. 2

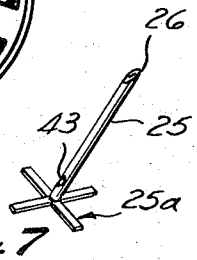


Fig. 7

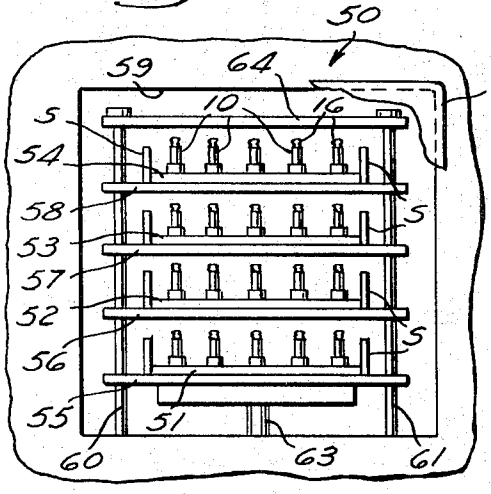


Fig. 5

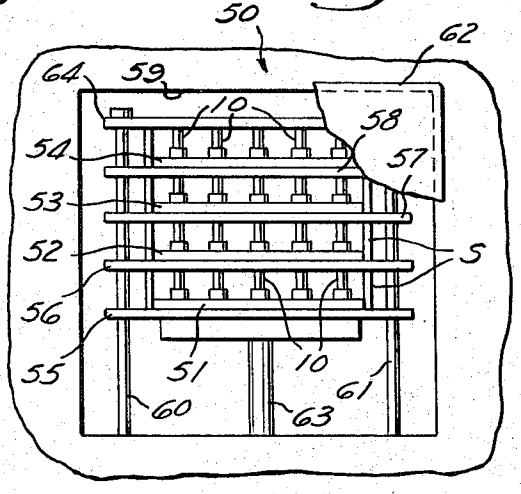


Fig. 6

MULTIPLE COMPARTMENT HYPODERMIC DEVICES

BACKGROUND OF THE INVENTION

This invention relates to disposable hypodermic ampoules which include multiple chambers for premixing a powdered, lyophilized medicament with a diluent. 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 or diluent (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, is withdrawn as a solution by the same needle and syringe, and the injection is effected therewith in a conventional manner.

Attempts have been made to provide a multicompartment 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. 18, 1967. In that patent, the patentees provide a vial which is separated into two chambers by a plunger. Powder 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, all have been subject to severe limitations on their practical utility, and their uses have been restricted accordingly. These problems have been largely overcome by the multichamber hypodermic ampoule disclosed in the copending application of Hurschman et al, Ser. No. 114,493, filed Feb. 11, 1971, now U.S. Pat. No. 3,735,761. According to that application, a multichamber hypodermic device is provided 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 operatively associated with 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.

According to assembly and filling techniques described in the copending application of Hurschman et al., the first chamber is partially filled with a carefully measured amount of a powdered medicament and is partially evacuated. Since a typical charge of powdered medicament weighs 18 milligrams, considerable care must be exercised during this particular charging operation. The necessary weighing operation, therefore, militates against the filling and assembly of such multichamber hypodermic devices on a high production basis.

SUMMARY OF THE INVENTION

This invention provides a method for assembling and filling a multichamber hypodermic device and provides a multi-chamber hypodermic device having one chamber which is capable of being partially filled with a liquid medicament to be lyophilized or freeze-dried to a powdered state so that the powdered medicament need not be separately lyophilized, carefully weighed, and then deposited in the first chamber. According to this invention, the multichamber hypodermic device includes first and second coaxially disposed cylinders which 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 operatively associated with 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 hypodermic device is assembled and filled by first assembling the first diaphragm across an end of the first cylinder and inserting the first diaphragm in one end of the second cylinder. A pointed hollow needle is then inserted in the first cylinder and staked in the first diaphragm to complete a sub-assembly which consists of the first and second cylinders, the first diaphragm, and the needle. The second cylinder is filled with the diluent and the clip and second diaphragm are applied to the open mouth of the second cylinder. A measured amount of the liquid to be lyophilized is then metered into the open mouth of the first cylinder to partially fill the same.

The plunger according to this invention comprises a plug having first and second adjacent cylindrical portions. The first cylindrical portion has a surface which is adapted to form a liquid-tight seal with the inner wall of the first cylinder. The second cylindrical portion includes a plurality of axially extending and radially projecting ribs which are adapted to provide axial passageways to the interior of the first cylinder when the second cylindrical portion is inserted in the first cylinder with the first cylindrical portion extending axially out of the first cylinder. With the first portion extending axially out of the cylinder, and with the ribs providing access to the interior of the cylinder, the entire assembly is placed in a conventional lyophilization chamber. If desired, the ampoules may be pre-frozen prior to placement in the lyophilization chamber to reduce the in-chamber cycle time.

A conventional lyophilization chamber includes a sealable enclosure having a plurality of shelves which are initially spaced apart but which may be moved together by a hydraulic ram. Trays of hypodermic devices are placed on the shelves so that the devices are in an upright position with their partially inserted plungers directed toward the lower surface of an upper adjacent shelf. The chamber is sealed and the ampoules are subjected to extremely low temperatures to freeze the liquid medicament in the first chamber and, of course, the diluent in the second chamber (or, if the ampoules are pre-frozen, to maintain the frozen condition of the liquids). The lyophilization chamber is then evacuated so that the frozen liquid phase of the medicament in the first chamber is sublimed and drawn as a vapor through the passageways formed by the ribs of the plungers. During this operation, some heat may be supplied to the chamber to balance the latent heat of vaporization or sublimation of the frozen liquid. Care must be taken, however, so as not to permit the frozen liquid to achieve a liquid state. After the medicament is dried in this manner and reduced to a highly porous mass of powder, the hydraulic ram is actuated to move the bottom shelf upwardly so that the plungers on each shelf engage the lower surface of an upper, adjacent shelf. In this manner, the plungers are fully seated in their cylinders and each first cylinder is sealed to produce a completed product.

Just prior to an injection, the powdered medicament is mixed with the diluent 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 clip and puncturable diaphragm assembly against the skin of a patient and further depressing the plunger to the end of its stroke.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a cross sectional view of a multichamber hypodermic ampoule according to this invention, showing the plunger partially inserted for lyophilizing a medicament in a first chamber of the ampoule.

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

FIG. 3 is a cross sectional view of a multichamber hypodermic ampoule according to this invention, showing the plunger in a position which seals the first chamber after completion of the lyophilization process.

FIG. 4 is a cross sectional view of a multichamber hypodermic ampoule according to this invention, showing the component parts of the ampoule in the position attained after completion of a mixing operation.

FIG. 5 is a fragmentary, elevational view of a lyophilizing chamber having a multiplicity of multichamber hypodermic ampoules loaded therein.

FIG. 6 is a fragmentary, elevational view of a lyophilizing chamber similar to FIG. 5, but showing chamber shelves in positions attained during the latter stages of a lyophilizing process.

FIG. 7 is a perspective view of a hollow, pointed needle employed in this invention.

DETAILED DESCRIPTION OF THE INVENTION

An ampoule 10 is adapted to perform a subcutaneous injection and includes a first cylinder 11 and a second cylinder 12 of larger diameter, both being preferably made from glass tubing. One end of the first cylinder 11 has a radially extending annular bead 13 which is received within an annular groove 14 provided in a first diaphragm 15. The first diaphragm 15 is preferably made from rubber, and is received with an interference fit within one end of the second cylinder 12. This radially compresses the diaphragm 15 and causes it to more tightly embrace the annular bead 13.

The other end of the first cylinder 11 is closed by a rubber plunger 16 which comprises a cylindrical plug having a first cylindrical portion 17 and a second cylindrical portion 18. The first cylindrical portion 17 includes a pair of beads 19 and 20 which are separated by a land 21 and which have a diameter which is slightly greater than the inside diameter of the first cylinder 11, to thereby effect a substantially liquid-tight seal with the first cylinder when the beads are positioned as indicated in FIGS. 3 and 4. The second cylindrical portion 18 includes a plurality of axially extending and radially projecting ribs 22 which are defined by

axially extending slots 23. The slots 23 and the ribs 22 define axial passageways to the interior of the first cylinder 11 when the plunger is partially inserted in the cylinder 11, as is illustrated in FIG. 1.

The rubber plunger 16, the first cylinder 11, and the first diaphragm 15, together, define a first chamber 24. Entirely enclosed within the first chamber 24 and staked in the diaphragm 15 is a hypodermic needle 25. The needle 25 is hollow and has a pointed end 26. For reasons which will become apparent, the needle 25 has a cross-shaped base 25*a*.

In a manner which will be hereinafter explained in greater detail, the chamber 24 is partially filled with a powdered medicament 27 and is partially evacuated. In the condition illustrated in FIG. 3, friction between the plunger 16 and the wall of the cylinder 11 and resistance of the diaphragm 15 to penetration by the needle 25, of course, aid in preventing the plunger 16 from prematurely moving toward the diaphragm 15. To further aid in preventing premature movement of the plunger 16, a radially extending lip 28 is provided at one end of the cylindrical portion 17 so that it engages the upper end of the cylinder 11 during this condition of the assembly.

The other end of the second cylinder 12 is closed by a second diaphragm 29 and a clip 30. The clip 30 is cup-shaped and has an inner annular groove 31 in its cylindrical side wall which snaps over a bead 32 which is provided on this end of the cylinder 12. The clip 30 also includes a bottom wall 33 having a central aperture 34 therethrough. The bottom wall 33 has a concave outside surface which includes an outer rim 35 which tapers upwardly toward the aperture 34.

The diaphragm 29 is preferably molded from rubber or synthetic 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 36, a thick, elongated, centrally located needle guiding and liquid sealing gland 37, and a relatively thin, flexible, corrugated, intermediate portion 38 connecting the gland and the outer portion to permit relative axial movement therebetween. The gland extends through the aperture 34 in the clip 30. An axial needle passage 39 may extend into the upper end of the gland from the inside and terminate short of the opposite, lower end of the gland to form a thin, easily puncturable wall 40 closing the bottom of the passage.

The first diaphragm 15, the second diaphragm 29, and the cylinder 12, together, define a second chamber 41. The second chamber 41 is filled with a diluent in a manner which will hereinafter be explained.

The diluent 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. With the plunger 16 in the position illustrated in FIG. 3, and with the pointed end 26 of the needle 25 received and staked within a passageway 42 in the diaphragm 15, the plunger 16 is pushed axially toward the first diaphragm 15 until the needle 25 pierces this diaphragm and provides communication through the needle and through an opening 43 in the needle cannula between the second chamber 41 and the first chamber 24. Once communication is established between these chambers, the liquid is drawn upwardly into the first chamber by downward movement of the cylinder 11 and the first diaphragm 15, together, into engagement with the second diaphragm 29, as shown in FIG. 4. At this stage, the pointed end of the needle 25, which previously pierced the first diaphragm 15, has entered the gland 37 of the diaphragm 29.

To ensure that the pointed end of the needle will not be initially extended too far beyond the first diaphragm 15 after it pierces that diaphragm, the plunger 16 is provided with a centrally raised portion 44 which extends beyond the end of the cylinder 11 when the ampoule is initially assembled and is in the condition illustrated in FIG. 3. The raised portion 44, therefore, extends beyond the end of the cylinder 11 for a distance which substantially corresponds to the thickness of the portion of the diaphragm 15 to be pierced plus the desired extension of the needle beyond the diaphragm 15 during the mixing operation. To perform the penetration operation, therefore, the raised portion 44 is depressed until the top of the raised portion 44 is flush with the top mouth of the cylinder 11, as illustrated in FIG. 4.

When the ampoule 10 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 clip 30 and the diaphragm 29 are placed adjacent the patient's skin and the plunger is fully depressed until the plunger 16 engages the diaphragm 15. During the plunger depressing step, the needle penetrates the wall 40, and fluid is exhausted from the first chamber through the needle opening 43 and through the opening in the end of the needle as the needle penetrates the skin and subcutaneous fat of the patient. This operation is normally performed by mounting the ampoule in an applicator.

The ampoule 10 is assembled and filled by applying the diaphragm 15 to one end of the cylinder 12 and then inserting the diaphragm 15 in an open end of the cylinder 12. The cylinder 12 is then filled with a suitable diluent such as water. The diaphragm 29 is then placed over the beaded end of the cylinder 11 and is secured in place by snapping the clip 30 over the bead 32. The needle 25 is then inserted in the open end of the cylinder 11 and staked within the passageway 42 of the diaphragm 15. A powdered medicament-containing solution is then metered into the cylinder 11. The amount of medicament-containing liquid metered into the cylinder 11 depends upon the amount of powdered medicament which is to be retained in the chamber 24. After the liquid is metered into the chamber 24, the plunger 16 is partially inserted in the cylinder 11 so that a part of the second cylindrical portion 18 extends beyond the end of the cylinder 11, as is illustrated in FIG. 1.

The ampoule is then placed in a lyophilization chamber and is subjected to a conventional freeze-drying cycle to remove substantially all of the moisture from the chamber 24. To accomplish this objective, a multiplicity of ampoules 10 are placed in a lyophilization chamber 50, shown schematically in FIGS. 5 and 6. A number of ampoules 10 are loaded on trays 51, 52, 53, and 54. The trays 51–54 are respectively placed on movable platens or shelves 55, 56, 57, and 58, which are located within an enclosure 59. The shelves 55–58 are slidably mounted for upward movement on guide rods 60 and 61, but are prevented from downward

movement beyond the positions illustrated in FIG. 5 by stop means (not shown).

With the ampoules **10** loaded on the trays so that the plungers are directed upwardly toward an adjacent shelf, the enclosure **59** is closed and sealed by a door **62.** After the enclosure is sealed, the ampoules **10** are subjected to extremely low temperatures to freeze the medicament in each chamber **24.** The freezing process is controlled in a known manner so that the ice formation has a multiplicity of cracks or spaces between ice crystals. After the medicament is frozen, the frozen liquid matrix is removed by evacuating the enclosure **59** to thereby subject the frozen medicament to extremely low pressures. The frozen liquid matrix is thereby drawn off as a vapor through the passageways provided by the ribs **22** and the slots **23** in each plunger **16.** It should be noted that the cross-shaped base **25***a* of the needle **25** permits passage of the vapors from the chamber **24** and also serves to retain the needle in a preselected position by contacting the inner wall of the cylinder **11.** During the sublimation operation, it may be necessary to add some heat to balance the heat of vaporization or sublimation. When the moisture has been removed from each chamber **24,** and while the vacuum is applied, the plungers **16** are driven to the position illustrated in FIG. **3** to seal the chambers **24** in the following manner.

Referring now to FIG. **6,** a ram **63** is actuated to drive the lowest shelf **55** upwardly. When the plungers of the ampoules positioned on that shelf engage the shelf **56,** the shelf **56** is also driven upwardly. This procedure continues until the plungers of the ampoules on the shelf **58** engage a top stationary plate **64.** The ram **63** then subjects the plungers **16** to a predetermined movement sufficient to advance the plungers to the position illustrated in FIG. **3** and into contact with the needle base **25***a*. To prevent advancement of the plungers **16** beyond that position, spacer bars S are provided on each shelf. The spacer bars S have a longitudinal dimension corresponding to the longitudinal extent of the ampoule illustrated in FIG. **3.** The ram **63** is then lowered, atmospheric pressure is applied to the chamber **59,** the door **61** is opened, and the trays are removed from the lyophilization chamber.

It should be appreciated that this invention is applicable not only to the subcutaneous multichamber hypodermic ampoule illustrated herein, but is also applicable to the various multichamber hypodermic ampoule variations disclosed in the copending application of Hurschman et al. Therefore, the invention is not restricted to the slavish imitation of each and every detail set forth above. Obviously, multichamber hypodermic ampoules and assembly and filling techniques may be provided which change, eliminate, or add certain specific details without departing from the scope of the invention.

I claim:

1. A multichamber hypodermic ampoule 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 the first cylinder to provide a first chamber between said plunger and said first diaphragm; said plunger comprising a cylindrical plug having a first cylindrical portion which comprises means to effect a substantially liquid-tight seal with said first cylinder, and having a second cylindrical portion which comprises means engaging said first cylinder, and means providing at least one passageway along an axial extent of said second cylindrical portion; a hypodermic 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; a powdered 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 alignment 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 making an injection 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 said needle through said second diaphragm upon further movement of said plunger toward said first and second diaphragms.

2. A multichamber hypodermic ampoule according to claim **1,** wherein said second cylindrical portion is adjacent said hypodermic needle.

3. A multichamber hypodermic ampoule according to claim **1,** wherein said second cylindrical portion includes a plurality of radially projecting ribs which engage said first cylinder and wherein passageways along said axial extent are defined by adjacent ribs.

4. A multichamber hypodermic ampoule according to claim **1,** wherein said cylindrical plug has an axially projecting portion extending from said first cylindrical portion, the axial extent of said projecting portion being greater than the axial extent of said first diaphragm but being less than the combined axial extents of said first and second diaphragms.

5. A multichamber hypodermic ampoule according to claim **1,** wherein said plug is provided with radially extending lip means at one end of said first cylindrical portion and spaced from said second cylindrical portion.

6. A multichamber hypodermic ampoule according to claim **1,** wherein said second cylindrical portion is adjacent said hypodermic needle and includes a plurality of radially projecting ribs which engage said first cylinder, wherein passageways along said axial extent are defined by adjacent ribs, wherein said cylindrical plug has an axially projecting portion extending from said first cylindrical portion, the axial extent of said projecting portion being greater than the axial extent of said first diaphragm but being less than the combined axial extents of said first and second diaphragms, and wherein said plug is provided with radially extending lip means at one end of said first cylindrical portion and spaced from said second cylindrical portion.

* * * * *