Sept. 19, 1967 E. R. SANDHAGE ET AL 3,342,180

DISPOSABLE LIQUID-POWDER PACKAGE AND HYPODERMIC SYRINGE

Filed April 24, 1964 2 Sheets-Sheet 1

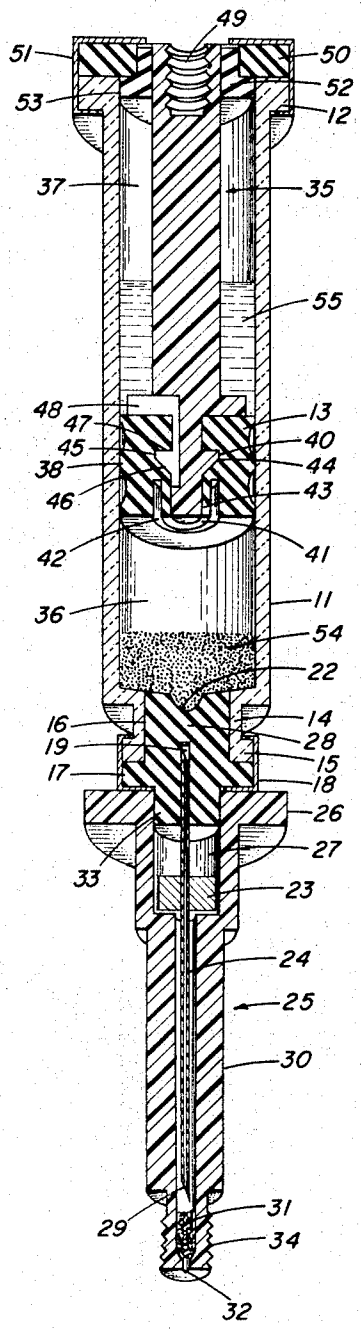

FIG - 1

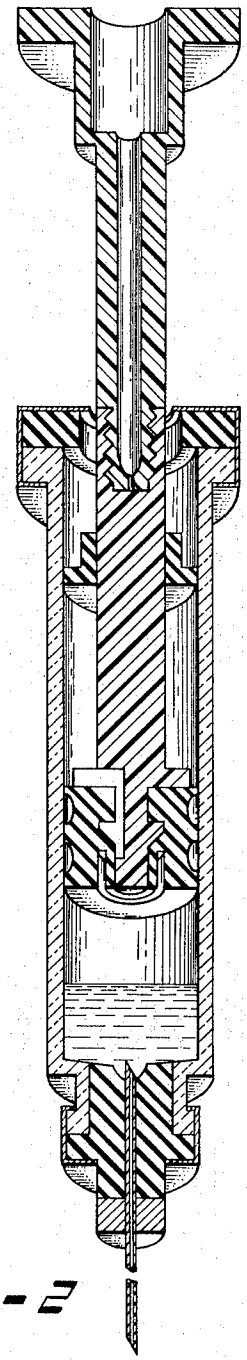

FIG - 2

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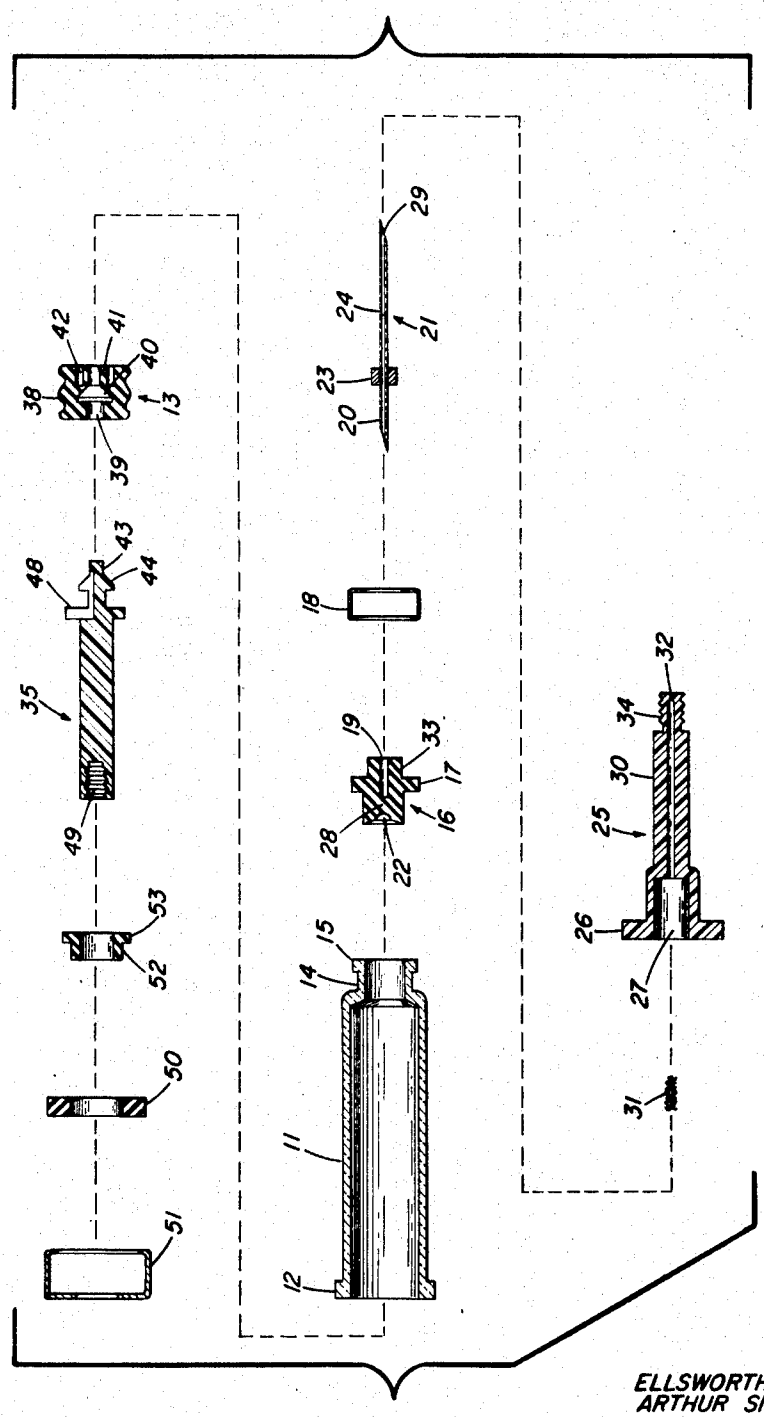

FIG. 3

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United States Patent Office 3,342,180
Patented Sept. 19, 1967

3,342,180

DISPOSABLE LIQUID-POWDER PACKAGE AND HYPODERMIC SYRINGE

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Filed Apr. 24, 1964, Ser. No. 362,444
4 Claims. (Cl. 128—218)

ABSTRACT OF THE DISCLOSURE

A two compartment disposable combination storage package and hypodermic syringe has a liquid diluent in one compartment, and a powder in another. Between the two is a piston, with a one way valve for the liquid, which permits storage without the liquid adversely affecting the shelf life of the powder. A combination needle guard and plunger extension protects the needle from displacement or contamination during storage. A double pointed needle punctures a front stopper after mixing the components, so the contents are immediately ready for use.

This invention relates to a two-compartment hypodermic syringe and package providing for the storage of a readily soluble solid component and a liquid component of an injectable product under sterile conditions with the solid component ahead of a piston and the liquid behind the piston and a one-way valve through the piston so that the liquid is transferred to and mixed with the solid in preparation for injection, and which piston is attached to the plunger so that on injection the location of the needle may be checked by aspiration; and which is conveniently fillable and sterilizable; and a needle assembly useful for such a package and/or other hypodermic packages.

The piston on the plunger incorporates a unique type of sleeve valve in which a resilient sleeve overlies a part of the plunger having at least one passage for the liquid so that the liquid flows through the passage, and expands the flexible sleeve for permitting the liquid to flow one way only, and which by its natural resilience closes against the plunger so as to give a positive one-way action with no leakage up to pressures sufficient to mechanically rupture the components.

In pharmaceutical practice, there are many products whose injection hypodermically is desired but which products must be dry for reasonable shelf life and must, therefore, be mixed with a liquid diluent just prior to injection. The diluent itself may contain pharmacologically effective constituents, or solubilizing constituents.

The art has long been familiar with various efforts to provide a hypodermic syringe in which a solid component could be stored with a separate compartment for a liquid diluent so that the two could be mixed just prior to injection. Among such is United States Patent 1,154,677, J. H. Wedig, "Hypodermic Syringe," Sept. 28, 1915, in which a solid medicant is stored ahead of a plunger in a hypodermic syringe barrel, complete with hypodermic needle, which plunger serves as a container for a liquid so that the plunger may be withdrawn and the liquid poured into the barrel, the liquid and the solid thus mixed, and used for injection. A variant on this appears in United States Patent 1,702,654, E. D. Kellogg, "Reptile-Venom-Antidote Container," Feb. 19, 1929, in which the entire package is in compact cartridge configuration for long storage. To avoid the exposure of the solid and/or the liquid to air, and compromise of sterility during reconstruction, various devices have been developed in which the liquid and solid components could be mixed by various manipulations, as for example by rupturing a diaphragm, as shown in United States Patent 1,943,120, S. Kabnick, "Hypodermic Syringe," Jan. 9, 1934.

Another approach to the problem has been to store the solid and liquid portions of the pharmaceutical preparations in separate compartments of a container so that the liquid may be withdrawn from one compartment by puncturing a stopper with a hypodermic needle and transferred to and mixed with the solid components, which mixture is then withdrawn from the second chamber for administration. Such a device in which the container can be likened to two glass vials with a common bottom serving as compartments is shown in Canadian Patent 550,-864, J. C. Bird and Henry C. Wendt, Jr., "Bottle," Dec. 31, 1957. Such a common container insures that the proper pair of components are stored and used together.

Another variant, parts of which are similar to the present device, is disclosed in an application of the present inventors, Ser. No. 254,766, filed Jan. 29, 1963, now U.S. Patent 3,161,195, "Two-Compartment Aspirating Hypodermic Syringe."

It is desirable that a package and hypodermic syringe combination be producible at such a low cost as to be disposable and that powder or other solid be completely separate from the liquid so that even moisture-sensitive powder medicaments can be stored at full potency for a prolonged period, and that the product be readily mixed for administration with a minimum of chance for error in manipulation, or compromise of sterility; and that the package preferably have available with it a hypodermic needle and; additionally, that the package be economical to manufacture and of such design that the product can be economically assembled in sterile form with a minimum chance of manufacturing error or compromise of sterility. A minimum dead space, or volume of liquid which cannot be injected is desirable.

The invention, comprising the features of construction and combination of elements and arrangement of parts to achieve these objectives and others which will be obvious from an inspection of the construction hereinafter set forth, is set forth in the description below, which applies to a specific embodiment. It is to be understood that certain of the features of construction of the preferred embodiment, together with their advantages, may be omitted while coming within the scope of the present invention, which is defined in the appended claims.

A fuller understanding of the nature and objects of the invention is had by studying the following detailed description and the accompanying drawings, in which:

FIGURE 1 is a pictorial sectional view of the combination package and syringe.

FIGURE 2 is a pictorial sectional view showing the product after reconstitution, but before injection.

FIGURE 3 is a diagrammatically exploded view showing the various components of the syringe and package of FIGURE 1 with the components appearing separately for clarity.

The barrel **11** may be glass or plastic and is cylindrical with a barrel flange **12** at the rear end. The flange may have flats to prevent rolling. The barrel itself may be either cylindrical or have a slight forward conical taper as a slight taper makes molding easier and the piston **13** is sufficiently resilient to permit minor variations in diameter. At the forward end of the barrel is the barrel neck **14**, at the front end of which is a barrel neck flange **15**. The barrel neck is preferably, but not necessarily, smaller than the rest of the barrel so that the barrel neck flange has a diameter not greater than the main portion of the barrel. This sizing is for convenience in storage and may be modified for special situations. In the barrel neck is the puncturable stopper **16**. The puncturable stopper fits in the barrel neck with the stopper head **17** consisting

of a flange portion of the stopper which is held against the barrel neck flange by the puncturable-stopper seal **18**. The front end of the puncturable stopper has a needle port **19** therein which is large enough to receive and store a part of the short end **20** of a hypodermic needle **21**. On the inner end of the puncturable stopper **16** is a needle point dimple **22**. The length of the puncturable stopper is preferably such that the inner end of the puncturable stopper extends completely through the barrel neck and is approximately the same length so that the end of the barrel when closed is nearly planar and, therefore, a minimum of liquid is trapped in the dead space on injection. The needle point dimple is centrally located to permit the needle point to penetrate without the needle point extending into the barrel far enough to interfere with operation of the piston **13**. The hypodermic needle **21** has a hypodermic needle hub **23** around the central portion of the needle with the short end **20** extending into the needle port in the stopper and the long end **24** extending forward for insertion into a subject. During storage there is fastened over the forward end of the stopper a combination needle guard and plunger extension **25**, hereafter called the needle guard. The needle guard has a thumb piece **26** at the rear end with a hub chamber **27** extending through the thumb piece and into the needle guard, which hub chamber is deep enough to hold the needle hub during storage. In use the needle hub is pressed against the forward end of the puncturable stopper causing the short end to penetrate the membrane **28** between the needle port **19** and the needle point dimple **22**, thus opening the interior of the hypodermic syringe to communicate with the bore **29** of the hypodermic needle and permit discharge of the syringe contents. The needle guard has a needle sheath **30** extending forward from the hub chamber which is slightly longer than the long end of the hypodermic needle. At the forward end of the needle sheath is an air filter **31** and just forward thereof is a sterilizing vent **32**. The sterilizing vent is to permit entry of a sterilizing gas, such as ethylene oxide, through the air filter to sterilize the interior of the needle sheath, the hypodermic needle, the needle hub, and the forward end of the puncturable stopper after assembly of the needle guard to the forward end of the puncturable stopper. Conveniently, but not necessarily, the puncturable stopper has a stopper boss **33** extending forwardly of the puncturable stopper seal **18** and of such diameter as to removably but snugly fit into the hub chamber. At the forward end of the needle sheath are threads **34**, or other convenient means for attaching the needle guard to the plunger **35**.

Inside of the barrel is a resilient piston **13**. Usually the piston is located near the center of the barrel during storage although it may be located at such a point that it divides the barrel into a forward compartment **36** and a rear compartment **37**, each having such volume as is desired for a particular pharmaceutical product. For some products the forward compartment for the solid component is markedly smaller than the rear compartment for the liquid component, but the choice of size is such as to conveniently hold the selected components. On the outside of the piston for contact with the barrel is at least one annular ring **38**. In the modification shown, three annular rings are used to give greater protection against moisture leaking past the piston and greater direction control to prevent the piston from becoming cocked in the barrel. The use of a plurality of annular rings, such as three rings, each of which is comparatively narrow, reduces the area in contact between the piston and the barrel, thus reducing friction and the resiliency of the rings gives greater tolerance towards variations in the diameter of the barrel. Inside of the piston and preferably axially, is a passage **39** extending through the piston. Preferably this passage is circular and has a groove **40** extending into the piston. Towards the front

of the passage is a resilient valve **41**, preferably circular in cross section, and surrounding which is a relief space **42**. The resilient valve sleeve may extend completely forward of the main body of the piston. It is preferred that the sleeve be inset into the piston to reduce dead space.

This piston is attached to the forward end of a plunger **35**. The forward end of the plunger is formed with a boss **43** which extends into the passage in the piston and has a cooperating enlargement **44** which fits into the retaining groove in the plunger and holds the piston firmly in position on the boss. Just behind the boss is a shoulder **45** against which the piston fits and which acts to keep the piston from sliding backwards on the plunger. The shoulder may be of greater diameter than the main body of the plunger, depending upon the capacity desired for the compartments. As shown in FIGURE 1, the enlargement on the boss has a forward conical configuration **46** and a flat rear configuration **47** so that the piston can slide over and be expanded by the conical configuration during assembly but is prevented from sliding off of the boss by the flat rear configuration of the enlargement. The forward end of the boss is slightly larger than and slightly expands the valve sleeve which is an integral part of the piston. Thus the resilience of the valve sleeve causes the valve sleeve to shrink slightly against the forward end of the boss. A liquid conduit **48** extends from the portion of the plunger behind the piston, and is in communication therewith, to the portion of the boss which is inside of the valve sleeve. The configuration shown in FIGURE 1 is a slot integrally molded in the boss at the time the plunger is manufactured. Drilled holes, or other shapes may be used.

In use, under pressure, liquid passes through the liquid conduit and slightly expands the valve sleeve and, hence, can readily flow between the plunger boss and the valve sleeve and into the forward compartment. Because the valve sleeve is slightly expanded by the boss the flow of liquid is prevented in the absence of operating pressures so that during storage there is no moisture leakage through the valve. Because the valve sleeve is pressed against the outside of the boss, the valve gives extremely effective one-way action and any reverse pressure tends to force the resilient sleeve into the liquid conduit which is thus completely obstructed and the valve will be completely leakproof against reverse pressures normally associated with hypodermic syringes; and, in fact, does not leak until the pressures are sufficient to cause mechanical failure of some of the components. Conveniently, the plunger is a plastic molding, and the plastic itself would fail in compression before the valve would leak.

In the rear end of the plunger is a threaded hole **49** into which the plunger extension and needle guard **25** fit. Other fastening means may be used.

The rear compartment **37** is closed, and the plunger **35** is held in position by a rear retaining stopper **50**, which is held against the barrel flange **12** by a rear stopper seal **51**, which may be a conventional aluminum seal, but with an axial hole. Between the rear retaining stopper and the plunger is a vacuum breaking sleeve **52** which rides on the plunger, and is prevented from escaping rearward by a guide bead **53**. This bead is conveniently of such size as to fill the barrel, and guide the rear of the plunger, but slide forward with the plunger, to avoid a vacuum forming behind the plunger during use.

During assembly the piston is expanded and slid over the end of the boss on the plunger and contracts down around the boss so that the groove **40** encloses the enlargement **44**. When the piston is inserted into the barrel, the barrel prevents the piston from expanding and thus firmly locks the piston on the forward end of the plunger.

METHOD OF USE

In use a solid component. as for example a powdered mixture of tetracycline with suitable adjuvants is placed in the forward compartment and water is placed in the rear compartment. The two components are separated from each other and the combination functions as a two-compartment package. The shelf life is not known, but is at least some several years, and may be a great many years. At the time when reconstitution is desired, the plunger extension is detached from the front, and secured to the plunger, the plunger is pulled back, thus decreasing the annular space between the barrel and the plunger, causing the liquid in the rear compartment to flow through the liquid conduit into the thus enlarged forward compartment. The powder quickly dissolves and is ready for injection. The hypodermic needle hub is pressed towards the stopper boss **33**, causing the short end **20** of the hypodermic needle to pierce the membrane **28**. The plunger is advanced, with the needle pointing upwardly to permit the escape of gas present in the forward compartment. After gas has escaped, the solution is ready for injection with the device being then used as a conventional hypodermic syringe. Because the valve sleeve presses against the boss and forms a very effective one-way valve, but requires considerable pressure to operate, the plunger may be pulled back slightly after insertion of the needle in the subject to check on the location of the insertion of the needle. If a vein or artery has been penetrated, blood is readily aspirated whereas if the needle is in tissue the usual resistance to aspiration for such a location exists. The present hypodermic syringe may be used for intramuscular, intravenous, or other hypodermic placement depending upon the medical requirements of the patient and the product. The user can be certain that its location is as desired, whatever that location may be.

MANUFACTURE

During manufacture the formation of the components is by conventional and obvious means. The assembly may be accomplished by separately sterilizing the components and assembling under sterile conditions or the device may be assembled complete and sterilized by radiation as, for example, a beam of high voltage electrons, or X-rays, or radiation. Monoenergetic radiation from a cobalt or cesium source gives excellent results. The barrel, and piston and plunger assembly may be sterilized by heat, or radiation with the front and rear compartments being separately filled with a solid medicament **54** and a liquid component **55**, under aseptic conditions. This permits gentle treatment of easily damaged compositions. After the medicament filling and closing, the needle assembly may be conveniently sterilized by a gas such as ethylene oxide.

The stopper and piston are coated with silicone oil to reduce friction in assembly, if desired. Coating the piston with silicone oil reduces the permeability of the stopper to moisture and prolongs the shelf life of moisture-sensitive solids in the package. A rubber composition of low moisture permeability is selected if required by operating conditions.

Other variants on this invention are obvious to those skilled in the art as, for example, the valve may be used in other types of construction. Other methods may be used for assembly, and the materials of construction may vary depending upon economic factors and the possible interactions by the medicament and component parts of the package. Such variations are within the scope of the present invention, which are defined by the following claims.

We claim:

1. A combination aspirating hypodermic syringe and two-compartment package comprising:

a generally cylindrical barrel, having at the rear end a barrel flange, and at the forward end a barrel neck;

a resilient piston in said barrel and located towards the center of said barrel, dividing the barrel into a forward compartment, for a solid components, a solid medicament component therein, and a rear compartment, for a liquid component, a liquid component therein, and on said piston, at least one annular ring in sealing engagement with said barrel, said piston having therein an axial passage and a plunger retaining groove in said passage, and coaxial with said passage, and at the forward end thereof a resilient valve sleeve, concentrically spaced from the main portion of the piston;

a plunger extending from the rear into said barrel, the forward end of the plunger having thereon a boss extending into the axial passage in said piston, and having on said boss a cooperating enlargement entering into and cooperating with the groove in the passage in said piston, thereby firmly retaining the piston on said plunger, the plunger boss having such size as to extend into and at least slightly expand the valve sleeve on the piston, and in said plunger a liquid conduit extending from the portion of the plunger behind the piston in the rear compartment to the boss portion of the plunger inside of the resilient valve sleeve, and on the rear of the plunger means for attaching a plunger extension;

a rear retaining stopper, spaced from the rear of the plunger, a vacuum breaking sleeve fitting around the rear of the plunger, and into the rear retaining stopper, a guide bead on said sleeve, at the front thereof, which prevents the sleeve from passing rearward through the rear retaining stopper, and which slides forward during forward operation of the plunger to break the vacuum behind the piston, and a rear stopper seal to hold the rear retaining stopper in place adjacent the barrel flange;

a puncturable stopper in the barrel neck having therein at the forward end a needle port, and at the rear end a needle point dimple, the solid membrane of the stopper therebetween being readily puncturable, and a stopper head on said stopper; a puncturable-stopper seal retaining the said stopper in the barrel neck;

a double ended hypodermic needle, a needle hub surrounding said needle, dividing the needle into a short end and a long end, said short end extending into the needle port;

a combination needle guard and plunger extension fitting over the front of the barrel and stopper assembly, and having a thumb piece at the rear, and means for connecting to the plunger at the front thereof, said guard having therein a hub chamber, and a needle sheath, into which fits the hub and needle respectively, and also having therein a sterilizing vent, to permit entry of a sterilizing gas, and an air filter adjacent said vent;

said combination cooperating to maintain the contents of the forward compartment moisture-free during storage, and to transfer liquid from the rear compartment to the forward compartment on rearward movement of the plunger; causing mixture of the solid and liquid components, establish communication with said needle on rearward movement of the needle, discharge gas by forward movement of the plunger and piston, aspirate as desired to confirm a desired location of the hypodermic needle on insertion, and permit hypodermic injection of the package contents, all mixing and injecting operations being sterilely performed.

2. A combination aspirating hypodermic syringe and two-compartment package comprising:

a generally cylindrical barrel, having at the near end a barrel flange, and at the forward end a barrel neck;

a resilient piston in said barrel and located towards the center of said barrel, dividing the barrel into a forward compartment, for a solid component, and a

rear compartment, for a liquid component, and on said piston, at least one annular ring in sealing engagement with said barrel, said piston having therein an axial passage and a plunger retaining groove in said passage, and coaxial with said passage, and at the forward end thereof a resilient valve sleeve, concentrically spaced from the main portion of the piston;

a plunger extending from the rear into said barrel, the forward end of the plunger having therein a boss extending into the axial passage in said piston, and having on said boss a cooperating enlargement entering into and cooperating with the groove in the passage in said piston, thereby firmly retaining the piston on said plunger, the plunger boss having such size as to extend into and at least slightly expand the valve sleeve on the piston, and in said plunger a liquid conduit extending from the portion of the plunger behind the piston in the rear compartment to the boss portion of the plunger inside of the resilient valve sleeve, and on the rear of the plunger means for attaching a plunger extension;

a rear retaining stopper, spaced from the rear of the plunger, a vacuum breaking sleeve fitting around the rear of the the plunger, and into the rear retaining stopper, a guide bead on said sleeve, at the front thereof, which prevents the sleeve from passing rearward through the rear retaining stopper, and which slides forward during forward operation of the plunger to break the vacuum behind the piston, and a rear stopper seal to hold the rear retaining stopper in place adjacent the barrel flange;

a puncturable stopper in the barrel neck having therein at the forward end a needle port, and at the rear end a needle point dimple, the solid membrane of the stopper therebetween being readily puncturable, and a stopper head on said stopper; a puncturable-stopper seal retaining the said stopper in the barrel neck;

a double ended hypodermic needle, a needle hub surrounding said needle, dividing the needle into a short end and a long end, said short end extending into the needle port;

a combination needle guard and plunger extension fitting over the front of the barrel and stopper assembly, and having a thumb piece at the rear, and means for connecting to the plunger at the front thereof, said guard having therein a hub chamber, and a needle sheath, into which fits the hub and needle respectively, and also having therein a sterilizing vent, to permit entry of a sterilizing gas, and an air filter adjacent said vent;

said combination cooperating to maintain the contents of the forward compartment moisture-free during storage, and to transfer liquid from the rear compartment to the forward compartment on rearward movement of the plunger, causing mixture of the solid and liquid components, establish communication with said needle on rearward movement of the needle, discharge gas by forward movement of the plunger and piston, aspirate as desired to confirm a desired location of the hypodermic needle on insertion, and permit hypodermic injection of the package contents, all mixing and injecting operations being sterilely performed.

3. A combination aspirating hypodermic syringe and two-compartment package comprising:

a generally cylindrical barrel, having at the rear end a barrel flange, and at the forward end a barrel neck;

a resilient piston in said barrel and located towards the center of said barrel, dividing the barrel into a forward compartment, for a solid component, a solid medicament compartment therein, and a rear compartment, for a liquid component, a liquid component therein, and on said piston, at least one annular ring in sealing engagement with said barrel, a one-

way valve means to transfer the liquid component into the compartment with the solid component; a plunger extending from the piston, and on the rear of the plunger means for attaching a plunger extension;

a rear retaining stopper, spaced from the rear of the plunger, a vacuum breaking sleeve fitting around the rear of the plunger, and into the rear retaining stopper, a guide bead on said sleeve, at the front thereof which prevents the sleeve from passing rearward through the rear retaining stopper, and which slides forward during forward operation of the plunger to break the vacuum behind the piston, and a rear stopper seal to hold the rear retaining stopper in place adjacent the barrel flange;

a puncturable stopper in the barrel neck having therein at the forward end a needle port, and at the rear end a needle point dimple, the solid membrane of the stopper therebetween being readily puncturable, and a stopper head on said stopper; a puncturable-stopper seal retaining the said stopper in the barrel neck;

a double ended hypodermic needle, a needle hub surrounding said needle, dividing the needle into a short end and a long end, said short end extending into the needle port;

a combination needle guard and plunger extension fitting over the front of the barrel and stopper assembly, and having a thumb piece at the rear, and means for connecting to the plunger at the front thereof, said guard having therein a hub chamber, and a needle sheath, into which fits the hub and needle respectively, and also having therein a sterilizing vent, to permit entry of a sterilizing gas, and an air filter adjacent said vent;

said combination cooperating to maintain the contents of the forward compartment moisture-free during storage, and to transfer liquid from the rear compartment to the forward compartment on rearward movement of the plunger, causing mixture of the solid and liquid components, establish communication with said needle on rearward movement of the needle, discharge gas by forward movement of the plunger and piston, aspirate as desired to confirm a desired location of the hypodermic needle on insertion, and permit hypodermic injection of the package contents, all mixing and injecting operations being sterilely performed.

4. A combination aspirating hypodermic syringe and two-compartment package comprising:

a generally cylindrical barrel, having at the rear end a barrel flange, and at the forward end a barrel neck;

a resilient piston in said barrel and on said piston at least one annular ring in sealing engagement with said barrel; said piston dividing the barrel into a front and a rear storage compartment; a separate component in each compartment during storage; a rear retaining stopper to prevent loss of contents from the rear compartment; one-way valve means to transfer the contents from the rear compartment to the front compartment at time of use;

a plunger extending from the rear of said barrel to said piston, and on the rear of the plunger, means for attaching a plunger extension;

a puncturable stopper in the barrel neck having therein at the forward end a needle port, and at the rear end a needle point dimple, the solid membrane of the stopper therebetween being readily puncturable, said stopper substantially filling said neck, and thereby minimizing dead space, a stopper seal retaining the said stopper in the barrel neck;

a double ended hypodermic needle, a needle hub surrounding said needle, dividing the needle into a short

end and a long end, said short end extending into and being stored in the needle port;

a combination needle guard and plunger extension fitting over the front of the barrel and stopper assembly, having a thumb piece at the rear and means for connecting to the plunger at the front thereof, said guard having therein a hub chamber and a needle sheath, into which fits the hub and needle respectively, said hub chamber being deep enough to hold the needle hub during storage, with the thumb piece positioned against the seal, and also having therein a

sterilizing vent, to permit entry of a sterilizing gas, and an air filter adjacent said vent.

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UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 3,342,180 September 19, 1967

Ellsworth Roland Sandhage et al.

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 1, line 59, for "medicant" read -- medicament --; line 70, for "reconstruction" read -- reconstitution --; column 2, line 21, for "Syringe."" read -- Syringe,"Dec. 15, 1964. --; column 4, line 1, after "valve" insert -- sleeve --; column 6, line 3, for "components" read -- component --; line 71, for "near" read -- rear --; column 7, line 9, for "therein" read -- thereon --; line 72, for "compartment" read -- component --.

Signed and sealed this 4th day of March 1969.

(SEAL)

Attest:

Edward M. Fletcher, Jr.

Attesting Officer

EDWARD J. BRENNER

Commissioner of Patents