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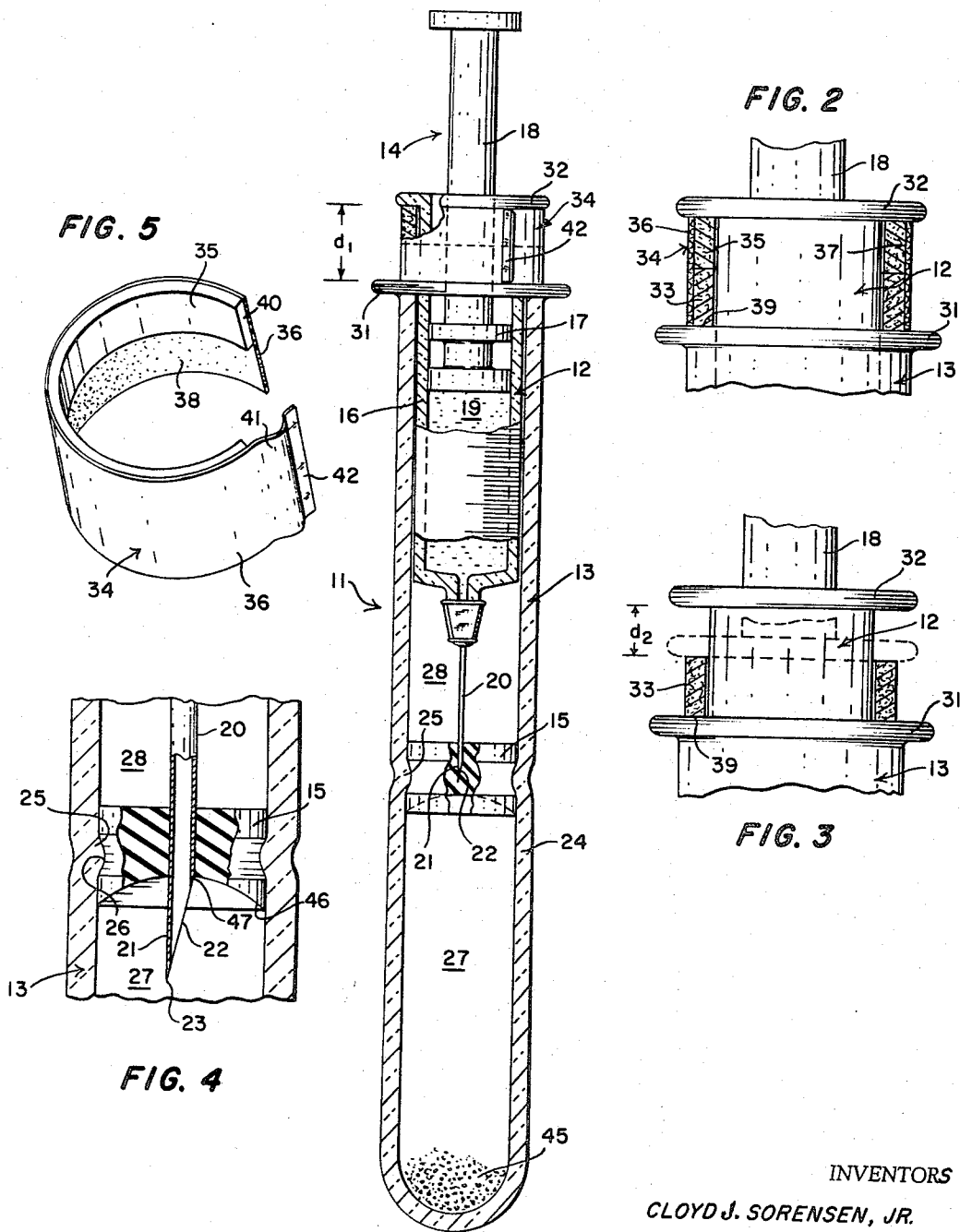
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SYRINGE ASSEMBLY UNIT

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FIG. 1



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SYRINGE ASSEMBLY UNIT

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ABSTRACT OF THE DISCLOSURE

A composite packaged unit containing a syringe and two substances that are isolated from each other until the time of use comprises a tubular vial in the mouth of which the syringe is mounted with the open end of its hypodermic needle imbedded in a fixed plug that also defines an isolated mixing chamber at the bottom of the vial. The syringe is loaded with one substance, and the other substance is disposed in the mixing chamber. A special removable holding collar arrangement maintains the syringe and vial in the foregoing relation in the package. After removal of the holding collar, the syringe can be advanced further into the vial to project the needle tip through the plug and enable discharge of the entire syringe contents into the mixing chamber and, after mixing, withdrawal of all of the mixture into the syringe. Now the syringe is pulled out of the remainder of the package and is ready for use.

BACKGROUND OF INVENTION

(a) *Field of invention.*—In recent years there has been an increasing number of drugs, especially the antibiotics, developed that in solution form for injection are highly unstable. The use of freeze drying or lyophilization process allows them to be stored in this dry form for a much longer period of time. These dry medications are then mixed with the proper diluent just prior to injection.

The advantages of storing many medications in the dry or lyophilized form are numerous, and the number of medications prepared and stored in this manner are increasing. While many liquid injectable medications will maintain their specified potency even under refrigeration for only a few hours, the same drugs in dry form have a shelf-life of several years.

The invention relates to the composite packaging of a loaded syringe containing one substance with another substance maintained in isolation until it is desired to use the hypodermic.

A few examples of drugs presently marketed in the dry form that would lend themselves to the invention include rattlesnake antivenom, intravenous estrogens (used in hemorrhage), various cortisone-like drugs used in acute shock, injectable stimulants used in various emergencies including cardiac arrest and overdoses of depressive drugs such as sleeping pills, a great number of injectable antibiotics, an antiepileptic injectable drug, several injectable narcotics, a number of injectable vitamin products, and several diuretic injectable products.

(b) *Prior art.*—Many methods have been proposed and developed for packaging and storage of these drugs and procedures for their mixing and injection. While most of these methods do finally meet the needs, each has considerable complications in structure or in procedures, or both, which are costly in production and packaging, and some are difficult to use.

Examples of such are disclosed in the U.S. Letters Patents to Lockhart No. 2,724,383; Ulert No. 2,772,677 and Neilsen No. 3,098,483.

SUMMARY OF INVENTION

The invention contemplates an entirely novel packaging system wherein a syringe assembly unit loaded with one

substance is safely packed with a mixing vial containing another substance in isolation, and wherein the unit components may be speedily rearranged in position for mixing the substances and loading the mixture into the syringe and then extracting the charged ready for use syringe by discarding the remainder of the package, in a manner much more efficient and involving less skill on the part of the operator than in hitherto known devices.

It is a major object of the invention to provide a novel packaged syringe assembly unit wherein a syringe preloaded with one substance is mounted in a mixing vial with its needle tip imbedded in a fixed plug that also provides an isolation chamber in the bottom of the vial containing another substance, and wherein removal of a special holding device enables the syringe to be moved to dispose the needle tip within the mixing chamber so that the substance in the syringe may be discharged into the mixing chamber, mixed with the other substance and drawn back into the syringe in a simple contamination-free operation.

A further object of the invention is to provide a novel positioning collar arrangement in the foregoing for pre-determining the operative positions of the syringe in the vial.

Another object of the invention is to provide in the foregoing a novel recessed plug structure whereby withdrawal of all of the mixture into the syringe is assured.

BRIEF DESCRIPTION OF DRAWINGS

FIGURE 1 is a side elevation mainly in section showing the syringe assembly unit according to a preferred embodiment of the invention;

FIGURE 2 is a fragmentary view of the upper part of the unit showing the holding collar in section;

FIGURE 3 is another fragmentary view of the upper part of the unit as it appears after the holding collar has been removed, and showing in dotted lines the downwardly displaced position of the syringe;

FIGURE 4 is another fragmentary view in section showing internal structure and the disposition of the open tip of the syringe needle after the syringe has been downwardly displaced to the dotted line position indicated in FIGURE 3; and

FIGURE 5 is a generally perspective view showing the holding collar apart from the unit.

PREFERRED EMBODIMENTS

In its preferred embodiment the unit will be described as a package wherein the syringe is preloaded with a diluent liquid for a dry powder that is contained isolated therefrom.

This wet-dry tube syringe package is mainly intended for the storage, mixing, and injection of dry or lyophilized medications. It eliminates most of the numerous conventional steps used in storing, preparing, and administering a hypodermic injection, thus not only saving time, but reducing the chances of contamination. Once used, it is a disposable unit.

The packaged and prepared syringe assembly unit 11 is shown in FIGURE 1 as comprising a syringe 12 thrust into the open end of a vial 13, a syringe positioning and holding collar arrangement indicated at 14, and a stationary plug 15 anchored within the vial.

Syringe 12 is a conventional type having a cylindrical barrel 16 containing a slidable plunger 17 operated by stem 18, a chamber 19 that in the preferred embodiment is filled with a liquid and the usual hypodermic needle 20 that has its tip 21 cut on an angle to provide a bias cut opening at 22 and to have a very sharp terminal edge 23.

Vial 13 is a cylindrical plastic, glass or like tube 24 that is pinched intermediate its ends to provide an internal annular rib 25 extending into a peripheral groove 26 in

plug 15 which is an integral body of rubber or like resilient sterile material, whereby plug 15 is anchored within the vial to separate the interior of the vial into a lower mixing chamber 27 adapted in the syringe unit assembly to contain a powder or other material to be mixed with the liquid in syringe barrel 19 and an upper chamber 28 adapted to contain the syringe 12 in the assembly unit. Plug 15 is peripherally sealed with the inner surface of vial 13.

Vial 13 has a top radially projecting flange 31, and syringe 12 has a similar radially projecting top flange 32 on the barrel. The collar assembly 14 is provided axially between flanges 31 and 32 for accurately positioning the syringe 12 in the unit assembly, and it may comprise a relatively fixed collar element 33 and a removable holding collar element 34.

Fixed collar element 33 is an axially stiff cardboard, plastic or like cylinder that surrounds the syringe barrel with a free sliding fit and it preferably is sealingly attached, as by an adhesive layer at 39, to the vial flange 31 so as to effectively constitute a rigid extension of the vial. In some embodiments in fact element 33 may be an integral tubular extension of vial 13.

Removable collar element 34 comprises an axial stiff, axially split cylinder 35 that is interposed between fixed collar 33 and the syringe flange, and an outer lamination 36 of cellulose tape or the like that (FIGURES 1 and 5) is wide enough to surround both collars 33 and 34. The upper part of tape 36 is permanently bonded to the split upper collar section 34 as at the interface 37, and it has a pressure sensitive adhesive area 38 (FIGURE 5) where it extends around the fixed collar 33. At one end (FIGURE 5) tape 36 ends flush with one edge 40 of the collar split, and at its other end tape 36 extends full width as a pull tab 41 that bridges the collar split and has pressure sensitive adhesive on its inner surface to form a tight band in the assembly unit.

Preferably the terminal 42 of tab 41 has no adhesive so as to be available for a finger grip, and usually the top and bottom edges of tape 36 are such as to provide annular air tight seals with the syringe and vial flanges so that no impurities may pass into the vial through the collar arrangement.

In the package syringe assembly unit, the barrel of syringe 12 has a smooth snug sliding fit within vial chamber 28, and the axial length d_1 of the collar arrangement is such as to limit displacement of the syringe 12 into the vial to the condition shown in FIGURE 1 wherein the tip 21 of the needle is entirely imbedded in plug 15 and closed thereby. With the holding collar in place as in FIGURE 1, this position of the syringe cannot be changed, and syringe 12 cannot be accidentally displaced further into the vial. Even an accidental slight push on plunger stem 18 will not result in any of the liquid in syringe chamber 19 entering the mixing chamber 27.

At this time the syringe is fully loaded with the liquid to be mixed, plunger 17 being in its uppermost position. The powder, liquid or other material to be mixed with the contents of the syringe is disposed in the bottom of mixing chamber 27 and indicated at 45.

The foregoing unit may be packed for shipment and/or stored for a considerable period, with the ingredients of the syringe and mixing chambers held apart in sealed isolation.

When it is desired to use the syringe assembly unit, the nurse, doctor or other operator merely pulls outwardly on tab 41 to split holding collar 34 and remove it from around the syringe barrel. The removed holding collar element is shown in FIGURE 5, and the relationship of parts after removal of collar 34 is shown in FIGURE 3. Now syringe flange 32 is spaced accurately a distance d_2 from the upper edge of fixed collar 33.

The operator now pushes the entire syringe bodily, without pushing in stem 18, further into the vial until syringe flange 32 abuts the upper edge of fixed collar 33.

The distance d_2 is such that needle tip 21 will be thrust through plug 15 to dispose its bias cut opening 22 entirely out of the plug.

As shown in FIGURE 4 the lower end of plug 15 is preferably a rounded concave downwardly open well 46 and in its lowermost position the uppermost edge 47 of needle opening 22 is disposed substantially flush with the deepest central bottom of well 46, for an important purpose to appear.

Now plunger 17 is depressed to discharge the entire contents of the syringe into chamber 27, and the unit may be shaken to insure proper mixing.

After the mixture in chamber 27 is complete, the entire unit is inverted so that the vial is uppermost, and the plunger 17 is slowly pulled back toward its FIGURE 1 position thereby drawing the mixture into the syringe barrel.

Now the syringe is fully charged with the desired mixture. By locating the syringe opening 47 at the bottom of well 46 the invention insures that all of the mixture is drawn out of chamber 27. This is important where dosage amounts are critical.

To use the loaded syringe, the operator now merely pulls it out of the vial, and discards the vial. The needle offers no resistance to this withdrawal, and a finger grip is afforded at flange 32.

The foregoing wet-dry tube packed syringe unit is not limited to use with a dry powder and its proper diluent, but works equally well for example with two liquids that are slowly incompatible over long periods of storage. One example here is a multiple vitamin solution containing vitamin B-12. The storage life of such a product is greatly increased if the vitamin B-12 is eliminated or added at the time of injection. A comparatively new example of potential use of the wet-dry tube pack is with two liquids such as a vaccine for diphtheria, tetanus, and pertussis with polio combined. Storage with the polio vaccine added presents a problem, but if the polio vaccine is separated from the "D.P.T." and is added just prior to injection, there is no problem.

The wet-dry tube packed syringe is intended to be a disposable unit in either glass or plastic of conventional "throw-away" syringe design. It can be used for direct injection into the patient, for injection of additional drugs into an IV bottle or IV tubing, or in almost any manner that a conventional syringe is used. While hospitals would be the greatest potential market, it would serve well in a doctor's bag, especially with drugs that in the liquid form would require refrigeration. Further economy can be accomplished with the unit in that the outside storage tube could be used in the initial lyophilization process of the drug and the syringe unit inserted at the time of assembly in the factory.

The time saved in mixing and administration of the drug using the wet-dry tube packed unit is also an added advantage in acute medical emergencies. After pulling the pull tab and thus removing the holding collar, a single forward movement, that is pushing the syringe down onto the outside tube, pierces the stationary plug. Then by pushing on the plunger of the conventional type syringe contained, the diluent is forced into the medication chamber, the mixing is accomplished by gentle shaking or rotation of the unit, the pack is then inverted with the medication chamber up, and the mixed solution is drawn back into the syringe with the plunger. The syringe is then withdrawn from the glass vial or tube and is ready for hypodermic injection.

The wet-dry tube packed syringe unit of the invention has the following advantages.

(1) A single syringe-storage unit is provided that eliminates several steps in the usual storage, mixing, and hypodermic injection in a number of commonly used medications.

(2) Faster mixing of diluent and powdered medication in that the only steps required for mixing are the re-

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removal of the holding collar, pressing down of the syringe to pierce the stationary plug, and pushing in the syringe plunger, allowing the diluent to enter the medication chamber of the vial.

(3) The unit contains only three parts in addition to the conventional disposable hypodermic syringe, so that the package lends itself to very economical manufacture and use as a completely disposable unit.

(4) There is no waste of mixed medications because the well of the stationary plug is designed to allow removal of all the mixture, and the hypodermic needle position in the well is predetermined to exact specifications by the distance it travels when puncturing the stationary plug.

(5) The simplicity of the design and function of the wet-dry tube packed syringe unit allows for use with standard and accepted hypodermic injection procedures.

(6) The construction and function of this wet-dry tube packed syringe unit allows for rapid mixing and use of many types of injectable medications used in acute medical emergencies as well as eliminating the possible contamination through several steps in conventional mixing.

(7) The stationary plug, made of accepted conventional material, and inserted in the vial at the time of assembly, tightly seals the medicine chamber. The designed thickness of the stationary plug allows the hypodermic needle tip to be sufficiently imbedded to prevent leakage of the contained diluent and insuring the complete separation of the dry medicine and diluent in storage and shipment. Only at the time of mixing and only after the removal of the holding collar is it possible to force the hypodermic needle tip through the stationary plug, into the medicine chamber.

(8) The holding collar, made of accepted conventional material, has three main functions, (1) it prevents the premature forward movement of the syringe and needle; (2) it establishes the exact distance of the forward movement of the syringe and needle, and the final position of the needle tip in the stationary plug well; and (3) it completely seals the upper part of the glass vial, thus insuring sterility, and at the same time preventing undesired movement of syringe.

What is claimed and desired to be secured by Letters Patent is:

1. A syringe assembly unit package comprising a vial having an open mouth, a stationary plug in said vial defining an isolated mixing chamber in the lower end of said vial, a hypodermic syringe having its barrel slidably mounted within the vial and extending through the vial mouth and a discharge needle projecting into the vial, and spacer means interposed between said vial and syringe and comprising detachable means for so limiting initial introduction of said syringe into said vial that the open end tip of said needle is imbedded within said plug, said detachable means when removed being separated from said unit and permitting said syringe to be further advanced into said vial sufficiently to extend the open end of said needle through said plug into said chamber.

2. In the unit package defined in claim 1, said syringe being preloaded with one substance and said chamber containing another substance, said substances being isolated while said syringe is held initially by said last named

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means, and said spacer means providing a seal against entry of foreign matter into said vial.

3. In the unit package defined in claim 1, said spacer means comprising means to limit said further advance to a predetermined amount whereby the open end of the needle is in predetermined communication with said chamber.

4. In the unit package defined in claim 3, said plug having a well facing said chamber and said last means being adapted to limit further advance of said syringe to dispose an edge of said needle opening substantially flush with the bottom of said well.

5. In the unit defined in claim 4, said needle having a bias cut opening at said tip, and said well being a downwardly concave recess in the plug having a bottom surface substantially intersecting the upper edge of said needle opening in the advanced position of said syringe.

6. In the unit defined in claim 1, said detachable means comprising an axially rigid removable holding member surrounding the projecting part of said syringe.

7. In the unit defined in claim 6, said holding member being a longitudinally split collar.

8. In the package unit defined in claim 1, said spacer means comprising axially rigid means consisting of a fixed collar surrounding the vial and a removable split collar interposed between the fixed collar and the syringe, the relative axial lengths of said collars defining the initial position of said syringe open end within the plug and the advanced position of said syringe open end within said chamber.

9. In the package unit defined in claim 8, said plug having a downwardly open central well and said syringe having a bias cut open end on its needle, and said fixed collar, following removal of the removable collar, limiting advance of the syringe and projection of the needle through said plug to dispose the upper edge of said needle open end substantially flush with the bottom of said well.

10. In the package unit defined in claim 8, said removable collar comprising an external tape adapted to bridge both collars in the assembly and seal against the entry of foreign matter into said vial.

11. A syringe assembly unit package comprising a vial having an open mouth, a stationary plug in said vial defining an isolated mixing chamber in the lower end of said vial, a hypodermic syringe having its barrel slidably extending through the vial mouth and a needle having its open ended tip imbedded in said plug, and combined spacer and seal means interposed between said vial and syringe for limiting introduction of said syringe into said vial and sealing the upper end of said vial, said means comprising means removable to permit said syringe to be advanced into said vial sufficiently to extend the open end of said needle through said plug into said chamber.

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