

- [54] **WET-DRY ADDITIVE ASSEMBLY**
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Related U.S. Application Data

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[51] Int. Cl. **A61j 1/00**
[58] Field of Search **128/DIG. 28, 272, 218 M, 128/218 NV, 218 R, 218 N, 215, 216, 221, 218 D, 218 DA**

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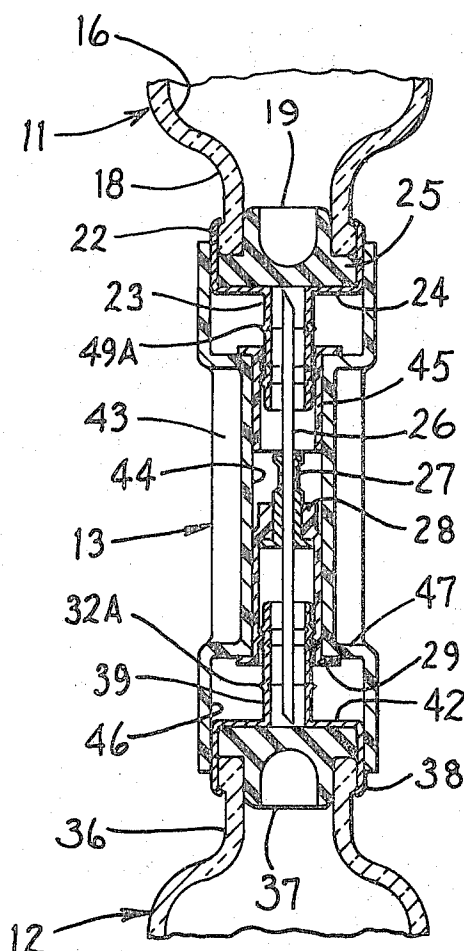
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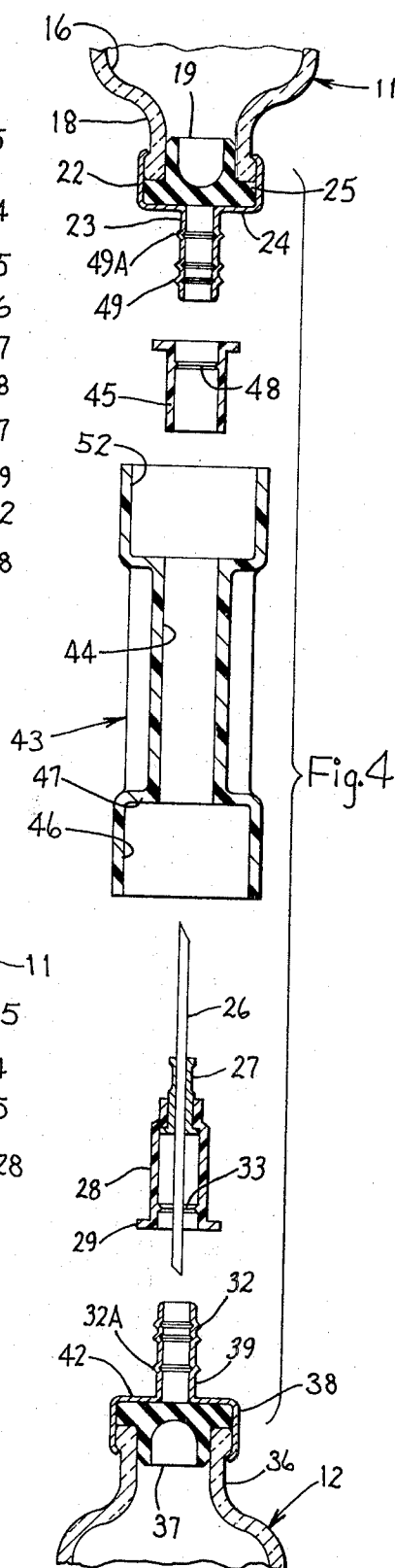
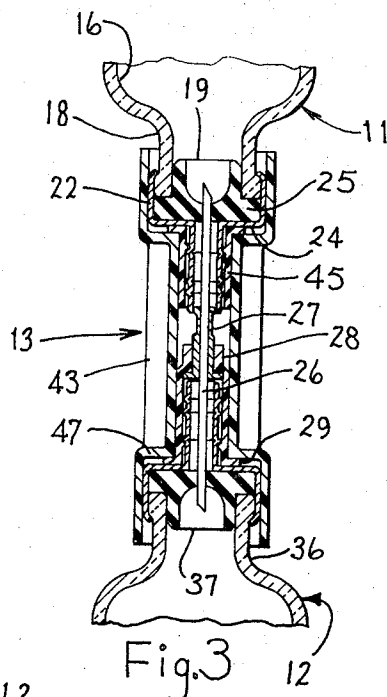
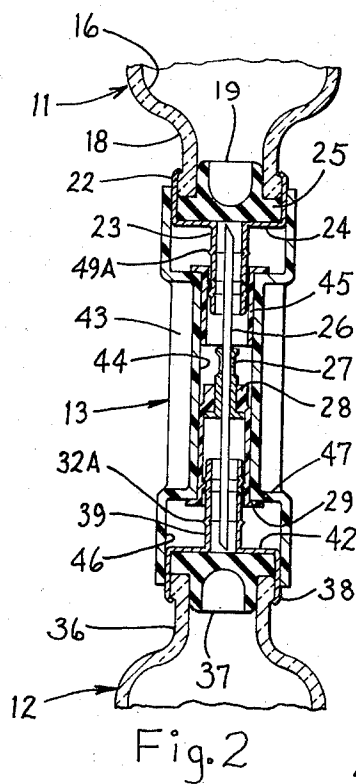
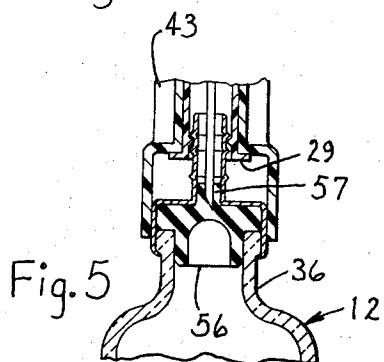
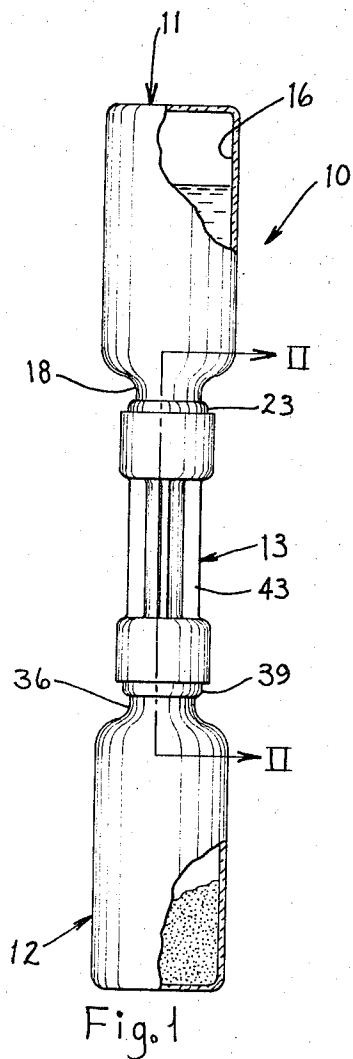
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ABSTRACT

A pair of vials each having a perforable seal closing an opening in one end thereof and a hollow cylindrical portion of reduced diameter adjacent the seal. A double-ended cannula is slidably receivable into the reduced end portions of the vials for perforating the seals to communicate with and between the interiors of the vials. A support on the cannula is removably engageable with the reduced portion on one of the vials. An elongated tubular sheath extends between and is slidably supported upon the cannula support and upon both of the vials.

4 Claims, 5 Drawing Figures





WET-DRY ADDITIVE ASSEMBLY

This application is a Continuation-in-Part of patent applications Ser. No. 149,321, filed June 2, 1971, now U.S. Pat. No. 3,788,369 and entitled "APPARATUS FOR TRANSFERRING LIQUID BETWEEN A CONTAINER AND A FLEXIBLE BAG," and Ser. No. 212,592, filed Dec. 27, 1971, now U.S. Pat. No. 3,826,260 entitled "VIAL AND SYRINGE COMBINATION."

BACKGROUND OF THE INVENTION

This invention relates in general to a device for storing and supplying additives or medicaments and, more particularly, to a type thereof including one sealed vial holding a diluent, another sealed vial holding an additive or medicament and interconnecting means for holding the vials together and for effecting selective communication between said vials, whereby said diluent can be mixed with said additive and thereafter fed into a passageway, such as a tube connected to a patient by a cannula for intravenous feeding.

Persons familiar with the preparation and use of parenteral additives or medicaments have long been aware of the fact that certain additives, for example, tend to lose their effectiveness rather soon after they are mixed with a diluent in preparation for administration. Thus, they must be stored in a dry or non-liquid condition and then mixed with a diluent, preferably just before the additive is supplied, for example, to an intravenous bottle.

In the past, it has been common practice to furnish separate vials of dry additive and diluent and to use a conventional syringe for transferring the diluent from one vial to another for the purpose of mixing the two in order to administer the additive. This arrangement involves the risk of contamination, the risk of improper dose and even the risk of mixing the wrong ingredients where the administration of additive must be handled by unskilled persons.

Numerous attempts have been made to solve the foregoing problems as by furnishing syringes and vials connected together so that the supply and administration means are part of a package which is more readily usable. However, the previous combinations or packages involving an additive and a diluent have not proven satisfactory, heretofore, for a variety of reasons. For example, they have not satisfactorily avoided contamination, they have been too delicate for conventional storing and handling procedures, they have been too susceptible to accidental actuation whereby the materials are mixed too soon, and in general they have been almost as complicated and delicate to operate as the devices which they were intended to replace.

Accordingly, a primary object of this invention is the provision of a double vial assembly with a connecting structure between the vials whereby the sterility of the diluent and the additive or medicament in the vials is maintained prior to and during the mixing of the diluent with the additive and, at the same time, the cannula for the administration of the solution is shielded from contamination during the mixing and up to the very moment of insertion into the intravenous system or bottle.

A further object of this invention is the provision of a double vial assembly, as aforesaid, in which injectable additives or medicaments can be safely stored for relatively long periods of time, as in drug stores, clinics and

doctor's offices, along with a suitable diluent in a single package capable of mixing the diluent and additive without any likelihood of contaminating the needle, the diluent or the additive.

A further object of this invention is the provision of an assembly, as aforesaid, which is rugged so that it cannot be readily damaged during shipment or storage, which is constructed so that accidental mixing of the diluent and the additive is positively opposed and, yet, wherein intentional mixing of the additive and the diluent can be effected safely, easily and quickly in preparation for supplying of the solution by any person capable of following simple instructions.

Other objects and purposes of this invention will become apparent to persons familiar with apparatus of this type upon reading the following description and examining the accompanying drawings, in which:

FIG. 1 is a side elevational view of a double vial assembly embodying the invention.

FIG. 2 is an enlarged sectional view taken along the line II—II in FIG. 1.

FIG. 3 is a sectional view similar to FIG. 2 and showing the parts thereof in different operational positions.

FIG. 4 is an exploded view of the structure appearing in FIG. 2.

FIG. 5 is a fragment of FIG. 2 showing a modified structure.

For convenience in description, the terms "upper," "lower" and words of similar import will have reference to the double vial assembly or parts thereof as appearing in FIGS. 1 and 2. The terms "inner," "outer" and derivatives thereof will have reference to the geometric center of the assembly and major components thereof.

SUMMARY OF THE INVENTION

The objects and purposes of the invention, including those set forth above, have been met by providing an assembly including one sealed vial containing a diluent, another sealed vial containing an additive or medicament, which may be liquid or dry, and a connection structure that includes a sheath and a cannula which extend between and are supported upon the sealed ends of the two vials. The connection structure is arranged so that the sharpened ends of the cannula can be held spaced from, or slightly embedded in, the seals over the open ends of the vials. By effecting relative movement of the vials toward each other, the cannula pierces the seals and thereby communicates with and between the interiors of the vials. The additive vial is under vacuum or the diluent vial is pressurized to effect movement of the diluent from its vial through the cannula into the additive vial after which the additive is dissolved in the diluent by gently shaking the assembly. The diluent vial and sheath are now removed from the assembly so that the cannula is exposed and can be injected into an intravenous system of bottle which is also under vacuum.

DETAILED DESCRIPTION

The double vial assembly 10 (FIGS. 1 and 2) is comprised of a vial 11 connected to a similar or identical vial 12 by an intermediate structure 13. The vial 11 has a chamber 16, and the lower open mouth portion 18 thereof is of reduced diameter and is covered by a seal 19 which may be a resilient, flanged stopper. The seal is held in place by the integral enlarged portion 22 of

the sleeve 23 which is preferably fabricated from metal. The sleeve 23 has a shoulder 24 which forms part of the enlarged portion 22 and presses the flange 25 of the seal 19 firmly against the lower end of the vial 16.

The vial 12 has an open mouth 36 which is covered by a seal, such as the flanged stopper 37, which is in turn held in place by the enlarged lower portion 38 of the sleeve 39. That is, the sleeve 39 has an integral shoulder 42 which bears downwardly against the flange of the stopper 37 thereby holding it tightly against the upper end 36 of the vial 12.

A cannula 26, which is sharpened on both ends, has a hub 27 rigidly secured thereto and spaced from both ends thereof. A tubular cannula support 28 has one end thereof secured to the hub 27 which it concentrically encircles. The remainder of the tubular support 28 is spaced radially outwardly from the cannula and projects toward the lower end thereof. The tubular support 28 has an integral flange 29 at its lower end. The hub 27 may be made from metal or plastic and the tubular support 28 is preferably fabricated from plastic. In some circumstances, the hub 27 may be integral with and part of the tubular support 28.

The upper end portion of the sleeve 39 (FIG. 4) and the lower portion of the tubular support 28 have interfering deformations, such as annular ridges 32 and 33, respectively, by which the spaced relationship between the lower end of the cannula 26 and the seal 37 is determined. This spaced position is shown in FIG. 2. By moving the tubular support 28, hence the cannula 26, downwardly, the ridge 33 on the tubular support 28 is moved downwardly from between the two uppermost ridges 32 on the sleeve 23 until said ridge 33 moves past the lowermost ridge 32A, during which the seal 37 is penetrated by the cannula 26. The ridge 32A and the ridge 33 hold the cannula in the penetrating position.

A substantially cylindrical sheath 43 (FIG. 4) extends from the enlarged portion 22 of sleeve 23 to the enlarged portion 38 of sleeve 39. Said sheath 43 has a central cylindrical opening 44 the lower portion of which is sleeved snugly but slidably upon the tubular support 28. Said sheath has a lower enlarged opening 46 with an inside diameter approximately equal to the outside diameter of the enlarged portion 38 of sleeve 39. Said lower opening 46 is also slightly larger than the flange 29 at the lower end of the tubular support 28. Thus, as the sheath 43 is moved downwardly relative to the vial 12, the engagement between the flange 29 and the shoulder 47 at the upper end of the lower opening 46 act to move the tubular support 28, hence the cannula 26, downwardly with the sheath 43. At the same time, the enlarged portion 38 is slidably received upwardly into the opening 46 in snug engagement with the lower part of sheath 43 defining the peripheral wall of the opening 46.

A flanged sleeve 45 is snugly disposed in the upper end of the central opening 44 (FIG. 3). Said sleeve has an annular ridge 48 which coacts with annular ridges 49 on the sleeve 23. In this case, there are three ridges 49, two near the lower end of the sleeve and one near the upper end. The ridge 48 is located between the ridges 49 when the upper end of the cannula 29 is spaced from, or at least is not penetrating through, the stopper 19. The sheath 43 can be moved upwardly relative to the sleeve 23 into a position where the ridge 48 is above the uppermost ridge 49A, at which time the cannula 26 penetrates completely through the stopper

19. Also, during this movement, the enlarged portion 22 on the sleeve 23 is slidably but snugly moved downwardly into the enlarged opening 52 at the upper end of the sheath 43 and coaxial with the central opening 44.

OPERATION

The operation of the double vial assembly (FIG. 1), to which this application applies, will be apparent to skilled persons upon reading the foregoing description. However, for convenience, such operation will now be summarized briefly.

In preparation, the vial 12 will be filled with a medicament, which may be a liquid or a dry powdery material produced by evaporative procedures, and the pressure in the vial 12 will preferably be reduced (that is, less than atmospheric). The stopper 37, which is held in place by the sleeve 39, will be unperforated, and the vial 11 may be pressurized.

The vial 11 will contain a liquid and the sleeve 23 (FIG. 2) will hold the seal 19, which is also unperforated. The cannula support 28, which is secured to the cannula 26 through the hub 27, will be mounted upon the upper end of the sleeve 39 so that the ridge 33 near the lower end of the interior wall of the tubular support 28 is located between the two ridges 32 near the upper end of the sleeve 39. In this position, the cannula will be spaced from the seal 37.

The sheath 43 is now sleeved downwardly over the cannula 26 at the tubular support 28 until the shoulder 47 engages the flange 29. At the same time, the lower end 46 of the sheath 43 will preferably slightly overlap the enlarged portion 38 of the sleeve 39, which portion 38 surround the vial mouth 36. The sheath 43 and vial 12 can now be simultaneously manually engaged in one hand while the vial 12 is engaged in the other hand and the sleeve 23 on the vial 11 is slidably inserted first into the enlarged opening 52 at the upper end of the sheath and then into the sleeve 45 in the upper end of the central opening 44. This sliding connection will be terminated when the ridge 48 on the wall defining the opening through the sleeve 45 is located between the ridges 49 on the sleeve 23. At this time, the upper end of the sheath 43 will be preferably telescoped slightly over the vial mouth 18, as by engaging the enlarged portion 22 of the sleeve 23.

The assembly 10 is now in condition for shipment and/or storage as long as desired. While the diluent has been disclosed in the upper vial 11 and the medicament in the lower vial 12, this situation can be reversed. Also, it will be seen that the flanged sleeve 45 can be an integral part of the sheath 43.

When it becomes desirable to administer the medicament in the vial 12, the two vials 11 and 12 are either simultaneously or sequentially urged toward the sheath so that the cannula perforates and extends completely through the seals 19 and 37, thereby communicating with and between the chambers within the two vials. The diluent in vial 11 will now move downwardly due to the differential pressure through the cannula into the vial 12.

By a gentle shaking action, the powdered or liquid material within the lower vial 12 is mixed with the diluent from the upper vial 11. If the mixed diluent and additive must be administered at once, the sheath 43 and vial 11 are moved upwardly away from the vial 12 and the tubular cannula support 28 so that the upper end

of the cannula 26 is exposed. The cannula will remain in position with respect to the vial 12 due to the interengagement of the ridges on the sleeve 39 with the ridge on the tubular support 28. That is, ridge 33 will be under the ridge 32A and the upper ridges 32 may be somewhat embedded in the interior wall of the tubular support 28. The cannula 26 is inserted downwardly into an intravenous bottle, for example, in which the pressure is reduced so that the liquified additive is withdrawn from the vial 12 through the cannula 26 and into the I.V. bottle.

In a modified construction, the stopper 37 of FIG. 3 may be replaced by the stopper 56 (FIG. 5) having an upward extension 57 into which the lower end of cannula 26 is embedded to seal the end thereof.

Although particular preferred embodiments of the invention have been disclosed in detail for illustrative purposes, it will be recognized that variations or modifications of the disclosed apparatus, including the rearrangement of parts, lie within the scope of the present invention.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A double vial assembly for storing a medicament, comprising:

first vial means defining a chamber therein and having a first elongated sleeve-like end portion of reduced diameter, said first sleeve-like end portion having a first flow opening therethrough for providing the only communication with said chamber;

perforable seal means blocking said first opening, said seal means being spaced inwardly from the outer end of said first opening as defined adjacent the free end of said first sleeve-like end portion;

second vial means defining a chamber therein and having a second elongated sleeve-like end portion of reduced diameter, said second sleeve-like end portion having a second flow opening therethrough for providing the only communication with said chamber in said second vial means;

perforable stopper means blocking said second flow opening, said perforable stopper means being spaced inwardly of said second sleeve-like opening from the outer end thereof as defined adjacent the free end of said second end portion;

elongated double ended cannula means extending between said first and second vial means, said cannula means having one end portion thereof loosely but slidably disposed within said first sleeve-like end portion, the other end portion of said cannula means being loosely but slidably disposed within said second sleeve-like end portion;

support means disposed in surrounding relationship to said cannula means and fixedly secured thereto at a location disposed between the ends thereof, said support means including a portion disposed in snug, slidable, telescopic engagement with said second sleeve-like end portion;

releasable detent means coacting between said portion of said support means and said second sleeve-like end portion for resisting movement of said cannula means relative to said second vial means;

removable tubular sheath means surrounding said cannula means and extending between said first and second vial means for connecting same together, said sheath means including a first annular end portion having first and second sleeve-like parts of different diameters disposed in surrounding relationship to said first sleeve-like end portion and said first vial means, respectively, and disposed in snug slidable engagement therewith;

said sheath means including a second annular end portion having first and second sleeve-like parts of different diameters disposed in surrounding relationship to said second sleeve-like end portion and said second vial means, respectively, and disposed in snug slidable engagement therewith, whereby said sheath means can be slidably disconnected from both said first and second vial means;

and

means, including releasable detent means, coacting between said first sleeve-like end portion and said sheath means for resisting relative movement of said sheath means toward said first vial means.

2. An assembly according to claim 1, wherein said second vial means has the chamber thereof maintained under a pressure which is substantially below atmospheric pressure.

3. An assembly according to claim 1, wherein said means coacting between said first sleeve-like end portion and said sheath means includes an intermediate sleeve member snugly and slidably disposed within the first sleeve-like part of said sheath means, said intermediate sleeve member being slidably disposed on and surrounding said first sleeve-like end portion, and said releasable detent means coacting between said first sleeve-like end portion and said intermediate sleeve member.

4. An assembly according to claim 1, wherein said first and second sleeve-like end portions are of substantially the same diameter, wherein the said first sleeve-like part associated with the first annular end portion and the first sleeve-like part associated with the second annular end portion are of the same diameter and are connected to one another to form an intermediate tubular portion of uniform diameter, said support means including a sleeve-like support member disposed within said intermediate tubular portion and positioned in surrounding relationship to said second sleeve-like end portion, and said means coacting between said first sleeve-like end portion and said sheath means including an intermediate sleeve member snugly and slidably disposed within the intermediate tubular portion of said sheath means and disposed in surrounding relationship to said first sleeve-like end portion.

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