CONTAINER FOR SUPPLEMENTAL MEDICATION AND METHOD OF USING THE SAME

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This invention relates to a container for supplemental medication and the method of using the same and, more particularly, to a vial-type container adapted to add a medicament to a parenteral solution bottle having its contents under a pressure less than atmospheric and the combination thereof.

The application is a continuation-in-part of my copending application Serial No. 497,572 filed March 29, 1955, now abandoned.

In the past, the production of parenteral solutions has been limited generally to those widely and frequently used in considerable quantity (i.e., glucose, saline, vitamins and the like). This limitation becomes meaningful when one considers that it is un economical to provide or stock infrequently called-for parenteral solutions which are generally bulky (being upwards of 500 cc. in volume) and more expensive than the common solutions. This inconvenience is not outweighed by the advantages of having a broad spectrum of available solutions, and the result is that the number of different solutions available is relatively small. It should be noted that the demand for parenteral solutions also includes the demand for solutions that have been especially formulated for a specific patient's condition.

Thus, when a physician feels that a patient's condition indicates a distinctive parenteral regimen, he must either resort to the time-consuming expedient of making a second and sometimes painful vein-puncture or attempt to combine the distinctive medicine with the basic parenteral solution. Since parenteral therapy should be carried out under sterile conditions, it is apparent that any addition of supplemental medicine to the parenteral administration system should likewise be performed as aseptically as possible. This appears all the more significant when one considers that parenteral solutions are generally produced with the liquid contents under vacuum so that breaking the vacuum seal gives the doctor or nurse performing the administration a signal whereby he or she can ascertain that the solution has remained uncontaminated. Additional procedures involving hypodermic syringes may avert contamination but at the expense of time which is often a critical factor.

The container of my invention, when used in combination with a parenteral solution bottle, not only eliminates the need for the aforementioned second vein puncture but also the addition of supplemental medication to the bottle under substantially aseptic conditions without loss of time.

Essentially my invention includes a separate container for the supplemental medicine, this container being provided with a dispensing cap that permits its contents to be introduced into the vacuum-packed parenteral solution container prior to administration of the parenteral solution itself.

My invention will be explained in conjunction with the accompanying drawing, in which Fig. 1 is an elevational view of the container for supplemental medication of my invention in conjunction with a typical parenteral solution container; Fig. 2 is an enlarged cross-sectional view of a supplemental medication container of my invention containing a liquid medicament; and Fig. 3 is a view similar to Fig. 2 but showing a modified form of my invention adapted to contain a solid medicament.

Referring now to the drawing, and in particular to Fig. 1, the numeral 10 designates the container for supplemental medication. The numeral 11 generally designates a typical parenteral solution bottle with its contents under vacuum. Bottle 11 is provided with a rubber stopper 12 mounted in its neck and provided with an annular flange portion 12a to prevent stopper 12 from being drawn into bottle 11 by virtue of the vacuum existing therein. Extending through stopper 12 is liquid discharge passage 13 which is sealed until use by frangible diaphragm 14c, provided by rubber disc 14 extending across the top surface of stopper 12 and being generally coextensive therewith. Both disc 14 and stopper 12 are further secured to the neck of bottle 11 by apertured metal cap 15 which is "rolled on" the neck and held in position by neck bead 11a.

Not shown as extending through stopper 12 is a second passage also closed by disc 14 at the "vacuum dimple" indicated as 14b. Mounted in this passage and extending into bottle 11 is air tube 16. In its discharging condition, bottle 11 is mounted in mouth-downward fashion by means of a suspension device consisting of ball 17 and band 18 so that air tube 16 permits air to enter container 11 through a puncture in diaphragm 14b to replace liquid 19 discharged through passage 13.

Rigid container 10 can be best seen by referring to Fig. 2, in which the numeral 20 designates a glass vial provided with one open end 20a. The external wall of vial 20 is thread ed as at 20b part way back from open end 20a. Threadably mounted on vial 20 is dispensing cap 21. Dispensing cap 21 is provided with female threads 21a which engage container threads 20b for mounting of dispensing cap 21. The end of dispensing cap 21, remote from the threaded portion, is pointed, as at 22, to permit ready puncture of diaphragm 14c of bottle 11 and is of an outer diameter so as to fit in air-tight engagement with the walls of passage 13 when inserted therein as shown in Fig. 1. Protecting the inserted portion of dispensing cap 21, and particularly point 22, is protector sleeve 23, which is mounted over cap 21. Inserted between cap 21 and the open end 20a of vial 20, and also closing the open end thereof, is rubber diaphragm 24. Diaphragm 24 is held in place by the cooperation of shoulder portion 21b of cap 21 and lip portion of the open end 20a of vial 20. Thus, diaphragm 24 also acts as a gasket between dispensing cap 21 and vial 20.

Diaphragm 24 is provided with a vacuum-operable valve 25 which, in the preferred embodiment, is a small aperture which substantially prevents outflow of liquid from vial 20 upon inversion except under the imposition of an external vacuum. Through possible die inverted container 20, which has been previously charged with supplemental medicine 26, even when protector sleeve 22 has been removed, without having medicine 26 flow out of container 20.

As noted above, Fig. 3 depicts a modified form of my invention useful for the addition of a solid medicament to parenteral solution bottles. The various elements of Fig. 3 being substantially identical to those of Fig. 2, are designated by like numerals except for the addition of a prime ('). The container 10' shown in Fig. 3 differs from container 10 of Fig. 2 in the provision of a substantially larger aperture 25' in diaphragm 24', so that diaphragm 24' serves primarily as a gasket.

Operation

In the operation of my invention, a container holding the desired supplemental medicament 26 is provided for a patient to whom parenteral therapy is about to be administered. The parenteral solution container is provided with its contents partially evacuated but with the vacuum seal provided by disc 14 still intact. Protector sleeve 23 is removed from the tip of dispensing cap 21, and vial 20 is inverted and inserted through frangible diaphragm 14c of bottle 11, substantially as shown in Fig. 1.
Then, under the influence of vacuum existing above liquid 19 liquid medicine 26 is drawn through capillary 25 into bottle 11. It is important to note that the structure of my additive container will operate successfully with any liquid or solid solution having its-container under vacuum and provided with a puncturable closure sealing the container. The embodiment of my invention shown in FIG. 2 is also useful in connection with other types of puncturable closures as where diaphragm 14a is provided integral with stopper 12. A modification of diaphragm 21 for use with closures by a sharper cap portion than that shown in FIG. 2 involves the provision of a cap 21 of a size and construction approximating a hypodermic needle. By using a cap of this modified nature not only can the same be inserted readily through greater thicknesses of stopper but diaphragm 24 can also be eliminated. Thus, the small bore of a needle substituted for the plastic molded cap 21 shown in FIG. 2 substantially prevents outflow of fluid upon inversion of vial 20 except when it is under the influence of an external vacuum. I have found that a diaphragm opening 25 of a diameter of 0.020″ provides this desired valve operation. This size opening corresponds to the bore of a 21 gauge needle. In this way the constricted passage communicating between vial 20 and bottle 11 is achieved without the use of diaphragm 24, the construction thereby being integral with cap 21.

In considering FIG. 2, it is seen that the supplemental medicine 26 occupies only a portion of vial 20 so that a substantial air space exists. Investigation has shown that this air space is essential for substantially complete discharge of the contents of vial 20 into bottle 11. Failure to provide suitable air space in vial 20 permits by partial discharge of its contents the building up of a vacuum within vial 20 approximately equal to that existing in bottle 11. Thus, it is impossible to discharge the last portions of medicine 26 from vial 20 since under such equilibrium conditions the internal pressure in vial 20 is not greater than the external pressure, i.e., that in bottle 11. Complete discharge of all medicine is considered essential since the medicine is accurately measured for prescription by a physician to achieve a desired parenteral regimen. An insufficient amount may preclude the achievement of the desired relaxant effect, as in the case of succinylcholine chloride, or an excess may be dangerous.

For example, when vial 20 has an internal capacity of 10 ml, and is equipped with a discharge cap 21 having a portion of its discharge passage constricted to an opening of about 0.020″ diameter, it was found that a newly produced liter solution bottle 11 would only fully empty vial 20 when it was charged with about 5 ml. of a supplemental medicine such as succinylcholine chloride. The vacuum existing in bottle 11 was of the order of 16″ Hg. Bottles standing for prolonged periods before use as is not unusual in hospital operation, sometimes lose part of their vacuum. Under such conditions, as where the bottle vacuum was reduced to about 10″ Hg, a vial of 10 ml. capacity charged with only about 3 ml. could be substantially emptied.

In adding the solid contents of container 10 of FIG. 3 to a parenteral solution bottle 11 having its contents under vacuum, the procedure outlined above with respect to liquid-containing container 10 of FIG. 2 is followed.

Thus it is to be noted that the possibility of contamination of the parenteral solution is relatively slight, since only the puncture tip of the additive container is exposed to the atmosphere for a few seconds and the vacuum condition within the parenteral solution container is preserved by the air-tight engagement of the puncture tip of cap 21 with the walls of passage 13. Another expedient to effect substantially complete discharge of medicine from vial 20 is to construct vial 20 so that its internal volume is diminished as medicine is drawn therefrom under the influence of the vacuum in bottle 11. Thus, no reduced pressure space is present to permit reaching the pressure equilibrium conditions that prevent the final discharge of the contents of medicine.

The foregoing detailed description has been given for the purpose of understanding only, and no unnecessary limitations are to be inferred therefrom.

I claim:

1. A parenteral solution equipment, a rigid vial containing medicine suitable for addition to a parenteral solution container, said vial having an open mouth, puncturing discharge cap means mounted on said vial to partially close the mouth thereof and providing a discharge passage for said medicine, said passage being equipped with construction means restricting gravity outflow of said medicine except when the discharge end of said cap means is subjected to a pressure less than atmospheric, and a dispensing parenteral solution container having its contents sealed under a pressure less than atmospheric, said dispensing container being provided with an air tube-equipped, puncturable resilient stopper, the said vial being positioned above said container with the discharge cap means of said vial being inserted through said stopper into communication with the interior of said dispensing container and thereby having the said discharge end thereof subjected to a pressure less than atmospheric, said dispensing container being substantially filled the said vial prior to the insertion of said discharge cap means through said stopper, the remaining interior volume of said vial constituting an air space effective to force said medicine into said container.

2. The structure of claim 1 in which said constriction means comprises a diaphragm sized opening extending therethrough.

3. In parenteral solution equipment, a rigid vial for liquid medicine having an open mouth, a puncturing discharge cap mounted on said vial to enclose the mouth thereof and equipped with a discharge passage for said liquid medicine, means constraining said passage to permit liquid discharge therethrough only when the discharge end of said cap is at a pressure less than atmospheric, and a rigid dispensing parenteral solution container having its contents sealed under a pressure less than atmospheric, said container being equipped with a puncturable resilient stopper, said vial being above said container with the discharge cap portion of said vial being inserted through said stopper into said container, said vial prior to insertion being only partially filled with medicine and with atmospheric air occupying the remaining vial interior so that greater pressure is exerted on the last liquid in said vial by the air therein than by the air above the liquid in said parenteral solution container.

4. The structure of claim 3 in which the said constraining means comprises a diaphragm sized opening extending across the mouth of said vial and equipped with an aperture sized to prevent gravity outflow of said liquid except when said discharge end is under a pressure less than atmospheric.

5. An additive vial for a parenteral solution container under vacuum, comprising a vial mouth open at one end, medicine only partially filling said vial, puncturing discharge cap means partially closing said open end, and constriction means associated with said cap means permitting medicine to flow therethrough only under the imposition of an external vacuum, the vial interior portion not filled with said medicine being subjected to atmospheric pressure thereby effective to force said medicine from said vial when the said cap means is subjected to sub-atmospheric pressure.

6. An additive vial for a parenteral solution container, comprising a liquid medicament container open at one end, liquid in said container only partially filling the same with the remainder constituting an air space at...
5 atmospheric pressure, a diaphragm provided with a vacuum-operable valve closing said open end, and discharge cap means mounted on said container for enclosing said diaphragm.

7. A vial containing a supplemental liquid medicine for a parenteral solution container, comprising a glass vial open at one end, liquid in said vial only partially filling the same with the remainder constituting an air space under atmospheric pressure, discharge cap means mounted on said vial and enclosing said open end, and a diaphragm mounted between said cap means and said container also closing said open end, said diaphragm having an aperture therein, said diaphragm permitting flow of medicine therethrough only upon application of a vacuum to the discharge end of said discharge cap means.

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