

[54] **METHOD FOR ADDING
MEDICAMENTS TO A SEALED
EXPANDABLE PARENTERAL FLUID
CONTAINER**

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141/1, 5, 7-10, 39, 51, 59, 100, 104, 114,
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[56] **References Cited**

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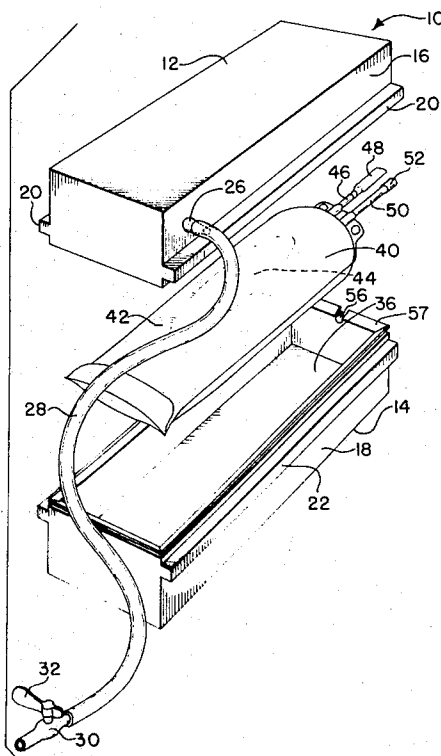
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Attorney—W. Garrettson Ellis

[57] **ABSTRACT**

A rigid chamber adapted to receive an expandable container such as a plastic bag of parenteral fluid contains an opening connected to a source of vacuum and an opening through which a tubular port on the container may be placed so that it will be accessible from the exterior of the chamber to permit the connection thereto of a vial containing a material such as a medicament to be added to the bag. By selective control of the vacuum supply to the chamber and of the position of the medicament vial relative to the fluid level in the bag, it is possible to add the contents of vials containing not only freely flowing liquid additives but also very viscous ones as well as powdered or granular materials. The system can also be operated in such a way that the contents of a plurality of medicament vials or syringes can be added to the bag even though the volume of the material to be transferred from the plurality of medicament containers is greater than the initial free air volume in the bag.

3 Claims, 11 Drawing Figures



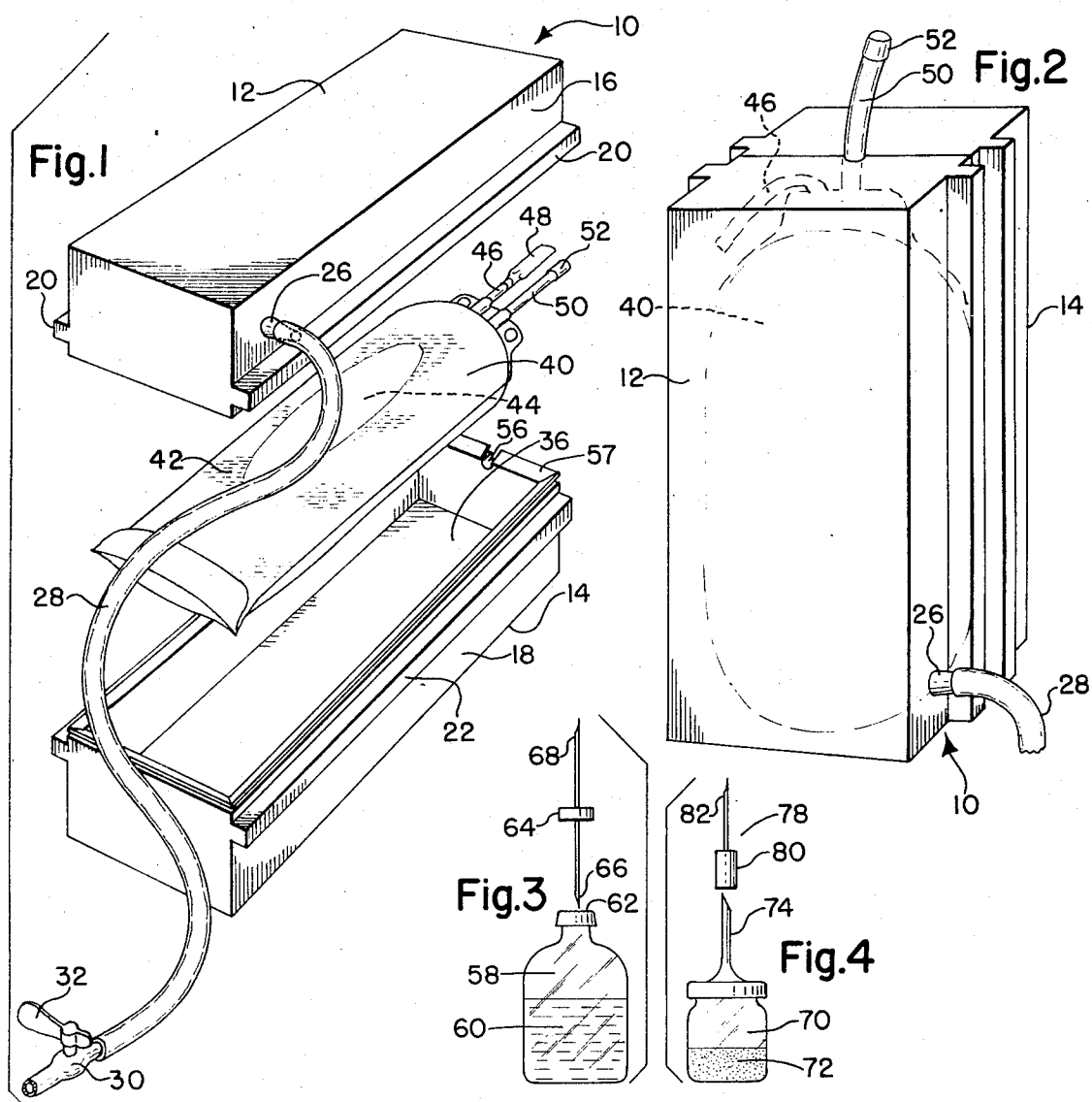


Fig. 9

Fig. 11

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METHOD FOR ADDING MEDICAMENTS TO A SEALED EXPANDABLE PARENTERAL FLUID CONTAINER

BACKGROUND OF THE INVENTION

This invention relates to an apparatus and method for adding liquid or dry medicaments or other materials to the liquid contents of an expandable container of parenteral solution.

It is extremely common to add medicaments such as vitamins and drugs to parenteral fluids. When such parenteral fluids are packaged in glass containers which commonly contain a vacuum, it is quite easy to add liquid medicaments to them since the vacuum in the bottle will pull the liquid out of the medicament vial and into the bottle. When the medicament is viscous or in a lyophilized state, a pump stopper on the vial of the type shown in U.S. Pat. No. 3,059,643 can be used to pump a portion of the liquid which is in the bottle into the vial. The transferred liquid is then mixed with the material in the vial and the mixture is retransferred to the bottle. Alternatively, liquid can be added to the vial with a syringe, the contents dissolved, and then injected into the bottle. The later process utilizes extra liquid which of course decreases the capacity of the bottles.

By packaging parenteral solutions in plastic bags instead of bottles it has become possible to eliminate the major drawback of glass container systems, namely, the requirement that room air enter the solution bottle during administration to displace the liquid administered. By using a flexible, collapsible plastic parenteral solution bag such as that sold under the trademark VIAFLEX by Travenol Laboratories, Inc. it is possible to achieve a closed administration system in which no air is required to enter the bag to displace the fluid since the collapsing of the bag as it empties serves the same purpose. Thus, no bacteria can enter the bag. However, since the bag does collapse, it is not possible for the bag to contain a vacuum for the purpose of aspirating liquid medicaments into the bag. To overcome this problem, it has been common practice to add the contents of medicament vials to plastic parenteral solution bags by repeatedly squeezing the bag while the vial is above it to force air out of the bag and into the vial and thereby permit the medicament to enter the bag. This known process is also mentioned in U.S. Pat. No. 3,554,256.

Although it is presently possible, as previously noted, to add supplemental medication to a parenteral solution bag by repeatedly squeezing the bag, this method is somewhat strenuous and time consuming as compared to adding medication to bottles which contain a vacuum. The problem is particularly significant for a hospital pharmacist who must add up to 10 different medications to a single container of parenteral solution and process hundreds of such containers during the course of a day. Where plastic containers are used, in addition to the work of squeezing the plastic containers to get supplemental medications into them, the pharmacist must also deal with an additional problem that arises due to the nature of the bags being flexible. The flexible nature of the bags makes them somewhat unwieldy when the pharmacist is trying to connect the spike or needle of the medicament vial or syringe to the inlet port of the bag. The latter operation is quite simple with glass solution containers since they stand vertical without additional support.

A disadvantage of adding medicaments to plastic bags by hand squeezing of the bag to force air into the vial and liquid from the vial into the bag is that the free air volume of the bag is ordinarily little greater than the contents of one medicament vial to be added to it. Since it requires great force to expand the bag by squeezing, it is difficult to place the contents of more than a few medicament vials into the bag.

Although glass solution containers offer an advantage in that they contain a vacuum which will draw a liquid medicament into them, they have a disadvantage in that when a medicament vial is inserted into them by means of a spike type of connector the vacuum is lost when the spike is removed so that additional medication must be added by means of a syringe. Even where the medicament is added by means of a double-ended needle which permits the bottle to reseal as the needle is removed, the vacuum is used up after only a few medicaments have been added.

Although it is common practice to draw blood into a plastic bag by placing the bag into a chamber which is then evacuated, (U.S. Pats. Nos. 2,982,286 and 3,032,037), or into a chamber which limits the amount of fill (U.S. Pat. No. 3,042,086), such apparatuses would not be suitable for adding medicaments to already filled bags since they positively prevent adding materials to a filled bag and teach no way to transfer liquid from the bag to a separate rigid container which is attached to it. For example, the device in U.S. Pat. No. 2,982,286 clamps the bag tubing and opens the door to the vacuum chamber when the bag is full.

U.S. Pats. Nos. 3,291,348, 3,375,824 and 2,290,355 utilize positive pressure or a pressure differential to mix a liquid in one container with a lyophilized material in another. However, there is no way to move the mixed product back to the liquid container.

SUMMARY

It is an object of this invention to provide a method and apparatus for adding medicaments to a sealed expandable container of parenteral fluid in a quick and easy manner.

It is a further object to provide a method and apparatus for permitting a greater volume of medicaments to be added to a plastic solution container than has previously been possible.

An additional object is to provide a method and apparatus for adding the contents of a medicament vial to an expandable container of parenteral fluid without the necessity for using pumps or syringes of hand squeezing of the bag.

These and other objects are obtained by the present invention wherein a chamber which is formed by at least a pair of rigid members, preferably formed of transparent plastic, has a sealing member positioned between its mating parts. An opening into the chamber is connected to a fitting member on the outside of the chamber which is in turn connected to a suitable source of vacuum which can be readily turned on and off. Preferably, the fitting is connected to the vacuum source by a length of flexible tubing. Another opening into the chamber, located in the vicinity of the sealing member, is adapted to fit snugly around a tubular port member extending outwardly from a bag of parenteral fluid made from a material such as polyvinyl chloride which can be expanded.

The operation of the apparatus and process is as follows: A bag of solution is placed into the portion of the chamber formed by one of the rigid members and the other rigid member is then brought into engagement with it so that a sealed tubular port extension on the bag extends through the opening in the sealing area. The vacuum source is then connected to the chamber while slight hand pressure is applied to the rigid members if necessary to cause the seal between them to be compressed sufficiently so that the vacuum can take over and complete the sealing operation.

As the chamber is exhausted of air by the vacuum source, the small amount of air normally in the bag will expand the bag. As the air expands, its pressure will be greatly reduced so that the interior of the bag will be at a relative vacuum as compared to the atmosphere outside the chamber.

With a vacuum applied to the chamber, the contents of a medicament vial can then be added to the bag by connecting the vial to the self sealing medication site on the port tube which protrudes from the opening in the chamber. If the medication in the vial is a freely flowing liquid, the apparatus should be positioned so that the bag is vertical with the port tube up. Connection is preferably made between the port tube and vial by means of a double ended needle which punctures the self sealing rubber stoppers of the tube and vial. Where the vial is of the type having a large diameter plastic spike rather than a rubber seal, an adaptor member which snugly surrounds the spike and terminates in a small diameter needle can be used. The liquid medication could also be withdrawn from the vial with a syringe and injected into the port tube.

Since air which is normally in the vial along with the liquid will be pulled into the bag along with the liquid medication and add to the volume of the bag, it is highly desirable that such air be eliminated. This can be accomplished by turning off the vacuum source while the vial is connected to the port tube and above the level of liquid in the bag. As the pressure in the chamber increases, due to air leaking into the chamber as the vacuum is released, the air in the bag will decrease in volume while it increases its pressure. A portion of it will also go into the vial which had been partially evacuated. Since it is not desirable that more air be returned to the vial than was removed from it, the vial should be disconnected from the bag before the bag has expelled more air than it contained when the contents of the vial were added to it. This insures that the bag graduations will read accurately as the bag empties during administration. It also provides sufficient air for bag expansion when additional medications are to be added. A free air volume in the bag of about 12-25 cc has been found to be satisfactory, regardless of the amount of liquid present, i.e., 150 or 1000 ml of liquid in the bag. Significantly larger amounts of air could present a possibility of infusing air to a patient whereas the volumes noted avoid this possibility since they are less than the volume of the administration set tubing and the air which will remain in the bag when it has collapsed as much as it physically can.

The foregoing and other objects, features and advantages will be apparent from the following more particular description of a preferred embodiment thereof, as illustrated in the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded perspective view showing the apparatus of the present invention in association with a plastic solution bag;

FIG. 2 is a perspective view showing the rigid members of FIG. 1 in their assembled relationship to each other;

FIG. 3 is an exploded front view of one conventional type of medicament vial and a double-ended needle connector which can be used to connect the vial to the bag in the apparatus of FIGS. 1 and 2;

FIG. 4 is an exploded front view of another type of conventional medicament vial and an adaptor member therefor which may be used to add a lyophilized medicament in the vial to the plastic solution bag of FIGS. 1 and 2;

FIGS. 5 through 11 illustrate the successive steps followed in the process of the present invention for adding the lyophilized contents of the container of FIG. 4 to the solution bag of FIG. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

In FIG. 1, the box-like device indicated generally at 10 includes a rigid, substantially hollow, top member 12 and a similar bottom member 14, each of which have a plurality of sides 16 and 18 respectively. Since the interior of the device 10 is subjected to a vacuum during operation it is preferable that the walls 16 and 18 be strengthened such as by means of the strengthening ribs 20, 22. Communicating with an opening (not visible) in the wall 16 of the rigid member 12 and attached to the wall 16 is a connection element or tubing adaptor 26 to which a length of tubing 28 may be readily attached. The opposite end of the tubing 28 is connected to a valve member 30 controlled by a shut-off handle 32. The valve member 30 is connected to a source of vacuum (not shown).

The interior of the device 10 comprises a chamber 36 into which an expandable bag type container 40, which may be made of a flexible plastic such as polyvinyl chloride, may be placed. The container 40 normally contains a quantity of parenteral solution 42 and a relatively small volume of air 44.

At one end of the bag 40 a sealed outlet tube 46 is integrally attached. This tube is adapted to be attached to and opened by a recipient administration set (not shown) at the time the solution 42 is administered to a patient. A tip protector element 48 covers the end of the tubing 46 until the tubing is ready to be punctured by the administration set. A second section of tubing 50 comprising an inlet port is sealed at its end by a plug or diaphragm member 52 which may be penetrated by a needle for the purpose of adding medicaments or other materials to the bag. The diaphragm member 52 is preferably made of soft rubber or other material which is capable of sealing itself when a needle is withdrawn from it.

Located at one end of each of the rigid members 12, 14 is a semi-circularly shaped opening 56 which is adapted to snugly engage and surround the inlet port tube 50 when the bag 40 is positioned in the chamber 36 and the rigid members 12 and 14 have their sidewalls 16, 18 brought into engagement with each other as shown in FIG. 2. In order to permit the rigid

members 12 and 14 to be tightly sealed to each other, a gasket member 57, which may comprise a coating of, or a strip of silicone rubber, is attached to the contacting edges of at least one of the members 12,14 in order to prevent leakage when the chamber 36 formed by the members 12,14 is subjected to a vacuum.

In operation of the device 10, a bag 40 is placed into the chamber 36 and the top member 12 brought into contact with the sealing surface 57 on the bottom member 14. The chamber 36 is then evacuated by connecting it to a source of vacuum (not shown) by actuation of valve handle 32. Once the chamber 36 is evacuated the device 10 can be lifted and placed on one end (as shown in FIG. 2) so that the inlet port tube 50 and the diaphragm 52 will be uppermost. The port tube 50 is held in a somewhat rigid position by the device 10 making it substantially as easy to add medications to the bag 40 as it is to add medication to a conventional self supporting parenteral solution bottle standing on a table.

The medications which may be added to the bag 40 may comprise freely flowing liquids, quite viscous liquids, or be dry as in the case of lyophilized materials. One type of container in which liquid medicaments are often provided is shown in FIG. 3 wherein a glass vial 58 contains a liquid 60 which is sealed into the vial by means of the self sealing diaphragm member 62. In order to transfer the liquid medicament 60 from the vial 58 to the bag 40 a connector member indicated generally at 64 may be used. The connector member 64 includes a double-ended needle having one end 66 which may be passed through the diaphragm 62 in vial 58 to communicate with the fluid 60 and an opposite end 68 which can puncture the diaphragm 52 on the port tube 50 to communicate with the interior of the bag 40.

FIG. 4 illustrates another type of medicament vial 70 which contains a dry or lyophilized material 72. The vial 70 is shown as including a large diameter plastic spike member 74 extending from its open end. The spike member 74 is normally sealed by a protective overcap (not shown). In order to transfer the contents of the vial 70 to the bag 40 without destroying the seals on the bag 40 a needle adaptor member indicated generally at 78 may be used. The needle adaptor member has a hub portion 80 which is adapted to slide over the exterior of spike 74 in tight sealing relationship. A needle member 82 attached to the hub 80 permits the contents of vial 70 to be added to the bag 40 through diaphragm member 52 on inlet port tube 50.

When it is desired to add a freely flowing liquid medication, such as medication 60 in vial 58, to the bag 40, it is merely necessary to place the bag 40 in the vacuum chamber 36, connect the source of vacuum to the chamber 36 to evacuate the chamber, and connect the vial 58 to the bag 40 by inserting the needle end 68 of adapter 64 into the diaphragm 52 after the end 66 of the needle has been placed into the vial 58 through the diaphragm 62. The relative vacuum created in the bag 40 by the vacuum in the chamber 36 on the outside of the bag will cause the volume of air 44 in the bag to expand and create a partial vacuum which will immediately draw into the bag 40 the contents of the vial 58. Since the partial vacuum in the bag will also draw into the bag the air which was present in vial 58 a

similar volume of air should be expelled back to the vial 58 before the vial is disconnected from the bag. This may be done by releasing the vacuum by actuation of valve actuator handle 32. When the level of air 44 in the bag 40 approaches its initial volume the vial 58 should be withdrawn.

Since the procedure for adding a lyophilized medication to the bag 40 involves more steps than are required for adding a liquid, the sequential steps for selectively evacuating the chamber 36 and varying the relative positions in space of the bag 40 and the vial 58 have been illustrated in FIGS. 5 through 11.

Referring to FIG. 5, the bag 40 is loaded into the device 10 in a horizontal position. Vacuum is then applied through tubing 28 to the chamber 36 as shown in FIG. 6 to cause the air in the bag 40 and thus the bag to expand outwardly toward the walls of the chamber 36. At this point, a vial 70 containing lyophilized material 72 is connected to the inlet port tube 50 of the bag 40 by means of the connector member 78. As soon as the connection is made, any air within the vial 70 will be drawn into the bag 40 until the interior of the bag and the vial are at the same pressure. The vacuum supply is then turned off as illustrated in FIG. 7, causing the bag 40 to collapse to its normal size and causing a portion of the liquid in the bag to go into the vial 70 which had been substantially evacuated in the preceding step. The vial 70 may then be agitated by swinging it back and forth to cause the dry material 72 to mix with the liquid. The device 10 is then stood on one end as shown in FIG. 8 or otherwise positioned so that the liquid level in the vial is above the liquid level in the bag and the vacuum again applied to cause the liquid in vial 70 to be drawn into the bag 40. The vacuum is then turned off as shown in FIG. 9 and the vial 70 is removed from the inlet port tube 50 at about the time that the bag has partially collapsed due to the air returning to the vacuum chamber to a point where the volume of air 44 in the bag is substantially the same as it was before the contents 72 of vial 70 were added. FIG. 10 shows the bag 40 after the vial 70 has been removed and after the bag has returned to its normal shape while FIG. 11 shows the device 10 placed in a horizontal position from which the bag 40 can be easily removed from it.

Where the medicament to be added to the bag is quite viscous it can be added to the bag in a manner similar to that set forth above for adding dry medications.

I claim:

1. A process for adding a dry or not readily flowable liquid product in a first container to a readily flowable liquid in an expandable second container, each of said containers being connected by a passageway between the containers which is sealed from the atmosphere, said process comprising the steps of: applying a vacuum to the exterior of said expandable second container to cause a reduced pressure to be established in the interior of said first container; releasing said applied vacuum while the liquid in said second container at least partially covers said passageway to cause a portion of said liquid to be drawn into said first container to cause the product therein to mix with the said portion of said liquid; and reapplying a vacuum to the exterior of said expandable second container while the liquid mixture in said first container at least partially covers said

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passageway, to expand said second container and to create a reduced pressure therein to draw the mixture from said first container into said second container.

2. A process for adding the contents of a first container to a sealed, expandable second container of liquid wherein the total volume of the contents of said first container is greater than a volume of air in the second container, comprising the steps of: connecting the interior of said first container to the interior of said second container through a resealable inlet port; exposing the exterior of said second container to a source of vacuum to expand said second container and the volume of air therein while positioning the connected containers so that solid and liquid contents of said first

container are drawn into said second container by the resultant reduced pressure created by said source of vacuum; decreasing the reduced pressure created by said source of vacuum while the resealable inlet port communicates with said volume of air in said second container, whereby a portion of the air in said second container will be expelled into said first container; and disconnecting said first container from said second container.

3. The process of claim 2 in which said step of disconnecting the first and second containers is performed while subjecting said second container to reduced pressure from said source of vacuum.

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