April 2, 1968 D. A. JELLIES 3,375,858

VARIABLE DOSE MEDICAMENT VIAL

Filed Oct. 22, 1965

FIG. 1.

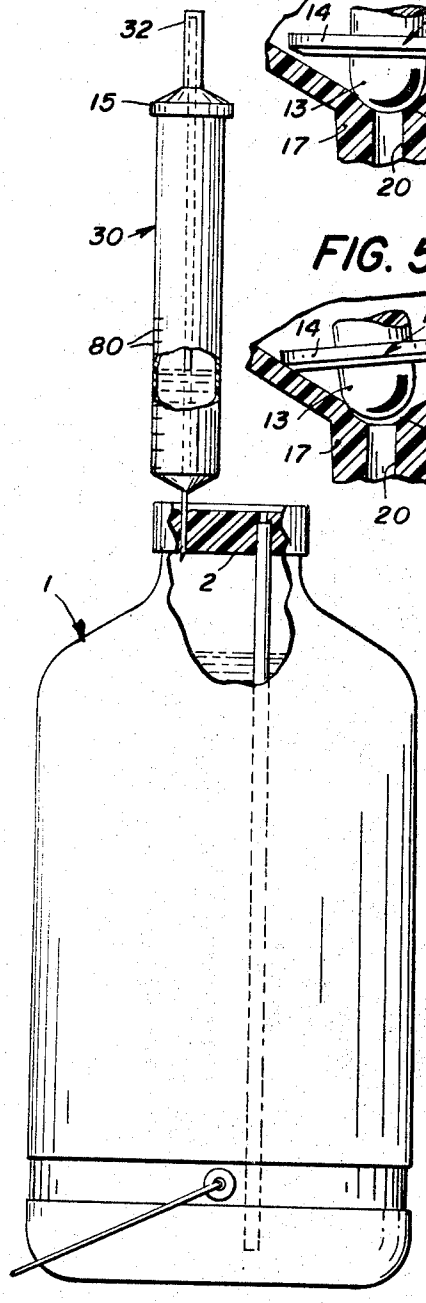


FIG. 4.

FIG. 5.

FIG. 2.

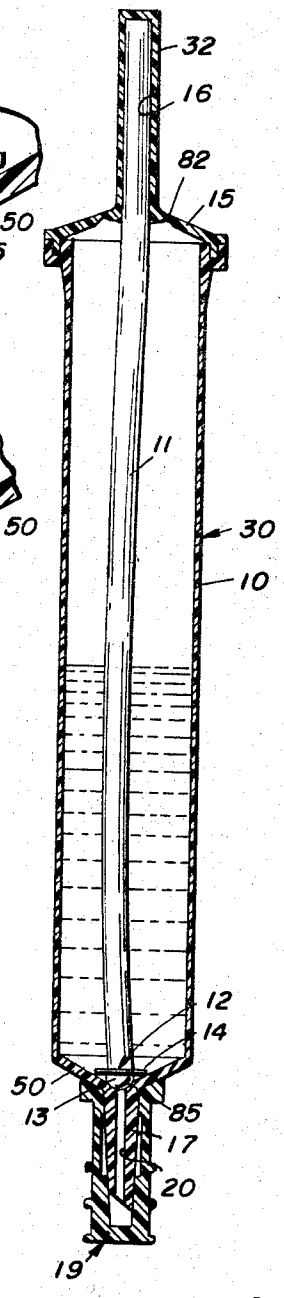
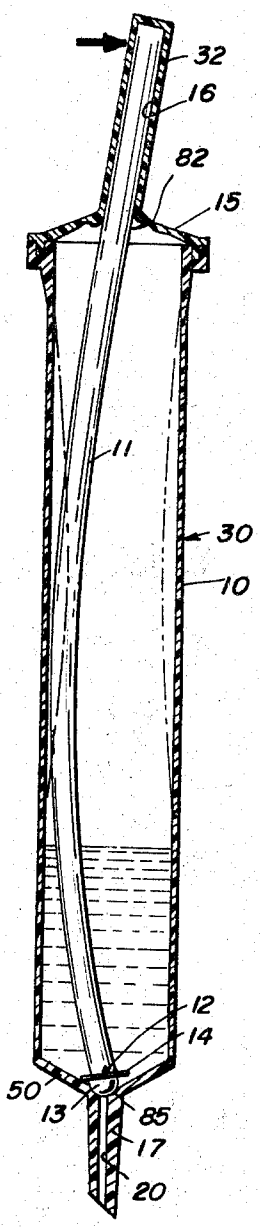


FIG. 3.



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VARIABLE DOSE MEDICAMENT VIAL

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ABSTRACT OF THE DISCLOSURE

A sterile additive vial for use with a parenteral liquid container or the like in which a closed flexible chamber communicates with an outlet spout and includes a one-piece valve operable through the walls of the chamber by manipulating the walls and in which the valve comprises an elongated flexible rod which is normally axially deformed, and the normal axial deformation urges one end of the valve head of the rod into seated relation on a valve seat controlling fluid flow through the spout.

This invention relates to a vial for adding supplemental medicament to a parenteral liquid container.

Parenteral liquids such as normal saline, 5% dextrose, etc. are administered intravenously to patients to replace body fluids lost during surgery and to correct electrolyte imbalances in the human body. These parenteral liquids are administered by means of the familiar one liter bottle hanging above the patient with a flexible tube leading from the bottle to a needle inserted into the patient's vein.

Often sterile additive drugs are aseptically added to the parenteral liquid container prior to administering the liquid to the patient to tailor the particular liquid to the patient. These additive drugs are supplied to the doctors' offices and hospitals in vials which are generally referred to as "additive vials." It is to such vials that this invention is related.

After connecting previous additive vials to a parenteral liquid container to transfer medicament to the container, the entire contents had to be transferred. To get less than the full vial dose into the parenteral liquid bottle, the physician had to take a separate calibrated syringe, withdraw part of the additive medicament from the vial, and then inject this desired amount into the parenteral liquid bottle. This was very time consuming and the double transfer procedure increased chances of contamination.

An object of this invention is to provide an additive vial for metering out a precise portion of its medicament contents and aseptically transferring this portion to a parenteral liquid container.

Another object of this invention is to provide an additive vial with an on-off valve within the vial which is manipulatable from without the vial.

Another object of this invention is to provide an additive vial which will administer a precise portion of its medicament contents to a parenteral liquid container whether or not the contents of the parenteral liquid container are under vacuum.

Other objects of this invention will become more clear upon further description with reference to the following drawings, in which:

FIGURE 1 is a front elevational view of the additive container showing it transferring medicament to a parenteral liquid container;

FIGURE 2 is an enlarged sectional front elevational view of the additive vial showing its outlet passage closed off;

FIGURE 3 is a view similar to FIGURE 2 but showing the additive vial with its outlet passage open;

FIGURE 4 is an enlarged fragmentary view of a valve and valve seat inside the additive container showing the valve closing off the vial's outlet passage; and

FIGURE 5 is an enlarged fragmentary view similar to FIGURE 4 but showing the valve lifted from its seat to open the vial's outlet passage.

Just how my novel additive vial operates can best be understood with reference to the drawings. FIGURE 1 shows the additive vial **30** connected to a parenteral liquid container **1** through a resilient closure **2**. Calibrations **80** on vial **30** show exactly how much medicament has been transferred to the parenteral liquid container.

At a lower end of the vial **30** is a pointed spout **17** with an outlet passage **20** therein communicating with an interior of vial **30**. A removable protector **19** keeps the spout sterile and is removed just prior to inserting the spout through the resilient closure **2** of parenteral liquid container **1**.

The outlet passage **20** is opened and closed by a valve head **12**. FIGURE 4 best shows valve head **12** which has a spherical nose **13** firmly seating in spherical seat **85** in partially closed end **50** of vial **30** closing off outlet passage **20**. Valve nose **13** is pressed against spherical seat **85** by axial compressive force applied to actuating member **11**. I have found this compressive force will sometimes slightly bow actuating member **11** shown in FIGURE 2. Flange **14** surrounding nose **13** on valve head **12** is spaced a slight distance from partially closed end **50**, and so does not unseat valve nose **13** when actuating member **11** is only slightly bowed. Instead, valve head **12** remains substantially axially aligned with outlet passage **20**, closing it off as shown in FIGURE 4.

When valve head **12** is materially cocked or canted, such as shown in FIGURES 3 and 5, flange **14** dips down and contacts partially closed end **50**, thus lifting valve nose **13** out of spherical seat **85** and opening outlet passage **20**.

It should be realized that the valve head **12** and flexible laterally displaceable actuating member **11** are completely enclosed within the vial **30**. The actuating member **11**, however, is manipulatable from without the vial **30**. Any contamination to the outside surface of the vial, such as by touching it, cannot reach the medicament inside vial **30** or contaminate actuating member **11** or valve head **12**. The actuating member **11** is laterally displaced or bowed by laterally pushing one's thumb against an external protrusion **32** on a closure **15** sealed to elongated chamber wall **10** of vial **30**. One end of actuating member **11** connects to valve head **12** and an opposite end fits within a socket **16** inside protrusion **32**. Lateral external manipulation of protrusion **32** opens and closes passage **20**.

In FIGURES 2 and 3, I have shown a closure **15** of a thermoplastic material bonded to a transparent thermoplastic elongated cylindrical chamber **10**. Such bonding can be accomplished by sonic or spin welding the two thermoplastic parts together. Chamber **10** and closure **15** are made of such thermoplastics as polyethylene, polypropylene, ethylenepropylene copolymer, etc. I have found that a thermoplastic closure **15** has sufficient "give" without breaking to laterally displace or bend actuating member **11**, particularly if an annular thinned portion or hinge **82** is provided about protrusion **32**. A closure **15** of rubber hermetically sealed in a bacteria-type manner to transparent chamber **10** could also be used.

In use, the additive vial of my invention is connected to a parenteral liquid container as shown in FIGURE 1, and the protrusion **32** pressed to one side with a thumb to open passage **20**. When the desired portion of medicament has been transferred, the protrusion **32** is released and outlet **20** is closed off by valve head **12**.

The additive vial of my invention will aseptically transfer medicaments to a parenteral liquid container whether or not the parenteral liquid container contains a vacuum. A parenteral solution container under vacuum simply

sucks the medicament from the vial **30** into the parenteral liquid container **1**. If container **1** is at atmospheric pressure, the medicament from vial **30** can be manually pumped into container **1**. The elongated chamber walls **10** are sufficiently thin so as to partially collapse and spring back upon alternately laterally squeezing and releasing them. This changes the volume of vial **30** and pumps the medicament into container **1**. The partially collapsed elongated chamber walls **10** are shown in dotted lines in FIGURE 3.

In the above description of my invention I have used specific examples to illustrate my invention. It is understood that persons skilled in the art may make certain modifications to these examples without departing from the spirit and scope of this invention.

I claim:

1. In combination, a parenteral solution container partially filled with parenteral solution and a variable dose additive vial containing a medicament, said additive vial connected to the parenteral solution container for aseptic transfer of the medicament to the parenteral solution container through an outlet passage of said vial, a valve means within said vial closing off the outlet passage, and a laterally displaceable actuating member enclosed within the vial but laterally manipulatable from without the vial to move said valve means to open the passage for fluid flow, said additive vial having a thin tubular body, the internal volume of which can be varied by alternatively laterally squeezing and releasing the tubular body to thereby pump the medicament into the parenteral solution container when the outlet passage is open, said outlet passage closable by said valve means through lateral manipulation of the actuating member after a portion of the medicament has been transferred to the parenteral solution container.

2. A sterile additive vial for adding medicament to a parenteral container or the like comprising:

an, elongated, flexible chamber including a spout communicating with and extending from one end theref, said chamber including a valve seat at said spout and opening toward the longitudinal axis of said chamber; and

one-piece valve means mounted within said chamber for manipulation through and exteriorally of said chamber while maintaining the sterile integrity of the medicament in said chamber,

said valve means comprising an elongated, laterally flexible actuator rod, said rod extending along the longitudinal axis of said chamber and including an integral valve head at one end and normally in seated controlling engagement on said valve seat, said rod including another end abuttingly engaged at the opposite end of said chamber, said rod being normally axially deformed between the opposite ends of said chamber and normally applying an axial force on said valve head at said valve seat.

3. The structure as claimed in claim **2** in which said chamber includes a flexible, tubular protrusion communicating with said opposite end of said chamber and into which the adjacent end of said rod is telescopically and abuttingly received.

4. The structure as claimed in claim **3** in which said tubular protrusion includes a weakened hinge portion at its connection to said chamber for facilitating deformable manipulation of said rod from outside said chamber and through said protrusion.

5. The structure as claimed in claim **2** in which said chamber includes a tapered bottom concentric to the longitudinal axis of said chamber and surrounding converging toward said valve seat, said actuator rod including a flange integral therewith and spaced axially from but adjacent said valve head and engageable on said tapered bottom when said actuator rod is deformed to pivot said valve head off said valve seat about the edge portion of said flange.

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