

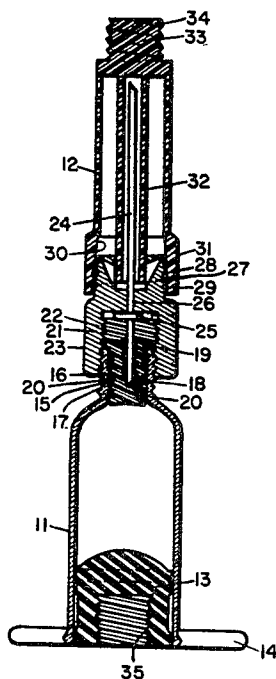
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[21] Appl. No. **696,390**
[22] Filed **Jan. 8, 1968**
[45] Patented **Dec. 15, 1970**
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[32] Priority **June 9, 1967**
[33] **Germany**
[31] **Nos. B71354 and B71349**

[56] **References Cited**
UNITED STATES PATENTS
2,453,590 11/1948 Poux 128/218.1
2,972,991 2/1961 Burke 128/218(P)
3,141,583 7/1964 Mapel et al. 222/309
FOREIGN PATENTS
1,019,500 2/1966 Great Britain 128/272
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[54] **INJECTION AMPOULE**
10 Claims, 3 Drawing Figs.

[52] U.S. Cl. **128/218**
[51] Int. Cl. **A61m 5/24**
[50] Field of Search **128/218,**
218(P), (PA), (M), 218.1, 218.2, 221, 272;
222/309

ABSTRACT: An injection ampoule having a nonelastic chamber for a solid component of an injection material and an elastic chamber for a liquid component, an elastic stopper in the nonelastic chamber having a plurality of peripheral grooves to substantially eliminate axial elongation when the stopper is used with nonelastic chambers having standard manufacturing tolerances and irregularities, and a closure between the nonelastic and elastic chambers having at least one peripheral rib between the closure and the inside of the elastic chamber to effectively seal the elastic chamber.



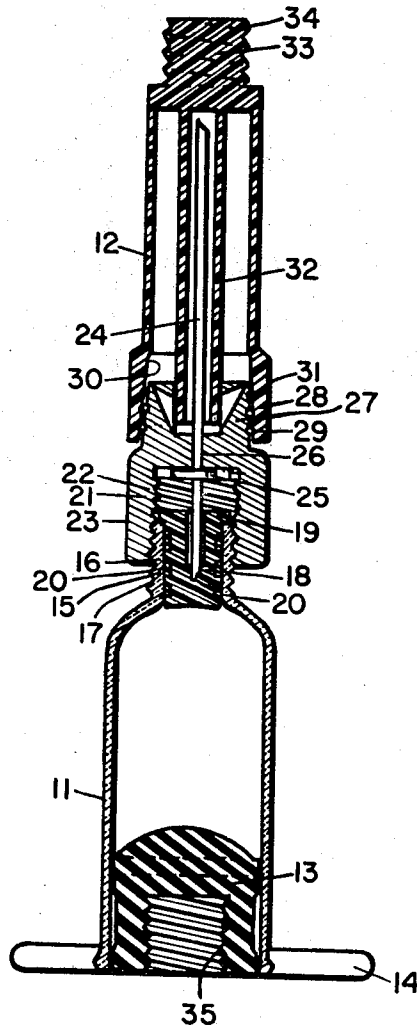


FIG. 1

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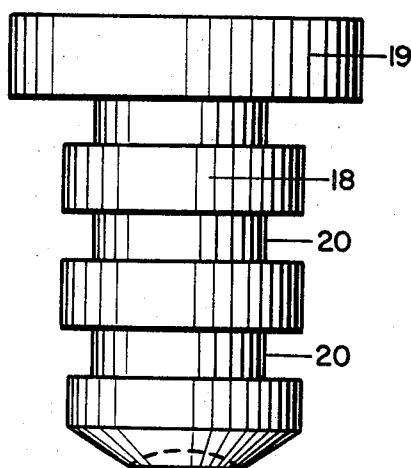


FIG. 2

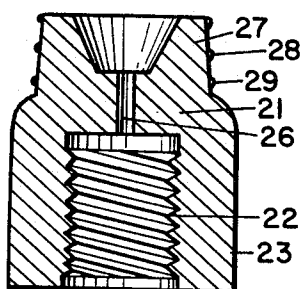


FIG. 3

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INJECTION AMPOULE

This invention relates to injection ampoules having two chambers, one for a solid component of an injection material and the other for a fluid component, and more particularly to improved means for sealing the chambers.

Many injection materials which are used for medical purposes will not retain their potency when stored in liquid form. Therefore, it is highly advantageous to keep the solid and liquid components separated until just prior to use thereof in order to obtain a fresh injection material. Accordingly, syringes of the type disclosed in a German Pat. of Georg A. Rinser; No. 1,085,653, filed Jun. 26, 1957 include a nonelastic chamber for the solid component, an elastic stopper in the end of the nonelastic chamber, a closure mounted on the end of the nonelastic chamber, a hollow needle mounted in the closure, and an elastic chamber for the fluid component removably mounted on the closure. When it is desired to give an injection, the closure is moved into a second position on the nonelastic chamber causing the hollow needle to pierce the elastic stopper to place the elastic chamber in communication with the nonelastic chamber. Manual squeezing of the elastic chamber causes the liquid component to be expelled into the nonelastic chamber. The syringe is then shaken to mix the liquid and solid components. Subsequent removal of the elastic chamber places the syringe in readiness for use.

The foregoing syringe has many advantages. A freshly mixed injection material can always be obtained. As during storage the hollow needle is immersed in the liquid component and not in contact with the solid component, clogging of the needle by the solid component is prevented. Further the syringe is extremely compact.

However, the foregoing syringe has a number of serious disadvantages. Inelastic chambers which are composed of glass, for example, always have certain tolerances and irregularities because of the inherent characteristics of glass and the processes used in working it. Normally such tolerances and irregularities can be ignored. However, in a syringe it is absolutely essential that the glass chamber be kept fluidtight in order to prevent contamination of the solid component inside. Otherwise, the advantage of obtaining a freshly mixed injection material is largely, if not completely, obviated. If an elastic stopper is used composed of rubber, for example, and the opening in the glass chamber is larger than its nominal value the rubber stopper will elongate to a considerably lesser degree than in an opening which is smaller than its nominal value. Again, such a phenomenon could normally be ignored. However, in a syringe, elongation of the rubber stopper will vary the highly critical piercing characteristics of the hollow needle and adversely affect the entire performance of the syringe. If the hollow needle extends through the rubber stopper more than an optimum extent, dangerous air bubbles are formed, and clogging by the solid component is possible if the hollow needle extends through the rubber stopper less than the optimum extent; the rubber stopper will not be completely pierced and can be clogged by the portion of the rubber stopper which is pushed aside by the piercing action of the hollow needle.

In addition, it is also obviously important that the elastic chamber be kept fluidtight in order to avoid contamination and to prevent evaporation. And, the foregoing must be accomplished with an elastic chamber which must be easily removable. In elastic chambers composed of polyethylene, for example, closures which are sufficiently larger than the opening in the polyethylene chamber to achieve high enough sealing pressures cause the opening to become fissured and uneven. Tapered closures, in particular, which exert the greatest pressure at the extreme edge of the opening, cause the edge of the opening to become cracked and uneven. For obvious reasons, such a seal could be very treacherous in a syringe. The sealing problem is particularly acute under the extreme climatic conditions of the tropics. It is to eliminate the foregoing disadvantages in order to obtain a truly reliable and sterile syringe that the present invention is directed.

It is therefore an object of the invention to provide an improved syringe in which the solid and liquid components of an injection material can be kept separated until just prior to use and maintained in a sterile condition for a long period of time without substantial evaporation of the liquid component.

Another object of the invention is to provide a syringe in accordance with the foregoing object in which after the syringe is prepared for use the hollow needle always extends an optimum distance into a nonelastic chamber for the solid component.

Another object of the invention is to provide an elastic stopper for the nonelastic chamber in accordance with the foregoing object in which axial elongation of the elastic stopper is substantially eliminated when the elastic stopper is used with nonelastic chambers having standard manufacturing tolerances and irregularities.

Another object of the invention is to provide a closure in accordance with the foregoing objects which will effectively seal an elastic chamber for the liquid component.

Other objects and a fuller understanding of the invention will be had by referring to the following description and claims taken in conjunction with the accompanying drawings in which:

FIG. 1 is a longitudinal cross-sectional view of the syringe; FIG. 2 is an enlarged elevational view of the elastic stopper for the nonelastic chamber of the syringe; and FIG. 3 is an enlarged side elevational view partly in section of the closure for the elastic chamber of the syringe.

With reference to the drawings, the syringe includes a nonelastic chamber 11 for a solid component of an injection material and an elastic chamber 12 for a liquid component.

The nonelastic chamber 11 is composed of glass providing high visibility, and great resistance to attack by chemicals. A rubber piston 13 is housed in a first end of the glass chamber 11, and a polyethylene finger grip 14 is mounted on the first end. A second end of the glass chamber has a neck 15 and an opening 16. External screw threads 17 are formed on the neck 15.

Mounted in the opening in the neck of the glass chamber is an elastic stopper 18 composed of rubber. The rubber stopper 18 has a flange 19 at one end to limit its extent into the glass chamber. Annular grooves 20 are formed in the rubber stopper. The annular grooves 20 have a rectangular cross section and substantially eliminate axial elongation of the rubber stopper when it is used with glass chambers having standard manufacturing tolerances and irregularities.

Threaded onto the external screw threads 17 of the glass chamber is a closure 21 having mating internal screw threads 22. The closure has a knurled portion 23 to provide a gripping surface for turning on the external screw threads of the glass chamber. A hollow needle 24 having a flange portion 25 is mounted in the closure with the flange 25 seated in a recess 26 in the closure. The closure has a tapered portion 27 with two annular ribs 28 and 29 for sealing an opening 30 in the elastic chamber 12. The innermost rib 29 is farthest from the axis of the closure than the outermost rib 28 because of the taper. The ribs are shown with a semicircular cross section, but could have a triangular cross section, for example. The ribs effectively seal the elastic chamber without causing damage to the elastic chamber because pressure occurs over a small area away from the edge of the opening in the elastic chamber. Elastic chambers 12 composed of polyethylene, for example, assist the sealing characteristics of the ribs by cold flow of polyethylene at the pressure areas of the ribs.

The polyethylene chamber 12 has a knurled portion 31 to provide a gripping surface for removal from the closure 21. A scabbard 32 is formed inside the polyethylene chamber to house the hollow needle. The polyethylene chamber has a neck 33 with external screw threads 34 for mating with internal screw threads 35 in the rubber piston 13 in the glass chamber.

In operation, when it is desired to give an injection, the syringe is held in a substantially vertical position with the

polyethylene chamber 12 containing the liquid component of the injection material above the glass chamber 11 containing the solid component. The closure 21 is moved into a second position on the glass chamber by manually turning it on the external screw threads 17 of the glass chambers. The foregoing movement causes the hollow needle 24 to pierce the rubber stopper 18 an optimum amount because of the annular grooves 20 around the rubber stopper which have stabilized the length of the rubber stopper for all standard tolerances and irregularities of the opening 16 in the glass chamber.

Piercing of the rubber stopper by the hollow needle places the polyethylene chamber in communication with the glass chamber through the hollow needle. Manually squeezing the polyethylene chamber causes the liquid component in the polyethylene chamber to be expelled through the hollow needle into the glass chamber containing the solid component in a substantially loss-free operation. The syringe is then shaken to mix the liquid and solid components. The polyethylene chamber, which is now empty, is removed from the closure and threaded into the internal screw threads 35 in the piston 13 to serve as a plunger, and the syringe is ready for use.

Comparative tests conducted at room temperature with 50 percent relative humidity prove the superiority of the closure 21 of the invention. Evaporation of the liquid component from the polyethylene chamber 12 was so slight that a shelf life of at least two years is assured. In contrast, using the closure disclosed in the aforementioned German Pat. No. 1,085,653, resulted in approximately 120 mg of the liquid component evaporating per month.

Although the invention has been described in its preferred form with a certain degree of particularity, it is understood that the present disclosure of the preferred form has been made by way of example and that numerous changes in the details of construction and the combination and arrangement of parts can be resorted to without departing from the spirit and the scope of the invention.

We claim:

1. An improved syringe having a nonelastic chamber, means at a first end of the nonelastic chamber for ejecting fluid from the nonelastic chamber, an elastic stopper in a second end of the nonelastic chamber, a closure mounted on the second end

of the nonelastic chamber in a first position, a hollow needle mounted in the closure having a first end which will pierce the elastic stopper for communication with the nonelastic chamber when the closure is moved into a second position on the second end of the nonelastic chamber, and an elastic chamber removably mounted on the closure and covering a second end of the hollow needle, said improvement comprising the elastic stopper having a plurality of peripheral grooves to substantially eliminate axial elongation when the elastic stopper is used with nonelastic chambers having standard manufacturing tolerances and irregularities in which the portion of the closure on which the elastic chamber is mounted is tapered with the smallest cross section at the end and which includes at least two ribs, the innermost rib being farther from the axis of the closure than the outermost rib because of the taper, to effectively seal the elastic chamber.

2. The improved syringe of claim 1 in which the peripheral grooves in the elastic stopper have a substantially rectangular cross section.

3. The improved syringe of claim 2 in which the elastic stopper is composed of rubber.

4. The improved syringe of claim 3 in which the elastic stopper has a flange which is sufficiently larger than the inside of the second end of the nonelastic chamber to limit the extent of the elastic stopper into the nonelastic chamber.

5. The improved syringe of claim 4 in which the nonelastic chamber is composed of glass.

6. The improved syringe of claim 1 in which the rib on the closure has a semicircular cross section.

7. The improved syringe of claim 1 in which the rib on the closure has a triangular cross section.

8. The improved syringe of claim 1 in which the elastic chamber is composed of polyethylene.

9. The improved syringe of claim 8, in which the second end of the nonelastic chamber has external screw threads and the closure has internal screw threads for mounting the closure on the nonelastic chamber.

10. The improved syringe of claim 1 in which the peripheral grooves in the elastic stopper have a substantially rectangular cross section.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,547,122

Dated December 15, 1970

Inventor(s) 1) Georg A. Rinser 2) Peter Rieckmann 3) Werner

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Page 1

German Patent "B 71,354" should be --B 71,345--

SIGNED AND
SEALED
MAR 9 1971

(SEAL)

Attest:

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Attesting Officer

WILLIAM E. SCHUYLER, Jr.
Commissioner of Patent