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2,906,423

CLOSURE PUNCTURABLE BY POLYETHYLENE NEEDLE

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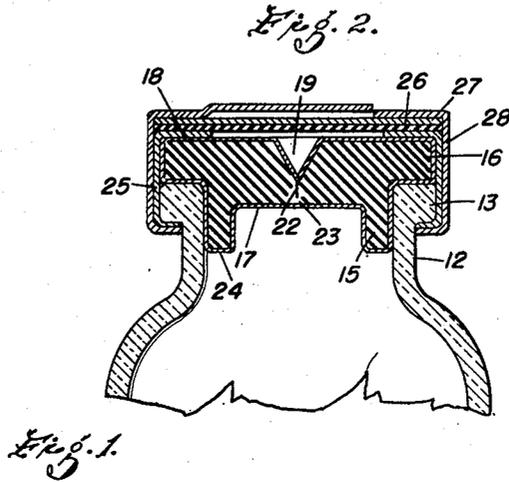
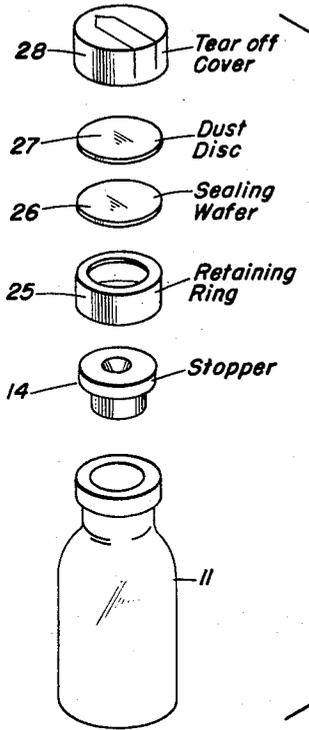


Fig. 1.

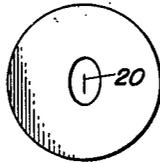


Fig. 3.

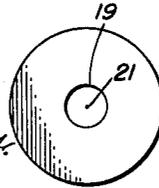


Fig. 4.

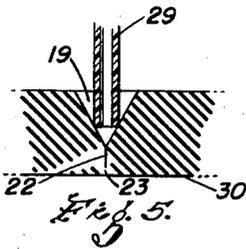


Fig. 5.

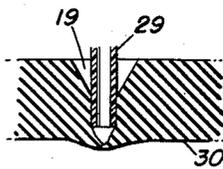


Fig. 6.

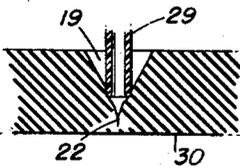


Fig. 7.

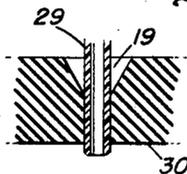


Fig. 8.

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CLOSURE PUNCTURABLE BY POLYETHYLENE NEEDLE

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1 Claim. (Cl. 215-47)

This invention relates to a container for liquid pharmaceutical preparations and includes a bottle comprising a resilient closure puncturable by a polyethylene needle, and the closure itself.

It is an object of this invention to provide a closure of a resilient rubber-like material which is retained in position in a bottle and is moisture-proof and contamination-proof before use, which may be easily punctured by a plastic needle and which is self-reclosing and contamination-resistant when in use, and is easily reopened, economical and tamper-proof. Additionally, the closure is easily attached with conventional sealing machinery.

With recent improvements in molding techniques it has been possible to produce inexpensive syringes in which the nose of the syringe in itself serves as a needle. Among other uses for such syringes is in the treatment of mastitis. With such syringes, the needle is inserted in the milk orifice of the cow's teat. Obviously, the needle must be smooth and rounded for such use. Such a rounded needle is too dull to puncture a conventional rubber stopper, but none the less, it is convenient to have the closure resemble an ordinary closure for use with hypodermic needles. One solution is, of course, to use an auxiliary pointed needle for the opening operation and change to a separate injection needle for the treatment of the cow.

Such a procedure is inconvenient.

Prior art closures using a solid membrane, such as disclosed in a U.S. Patent to Biehn, 1,413,703, April 25, 1922, "Closure for Hypodermic Solution Containers," would be suitable with a sharp needle. Other types of closures such as shown by McElroy, 1,180,665, April 25, 1916, "Closure or Stopper for Serum Containers, etc.," are also usable except that the lumen through the stopper can easily allow contamination of the contents and may require too long a needle, and induce an undue amount of friction.

I have now found that a stopper formed of a low tear-resistant rubber, with a conical well in the top face extending partway into the plug portion of the stopper, and which has a cut slit extending partway from the apex of the conical well towards the bottom face of the stopper provides a moisture-proof closure; and a closure which is easily opened by forcing a polyethylene needle therethrough.

Many materials are more easily torn after an initial line of weakness has been formed. For instance, conventional cellophane is extremely difficult to tear up until a tear is started, but once a tear is started, the cellophane tears extremely easy. Similarly, in rubber or rubber-like materials, it is easier to extend a tear than to start one, and by using a rubber of low tear resistance, as for example, synthetic rubber of the GRS type, there may be provided a resilient closure in which a slit once started is very easy to extend. Even with material conventionally used in preparing resilient rubber stoppers a tear once started by a cut slit is easy to extend when using a rounded point polyethylene needle.

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Certain embodiments of the invention are more clearly illustrated in connection with specific improvements thereof shown in the drawings:

Figure 1 is an exploded view of the preferred form of the closure.

Figure 2 is a sectional view through the top of the closed container.

Figure 3 shows an elliptical cone with a longitudinal slit.

Figure 4 shows a circular cone with a point slit.

Figures 5, 6, 7 and 8 show the progress of a polyethylene needle as it is forced through the stopper.

As shown in Figure 1, the bottle may be any size bottle 11 with a neck 12, having a rim 13 thereon. In the neck of the bottle is the stopper 14 itself. The stopper may be of conventional material such as rubber but preferably is of a grade of rubber having a low tear resistance. Many of the new synthetic rubbers, such as GRS are conventionally compounded to have a low tear resistance by methods known in the trade. This stopper 14 conveniently consists of the plug 15, which is the portion that extends into the neck of the bottle, above which is a flange 16 which fits against the rim of the bottle and may be used to retain the stopper in position. Preferably, but not necessarily, the lower portion of the plug has a recess 17 therein which extends partway up into the plug. The upper face 18 has therein a conical well 19. As shown in Figure 4 the conical well may be a right circular cone, or it may be elliptical in cross section as shown in Figure 3, and rather than terminating at an apex it may have a conoidal shape terminating in an apex line 20. At the apex 21 or the apex line 20 is a cut slit 22. The cut slit is cut in the stopper, after it has been molded, by a sharp instrument so that there is an actual tear started into the stopper itself. By having an actual tear started it is easier to extend the tear. This would not be the case if the slit were molded and had a rounded edge. The cut slit extends partway but not completely through the stopper. An unpunctured membrane 23 remains between the bottom of the cut slit and the top of the recess, so that the stopper forms an unperforated closure for the bottle.

By thus being unperforated, the stopper prevents the passage of moisture. Additionally, by inspection, it can be determined that the contents of the bottle have not been used. Once this slit is extended through the stopper the evidence of entry remains.

The stopper may have a thin lubricant coat 24 on the surface thereof which may be of a silicone fluid, such as disclosed in U.S. Patent 2,649,090, Parsons et al., "Rubber Closure for Pharmaceutical Vials," August 18, 1953. In addition to lubricating the stopper for ease of insertion, the lubricant tends to fill up the cut slit thereby preventing the entry of contaminating microorganisms and also lubricating the entry of the polyethylene needle through the conical well into the interior of the bottle.

In use the stopper may be held in the bottle by any convenient means but conveniently may be retained by a retaining ring 25 of a ductile material, such as aluminum, which may be spun or otherwise drawn under the rim of the bottle. The retaining ring holds the stopper in position during use and protects the bottle and its contents from tampering. Preferably, a resilient sealing wafer 26 is placed over the stopper and the retaining ring and held in place by dust disc 27. The lower side of the sealing wafer may have an adhesive coat which unites it to the retaining ring and aids in preventing contamination of the face of the stopper. The dust disc and the sealing wafer are held in position by a tear off cover 28. The tear off cover, the dust disc, the sealing

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wafer and the retaining ring may be preassembled and placed over the stopper in the bottle by conventional closing machines. When so closed, the top face of the closure is protected against contamination and tampering. The closure is opened by ripping the tear off cover; and removing the dust disc and sealing wafer thus exposing the face of the stopper in which there is the conical well.

As shown in Figures 5 to 8, the rounded end of a polyethylene needle 29 slides smoothly on the lubricant coat, separates the sides of the slit, and extends the tear from bottom of the cut slit to the bottom surface 30 of the stopper. Stages in this process are shown. After the partial withdrawal of the contents into the syringe attached to the polyethylene needle, the needle may be withdrawn, permitting the closure of the now extended slit which thus protects the contents of the bottle until the next usage.

The exact proportions such as the relative depth of the conical well, and the recess, the relative length of the plug, and the thickness of the flange may be varied depending upon the size of the bottle and manufacturing convenience. Conveniently, proportions are chosen such that the standard stoppering procedures may be used to place an aluminum seal thereon. Obviously, the bottle does not need to be glass and the retaining ring, dust disc,

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and the tear off cover need not be of aluminum, although conveniently a glass bottle and an aluminum seal are usually used.

Having thus described certain embodiments thereof, as my invention, I claim:

A closure for liquid pharmaceutical preparations comprising: a resilient stopper comprising a plug, a flange, an upper face having a conical well therein, a cut slit, terminating in a readily extendable tear, extending partway only from the apex of the conical well towards the bottom surface of the stopper, wherein an unpunctured membrane lies between said surface and said cut slit, and a thin lubricant coat of a silicone fluid, to lubricate the entry of a polyethylene needle through the well into the interior of the bottle, by extending the cut slit, and which lubricant also fills the cut slit to aid in preventing the entry of contaminating organisms.

References Cited in the file of this patent:

UNITED STATES PATENTS

1,180,665	McElroy	Apr. 25, 1916
2,108,583	Falk	Feb. 15, 1938
2,334,905	Cherkin	Nov. 23, 1943
2,649,090	Parsons et al.	Aug. 18, 1953