

[54] MULTI-MIX

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[73] Assignee: IMS Limited

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[52] U.S. Cl. 128/272, 215/6

[51] Int. Cl. A61J 01/00, B65d 01/04

[58] Field of Search 128/272, 218 M; 215/6

[56] References Cited

UNITED STATES PATENTS

2,717,601	9/1955	Brown	128/272
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2,869,745	1/1959	Lockhart	128/272 X
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Primary Examiner—Hugh R. Chamblee
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[57] ABSTRACT

This patent describes a novel medicament container comprising a vial having an open end and a closed end, at least one slidable resilient stopper within said vial normally positioned intermediate said open end and said closed end and normally forming a fluid tight seal on the walls of said container, said stopper being slidable within said container away from said open end toward said closed end, said vial having a zone of a diameter larger than the largest lateral diameter of said stopper and into which said stopper is received as it is slid away from said open end to permit fluid communication from one side of said stopper to the other side of said stopper and thereby permit mixing of different materials positioned above and below said stopper, said container also having closure means at said open end to provide a multi-compartment medicament storage device.

4 Claims, 15 Drawing Figures

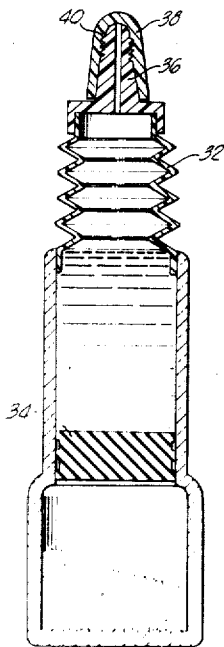


FIG. 1.

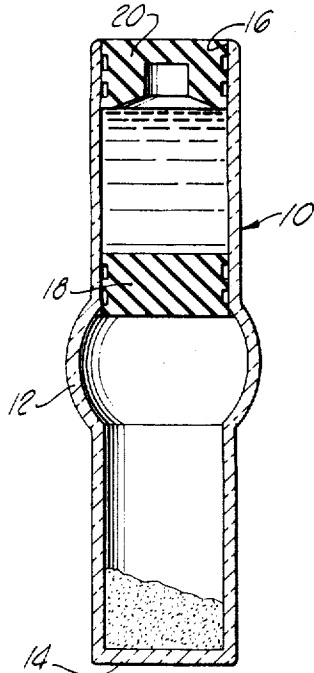


FIG. 3.

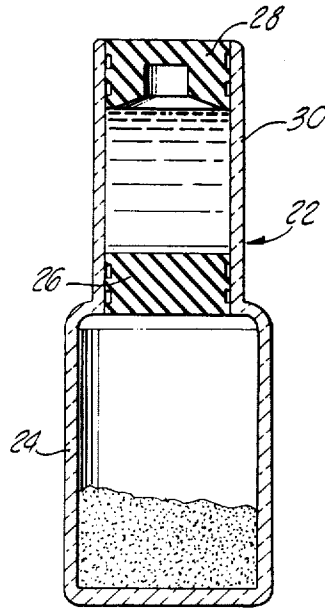


FIG. 4.

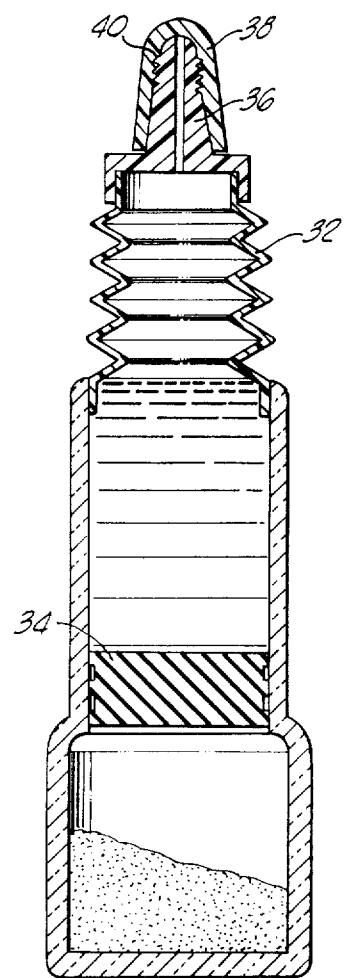


FIG. 2.

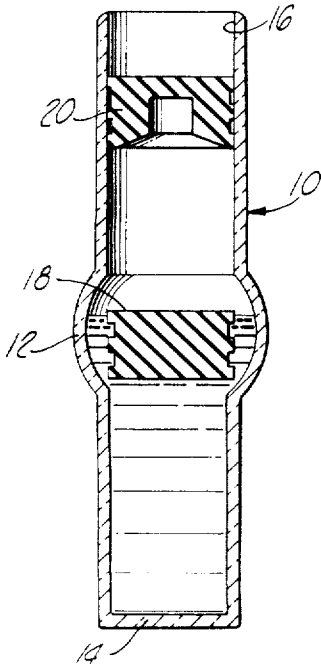


FIG. 5.

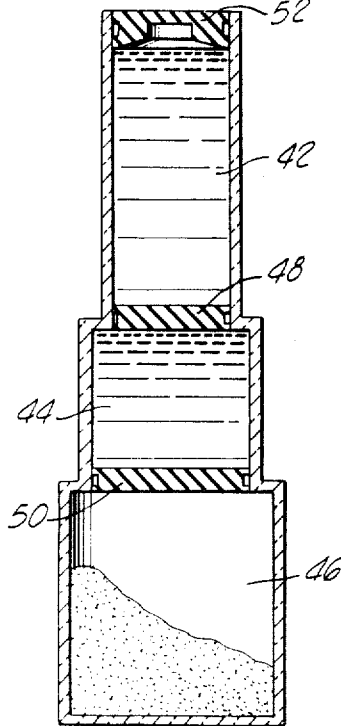
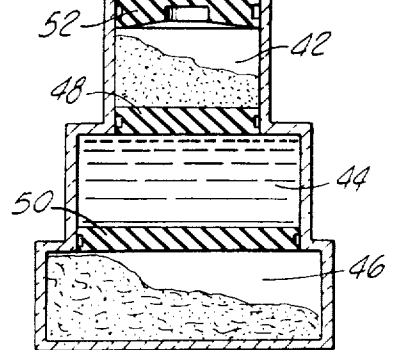


FIG. 6.



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FIG. 7.

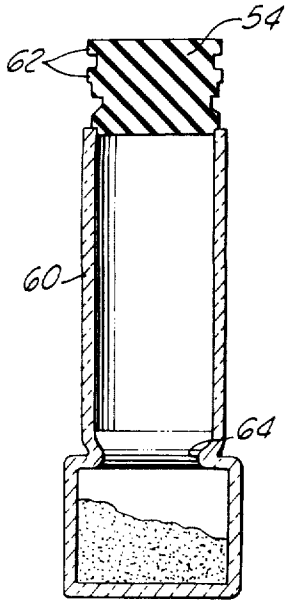


FIG. 8.

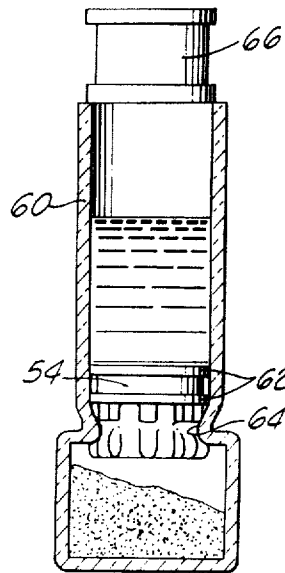


FIG. 9.

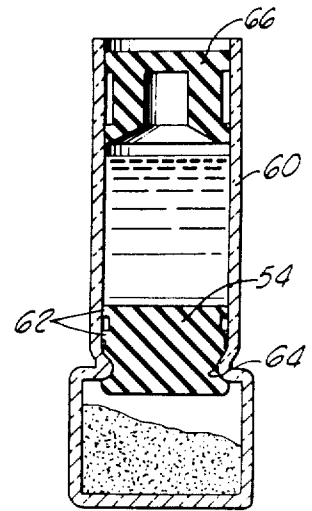


FIG. 11.

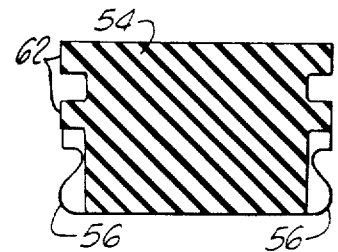
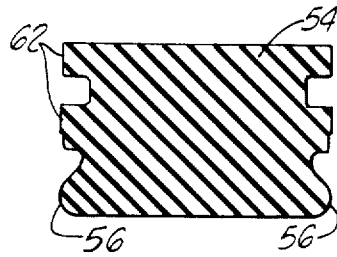
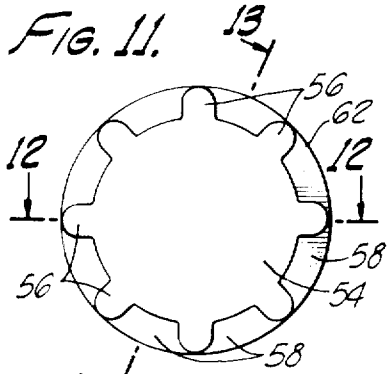


FIG. 12.

FIG. 13.

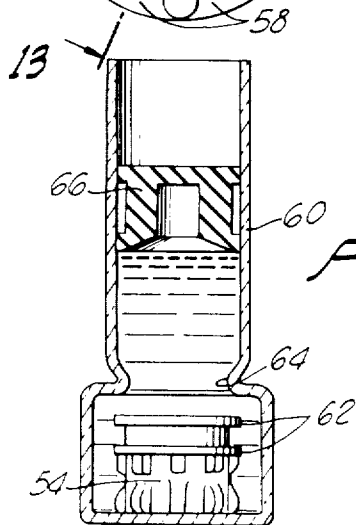


FIG. 10.

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FIG. 14.

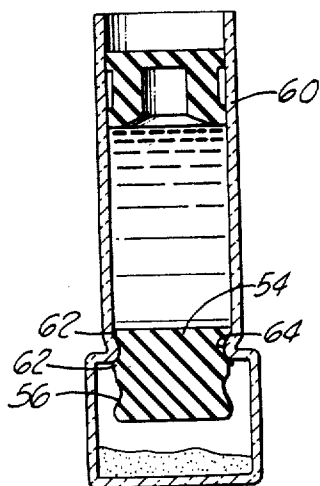
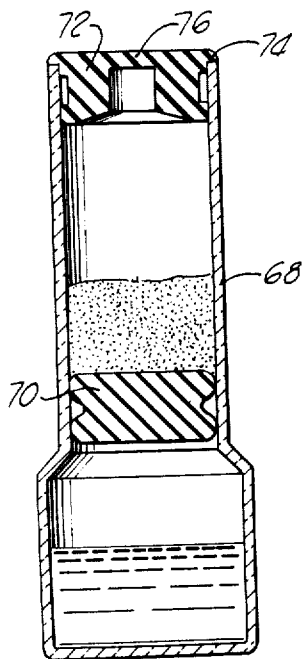


FIG. 15.



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BACKGROUND OF THE INVENTION

Brown U.S. Pat. No. 2,717,601 discloses a syringe ampule having a tubular body, the bore of the body at a zone intermediate the ends being oval or elliptical in cross-section to provide recessed portions and thereby create a bypass for liquid normally confined within the bore and to the rear of a resilient stopper as the stopper is shifted laterally of the bore in the zone of the oval cross-section. This device is, at least theoretically, capable of providing a two-compartment device in which a solid medicament and a liquid medicament or diluent are separated prior to the time of administration. However, in practice it has been found that the device of the above patent is essentially unacceptable because the oval cross-section is such that the minor diameter of the ellipse is approximately equal to the diameter of the stopper. Thus, when the stopper is moved, it still is maintained in the oval zone in an aligned position. The consequence of this is that when the operator applies force sufficient to laterally shift the center plug of the bore, which force is surprisingly great in most cases because of the seizure that the rings of the center plug take to the walls of the bore during storage, the center plug has sufficient inertia created by the force required to break the seizure that it traverses the zone of oval cross-section in an aligned state and comes to rest at the opposite end of the oval zone or beyond it thereby re-sealing the one compartment from the other. The consequence of this situation is that in many cases, the Brown device fails as a mixing device for wet and dry medicament components. The present invention is believed to represent a substantial advance in the art in that the center plug and the configuration of the enlarged portion of the container itself are such that the center plug when shifted in the bore passes into an enlarged zone where the plug can fall free. Therefore, it is impossible for the re-seating of the plug to occur as it commonly does in the Brown device.

SUMMARY OF THE INVENTION

Briefly, the present invention comprises a novel medicament container comprising a vial having an open end and a closed end, at least one slidable resilient stopper within said vial normally positioned intermediate said open end and said closed end and normally forming a fluid tight seal on the walls of said container, said stopper being slidable within said container away from said open end toward said closed end, said vial having a zone of a diameter larger than the largest lateral diameter of said stopper and into which said stopper is received as it is slid away from said open end to permit fluid communication from one side of said stopper to the other side of said stopper and thereby permit mixing of different materials positioned above and below said stopper, said container also having closure means at said open end to provide a multi-compartment medicament storage device. This patent also describes a three-compartment medicament container comprising a vial having a bottom cylindrical portion having a closed end, an intermediate cylindrical portion having an internal diameter less than that of said bottom portion and integrally joined thereto by a step-like transition zone, and a top cylindrical portion having an internal diameter less than that of said intermediate portion and integrally joined thereto by a step-like transition zone, said top portion having an open end, resilient slidable stoppers positioned in said top and intermediate portions immediately above said transition zones and forming fluid tight seals on the walls of said portions, said stopper having a lateral diameter less than the internal diameter of the cylindrical portion of the vial immediately below it, and a third slidable resilient stopper in said open end whereby when said third stopper is slid downwardly into said top portion, said other stoppers are dislodged from fluid tight sealing to permit communication between all three portions of said vial.

It is an object of the present invention to provide a novel multi-compartment medicament storage container.

Another object of the present invention is the provision of a two-compartment medicament container in which the center plug is dislodged into an enlarged zone where the center plug can fall free and thereby be rendered incapable of becoming re-seated or otherwise interfering with adequate mixing of the various medicament components within the device.

A further object of the present invention is to provide a multi-compartment medicament device in which the center plug is a lyophilizing plug.

Still another object of the present invention is the provision of a three-compartment medicament containing device adapted to mix two liquids and a powder or two powders and a liquid.

These and other objects and advantages of the present invention will be apparent from the more detailed description which follows taken in conjunction with the accompanying drawings.

DESCRIPTION OF PREFERRED EMBODIMENTS

Turning to the drawings:

FIG. 1 is a sectional view of one embodiment of the present invention as it appears during normal storage with a dry medicament in the lower portion and a diluent therefor in the upper portion.

FIG. 2 shows the device of FIG. 1 in operation with the center plug dislodged into the enlarged center section.

FIG. 3 is another embodiment of the present invention in which the lower portion is enlarged throughout its length as compared to the upper portion of the container.

FIG. 4 shows still another embodiment of the present invention in which the upper normally open end of a container is provided with an accordion-like device adapted to create hydraulic pressure within the container and dislodge the center plug. This device is also equipped with an outlet for the discharge of the mixed medicament ingredients.

FIG. 5 shows still another embodiment of the present invention in which two liquid materials and a solid are normally separated and yet are adapted to be mixed.

FIG. 6 is similar to FIG. 5 except that the device contains two solid materials and one liquid material.

FIG. 7 shows another and preferred embodiment of the present invention in which the center plug is provided with passages around its periphery to permit lyophilization of the dry powder at the bottom of the container after said center plug has been partially inserted but not seated in the container.

FIG. 8 shows the device of FIG. 7 after lyophilization has been completed and the center plug has been fully seated on the restricting ring.

FIG. 9 shows the completion of the device of FIG. 8 with the second plug fully inserted in place in the open end of the container.

FIG. 10 shows the device of FIGS. 7-9 in operation in which the second plug has been reciprocated longitudinally to dislodge the center plug and permit mixing.

FIG. 11 is an enlarged end view of the center plug shown in FIGS. 7-10.

FIG. 12 is a sectional view taken along the line 12-12 in FIG. 11.

FIG. 13 is a sectional view taken along the line 13-13 in FIG. 11.

FIG. 14 shows the device of FIGS. 7-13 wherein the center plug is seated in a different manner.

FIG. 15 shows another embodiment of the invention wherein the end plug is fixed or non-reciprocating.

Turning to the drawings in greater detail, as shown in FIG. 1 in one embodiment of the present invention the container 10 has an enlarged center portion 12, a closed end 14, and an open end 16. Received in container 10 is center stopper 18 and a second or end stopper 20. The enlarged portion 12 is sufficiently larger in diameter than the zones above it and below it so that the center stopper 18 is essentially free of any sealing action when it is present in an enlarged zone. This

result is provided by maintaining a greater inside diameter in portion 12 than the largest lateral diameter of stopper 18 over a longitudinal length of portion 12 which is at least slightly more than the longitudinal length of stopper 18.

Turning to FIG. 3, the container 22 has a lower portion 24 which is enlarged diametrically throughout its length as described above so that the center stopper 26 is free to fall therein when end stopper 28 is reciprocated in the upper part 30 of the container. A variation of this device is shown in FIG. 4 in which the end of the container is provided with a bellows or accordion-like section 32 which when longitudinally compressed dislodges the center stopper 34 and permits mixing. The contents of the device can be discharged through tip 36 after removal of cover 38 secured to tip 36 by complementary threads 40.

FIGS. 5 and 6 show a three-compartment device embodying the present invention. In this device the top compartment 42 contains a liquid, the intermediate compartment 44 contains a second liquid and the bottom compartment 46 of the device contains a powder. The stoppers 48 and 50 are dislodgeable to permit mixing upon reciprocation of end stopper 52. Obviously, this device may be used with two powders and a single diluent as shown in FIG. 6 or in any other combination of powders and liquids.

The embodiment shown in FIGS. 7-13 involves the use of a lyophilizing stopper or plug 54. This plug 54 is provided with projections 56 around its lower periphery. The spaces 58 between the projections 56 provide a passage for any vapors coming from the inside of vial 60 during the lyophilizing process. In operation, the vial containing the material to be lyophilized is fitted with the plug in the position shown in FIG. 7. The vial is then placed in the lyophilizer and vacuum applied in conventional manner until the material within the vial has dried and the vapors withdrawn by passage through spaces 58. Then the plates which those skilled in the art will recognize are standard in a lyophilizer, are lowered forcing the plug 54 into the vial 60 to an extent necessary for the sealing rings 62 to form a seal on the inner walls of the vial. Thereafter oxygen or air can be permitted to enter the lyophilizing chamber. The partial or complete atmospheric pressure on the exposed surface of the plug 54 will then force it down into the vial until it seats on restriction 64 in vial 60, as shown in FIGS. 8 and 9. In some cases, it is desirable after removal of the vial from the lyophilizer to manually or otherwise further advance the plug 54 within vial 60 so that the restriction 64 is positioned between rings 62. In any case, the diluent for the dry powder is then inserted into the upper portion of vial 60 as shown in FIGS. 8 and 9 and the second or end stopper 66 is inserted.

In operation of the completed vial, the operation at the time it is desired to administer the contents of the vial simply depresses the end stopper 66, as shown in FIG. 10 which dislodges the center lyophilizing plug 54 and permits mixing of

the dry and wet materials. After mixing, the contents of the vial can be removed using an ordinary hypodermic syringe provided with a needle which is used to puncture end stopper 66.

5 In the embodiment of FIG. 15, the vial 68 is provided with a center plug 70 and a fixed end plug 72 having an annular flange 74. The center plug and vial can be of any of the configurations previously described. This device can be operated by inserting a probe through the thin diaphragm portion 76 of plug 72 to reach and dislodge plug 70 into the enlarged area, permitting mixing. The mixed contents can then be withdrawn by a variety of techniques including an ordinary hypodermic syringe.

Those skilled in the art will immediately recognize that the device of the present invention represents a major advance in the art of packaging wet-dry medication. The device is capable of simple fabrication. For example, the vials used are normally glass and the stoppers or plugs are usually formed of rubber or some other resilient material.

20 Having fully described the invention it is intended that it be limited only by the lawful scope of the appended claims.

I claim:

1. A novel medicament container comprising a first cylindrical zone having an opening at each of its ends, one end of said first cylindrical zone opening into a second cylindrical zone, said second cylindrical zone having an internal diameter which is larger than the internal diameter of said first cylindrical zone, said second cylindrical zone terminating in an imperforate circular closed end, a slidable resilient imperforate stopper within said first cylindrical zone normally forming a fluid tight seal on the walls of said zone, said stopper being longitudinally slidable over the length of said first cylindrical zone while maintaining a seal with the walls of said zone, said stopper being receivable in said second cylindrical zone whereby fluid communication can be established between said zones to permit mixing of different materials contained above and below said stopper, said container also having a third zone at the other end of said first cylindrical zone and comprising a longitudinally compressible wall portion and an end closure which includes a sealable dispensing tip to provide a two-compartment medicament storage device, said compressible wall portion being adapted to create hydraulic pressure on said slidable stopper upon compression to slide the stopper from said first cylindrical zone into said second cylindrical zone.

2. The container of claim 1 wherein the longitudinally compressible wall portion includes a longitudinally compressible accordion-like section.

3. The container of claim 1 wherein said first and second cylindrical zones are of constant diameter.

4. The container of claim 1 wherein the stopper is provided with a plurality of sealing rings.

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