

[54] **RESEALABLE HERMETICALLY
SEALED AMPULES AND CLOSURE
THEREOF**

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206/47 A

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[58] Field of Search **215/6, 12 R, 32; 206/47 A**

[56] **References Cited**

UNITED STATES PATENTS

2,486,321	10/1949	O'Sullivan	215/32
1,956,568	5/1934	Fjord	215/32 X
2,908,555	10/1959	Grosskopf	215/32 X
2,977,014	3/1961	Kock	215/32 X
3,544,020	12/1970	Goldberg	215/32 X
2,048,219	7/1936	Putter	215/6
2,836,320	5/1958	Carroll	215/6
2,865,524	12/1958	Reznek	215/6

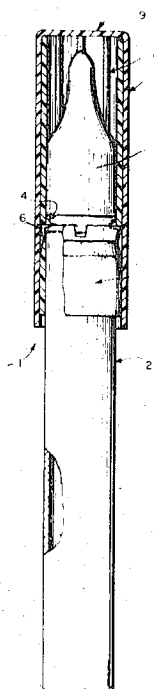
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[57] **ABSTRACT**

A resealable hermetically sealed ampule construction,

and a closure adapted for use therewith, are provided. The ampule is a hollow cylindrical glass body having hermetically sealed ends, and provided with scoring to facilitate opening of the ampule by breaking at the score line. The ampule is fitted with a first friction fitted cylindrical sleeve of a semirigid plastic material, such as nylon, polyethylene, or the like, provided with an annular, inwardly projecting shoulder adapted to engage with the scoring on the ampule. There is also provided a second sleeve, slidably engaged and friction fitted to the said first sleeve which serves, when slightly deformed by the user, to transmit force through the shoulder of the first sleeve to the scoring of the ampule. Such force serves to break open the ampule at the score without shattering the structure and endangering the user. The second sleeve is provided with the means to engage the upper portion of the ampule above the score line so that the second sleeve and the ampule cap can be withdrawn by slidably removing the second sleeve from engagement with the first. Once opened the ampule can be resealed by replacing the second sleeve in engagement with the first sleeve. An optional additional feature of the ampule is the provision in the upper part of the second sleeve, above the ampule cap, of at least one additional breakable ampule. In such a fashion, analytical testing procedures and the like are greatly facilitated by the employment of hermetically sealed, precisely measured quantities of reagents, which can be employed in sequential fashion in a single, resealable ampule construction.

4 Claims, 4 Drawing Figures



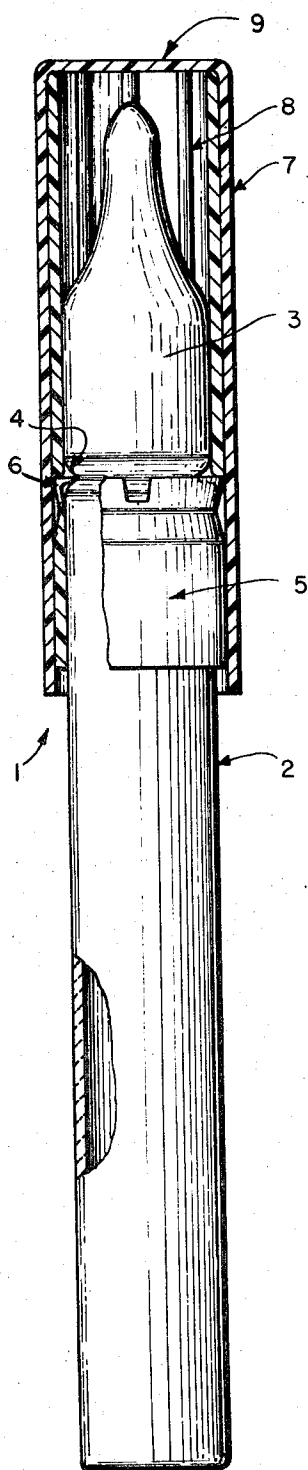


FIG. 1

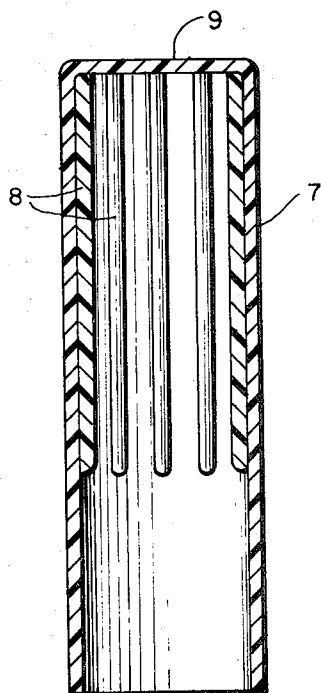


FIG. 2

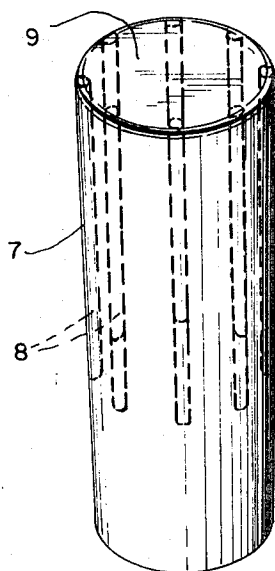


FIG. 3

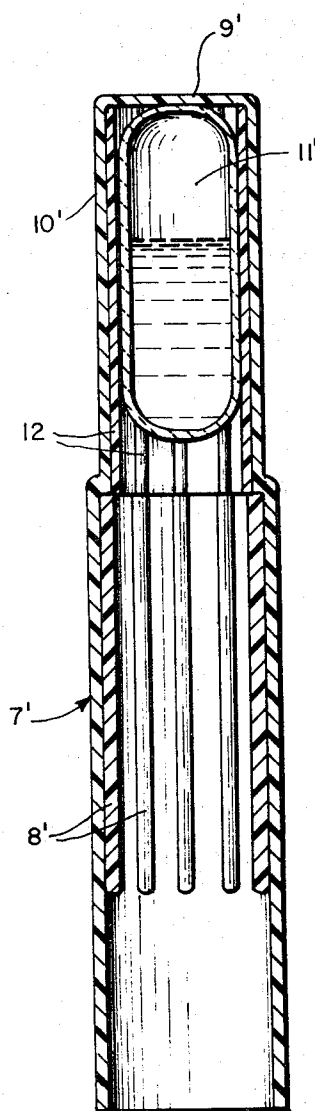


FIG. 4

RESEALABLE HERMETICALLY SEALED AMPULES AND CLOSURE THEREOF

The present invention relates to ampules and hermetically sealed containers. More particularly, it relates to glass ampules and hermetically sealed glass containers which are resealable after opening. Still more particularly, it relates to glass ampules and like glass containers provided with friction fitted sleeves about the portion designed to be opened, which serve as means for opening and for resealing the ampule after it is opened for use.

Glass ampules have been widely used as containers for a variety of materials, notably in the pharmaceutical and biological arts. They afford an excellent combination of properties which are mostly related to the employment of glass and the effectiveness of the seals attainable with glass containers. Hermetically sealed, breakable and disposable glass ampules are considered to be a necessary evil since, for all their advantages, their disadvantageous features present substantial problems for the user. Notably, it is difficult to maintain sterility of the package during the opening procedure, and frequently upon opening the glass will shatter with the resulting risks of cuts, contamination of personnel by toxic materials, loss of expensive materials, and delay of procedures. In addition, such ampules are not generally resealable and, as a consequence, ampules have proved awkward or unusable in a number of circumstances where such containers would otherwise be highly desirable.

The requirements of the art have made it necessary to rely on the use of vials provided with screw-cap closures for a number of situations where a glass ampule would be preferable but for the aforementioned problems. The use of screw-cap closures eliminates the problems of breakage of the container and provides simple and convenient reclosing of the container. A number of different disadvantages are associated with the employment of screw-caps, however; and foremost among these is the added expense. In addition, it has proved impossible to maintain an effective seal during the necessary shelf life of the material, particularly when packaged under vacuum or an inert gas fill.

Thus, it is abundantly clear that undesirable compromises have been necessary in packaging such products as pharmaceutical and biological materials. Numerous attempts have been made to improve upon the basic structures of both hermetically sealed glass ampules and screw-cap vials, but with limited success. Such efforts have resulted in substantial increases in costs to attain even modest improvements of the disadvantageous features.

The desirability of a simple, inexpensive, and effective means for providing a hermetically sealed, reclosable glass ampule is readily apparent to those of ordinary skill in the art. Particularly desirable improvements in the construction of glass ampules would be the provision of means facilitating opening of such glass ampules which would be effective to reduce or eliminate the shattering of the glass container, eliminating or reducing wastage of the contents and avoiding the risks of contaminating areas and personnel with toxic materials and the like contained in such ampules. Effective means for opening such glass ampules would also reduce the incidence of cut fingers of the personnel

handling and opening the ampules. An additional, highly desirable development would be effective means for resealing glass ampules after they have been opened since, in a number of contexts, it is desirable to conduct tests, incubations, reactions, and the like, in the opened ampule, and the inability to reclose the container, preferably with a substantially air tight closure, often renders such procedures impractical or impossible. Since it is often necessary to employ a plurality of separate reagents which cannot be combined before testing, or which must be employed in sequential fashion, it would also be highly desirable to provide a construction which accommodates a plurality of separate reagents.

It is an object of the present invention, accordingly, to provide a hermetically sealed glass ampule with means for opening the ampule without fragmentation of the glass and without exposure of the user to fragments and sharp edges of glass. A further object is to provide glass ampules with means for re-closing after the ampule is opened. Still another object is the provision of an ampule construction which contains a plurality of reagents. It is a still further object to provide such means by a single integrated structural means. Another object is the fulfillment of the foregoing objects by a simple structure and at minimal cost. These and still other objects are fulfilled by the present invention, described hereinafter.

The present invention comprises a conventional, hermetically sealed glass ampule of a generally cylindrical configuration, provided with scoring of the glass to facilitate opening the ampule at a predetermined point, and further provided with a novel opening and reclosing means. The said opening and reclosing means comprises a first friction fitted cylindrical sleeve of a semi-rigid plastic material, provided with an annular projecting shoulder, which is emplaced on the ampule in a position engaging the scoring on the glass. A second, concentric slidably engaged, friction fitted cylindrical sleeve is provided over the first sleeve and engaging, preferably also by friction fit, the upper cap portion of the ampule above the score line. By a slight deformation of the ampule provided with the sleeve construction in accordance with the present invention, the glass is fractured at the score. Once the score is broken, the ampule is readily opened by withdrawing the second sleeve from its engagement with the first sleeve, and, because of the friction fit, also removing the upper portion of the ampule, exposing the contents for operational purposes. When it is desired to reclose the ampule, the second sleeve is readily replaced and provides a substantially air tight seal.

The present invention is conveniently understood by reference to the drawing wherein:

FIG. 1 illustrates a hermetically sealed glass ampule provided with the novel opening and re-closing means in accordance with the present invention;

FIG. 2 illustrates a first portion of the novel opening and closing means of the present invention;

FIG. 3 illustrates a second portion of the novel opening and closing means of the present invention; and

FIG. 4 illustrates another embodiment of the second portion of the novel opening and closing means of the present invention.

With particular reference to the drawings in FIG. 1, there is provided a hermetically sealed glass ampule 1, which is a substantially cylindrical hollow container, provided with a lower barrel 2 adapted to hold the solid or liquid contents, not shown, and an upper cap portion 3. The lower barrel 2 and the upper cap 3 are separated by scoring which is located at the desired position for opening the ampule. The scoring can conveniently be a formed indentation or reduction in thickness in the wall of the ampule or, if desired, a mechanical or chemical weakening of the container wall, attained by abrasion, etching, or the like. Scoring of glass is wholly conventional and familiar to those of ordinary skill in the art, and accordingly needs no elaborate description and forms no part of the present invention. In addition, a portion of the lower barrel 2 is enclosed in a first cylindrical sleeve 5 which is fabricated from a semi-rigid plastic material, such as nylon, polyethylene, or the like. Suitable semi-rigid plastics are well known to those of ordinary skill in the art, and the choice of a particular material can readily be made on the basis of convenience, since the nature of the plastic forms no part of the present invention. The sleeve 5 fits by friction about at least the upper portion of barrel 2 and thereby forms a substantially air tight seal therewith.

The sleeve 5 is provided with an annular inwardly projecting shoulder portion 6 which is preferably constructed as a plurality of annular sections as shown in the figure although the shoulder can also be a continuous single annular if desired, which is adapted to engage scoring 4.

Over the first sleeve, 5, there is provided a second, concentric sleeve 7 which forms a friction fit slidably engaged with the first sleeve, and provided with means to engage the cap portion, 3, of ampule 1, preferably by means of axial ribs 8, inwardly projecting from the inner wall of second sleeve 7. The preferred construction of the second sleeve is shown in detail at FIG. 3, wherein the reference numerals correspond to the same numerals in FIG. 1. It should be noted that the axial ribs 8 do not run the entire length of the sleeve but rather only through that portion adapted to engage cap 3. The ribs thus also serve to prevent sliding the sleeve too far down on the ampule 1.

In use, the lower barrel 2 of the ampule 1 is filled with a material such as, for example, a vaccine, a toxin, a virus, bacterial specimens, or the like, and is hermetically sealed. The first closure sleeve 5 is then slid down over the upper cap 3 and down onto the lower barrel 2 until the shoulder 6 engages the scoring 4 on the ampule 1, and then the second sleeve 7 is slidably engaged with the first sleeve 5. The ampule can then be stored without concern for leakage, contamination or gas exchange and the contents thus retain their potency and effectiveness. When employment of the contents is desired, the ampule is readily and easily opened by a slight deformation of the sleeve 5, which is transmitted to the glass ampule 1 and the force is concentrated, by virtue of the shoulder segments 6, upon the second portion 4. A clean break of the ampule 1 occurs and, because of the scoring 4, the concentration of the force of the deformation at the shoulder 6, and the circumferential support of the cap 3, and the barrel 2 by the sleeves 5 and 7, the break is effectively confined to the scored portion 4 and fracture of the barrel 2 and the

cap 3 is substantially eliminated. The operation of opening is completed by sliding the second sleeve 7 upward from engagement with the first sleeve, 5, to expose the contents for use.

When the procedure utilizing the contents of the ampule requires a substantial period of time, or when the contents of the ampule are toxic, virulent, or otherwise not safe, or when contamination of the contents is undesirable, the ampule can be readily reclosed by sliding the second sleeve 7 back into engagement with first sleeve 5. By virtue of the tight friction fit, a substantially air tight seal can be attained and maintained for substantial periods of time.

While in the embodiment illustrated in FIGS. 1 and 2, the second sleeve 7 is provided with a top closure 9 of the same semi-rigid plastic, such a feature is not required if the engagement of the second sleeve 7 and the upper cap 3 is a good friction fit. The employment of the closure 9 is, however, preferred since it tends to shield the cap 3 from any phenomena which might tend to fracture that portion of the ampule.

Another aspect of the present invention devolves about circumstances when a plurality of reagents, vaccines, toxins, viruses, bacterial specimens, or the like, or mixtures thereof, or precursors thereof are to be employed in conjunction, either by mixing just prior to use or by sequential employment. In such circumstances it is usual to employ separate containers for each component, to open each as required, and to add these to a common container. As a consequence, the problems of breakage, spillage, contamination, and the like are obviously multiplied. Hence, the present invention has been adapted to employ a plurality of such materials in a single, integrated structure suitable for mixing such materials immediately prior to use or for employing each in sequential form, or a combination of these.

A construction of the desired sort is illustrated in FIG. 4, which shows a second sleeve, 7', constructed in accordance with the present invention, and further provided with an upper portion, 10', which is an extension of the barrel of sleeve 7' beyond the limit of cap 3 of ampule 1, and having disposed therein one or more secondary ampules, 11', held in place by attachment means, such as a continuation of axial ribs, 8'. The upper portion of sleeve 7' can be of the same diameter, or of greater diameter, or, as shown in the figure, of a smaller diameter than the lower portion of the second sleeve 7'. In use, the principal ampule 1 is opened in the aforementioned fashion, and thereafter, at appropriate times and appropriate sequences, which can be before or after or a combination of both, the secondary ampule or ampules, 11', are opened by applying pressure to the overlying portion of the second sleeve 7' to release the contents thereof and to permit them to pass downwardly into the barrel 2 of ampule 1. In such fashion, even relatively complex analytical procedures and the like can be conducted expeditiously and accurately with a minimum of time, effort, equipment, and operator skill. In most instances the only variable necessary for manipulation is sample preparation, measuring, and introduction into the primary ampule, and the notation of results. Thus the effect is a high degree of standardization and semiautomation at exceptionally low cost, together with greatly enhanced reagent shelf life, safety, accuracy, reproducibility, and reliability.

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While certain specific embodiments have been disclosed and discussed in detail, it is not intended that the present invention be limited to scope thereto rather it is intended that the invention be construed broadly to include the many variations that will occur readily to these of ordinary skill in the art in making adaptations of the invention to specific end uses. In particular, the invention should be construed as defined in the following appended claims.

What is claimed is:

1. A hollow, cylindrical, hermetically sealed, glass ampule having a lower barrel, a cap, and a scored portion and closure means comprising a first friction fitted cylindrical sleeve of a semi-rigid plastic, said sleeve provided with an annular, inwardly projecting shoulder

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adapted to engage said scored portion, and a second, concentric sleeve of a semi-rigid plastic, friction fitted to said first sleeve, and means engaging said second sleeve and said cap.

2. The ampule of claim 1 wherein said second sleeve is fitted with a closure at its upper end.

3. The ampule of claim 1 wherein said second sleeve extends upwardly from said cap, and wherein the extended portion of said second sleeve contains at least one secondary ampule.

4. The ampule of claim 1 wherein said means engaging said cap comprise a plurality of axial, inwardly projecting ribs on the interior surface of said second sleeve which engage said cap by friction.

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