

[54] **CONTAINER CLOSURE FOR LYOPHILIZED PRODUCTS**

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Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 308,096, Nov. 20, 1972, Pat. No. 3,834,571.

[52] U.S. Cl. **215/256; 215/307**

[51] Int. Cl. **B65d 51/16**

[58] Field of Search **215/254, 256, 307, 311**

[56] **References Cited**

UNITED STATES PATENTS

2,526,225	10/1950	Gronemeyer	215/256
2,820,564	1/1958	Solomon	215/307 X
2,927,709	3/1960	Hoffman	215/307 X
3,025,991	3/1962	Gillon	215/311
3,032,226	5/1962	Terwilliger	215/256

3,073,472	1/1963	Williams	215/256
3,084,823	4/1963	Reichstein	215/311
3,164,279	1/1965	Towns	215/307 X

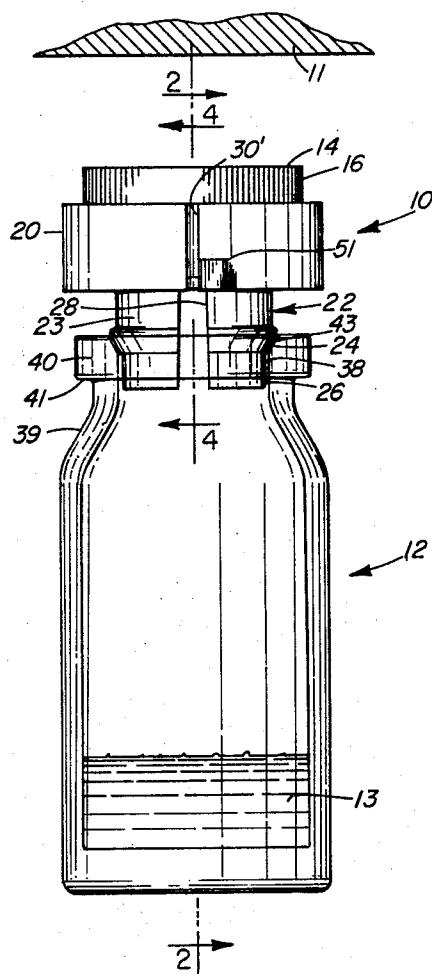
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[57] **ABSTRACT**

The specific disclosure provides an integrally formed closure for a lyophilized product container having a neck, an upwardly facing opening in the neck and an external radial bead on the neck. The closure comprises a downwardly extending stopper portion having port means for venting the container during a lyophilization process, and means for seating the closure in a first position in the neck during the lyophilization process with the port means being positioned at least in part above the opening. The closure also includes a downwardly extending tear away skirt portion having means for engaging the bead when the closure is seated in a second position in the neck with the port means positioned below the opening to prevent venting of the container.

6 Claims, 4 Drawing Figures



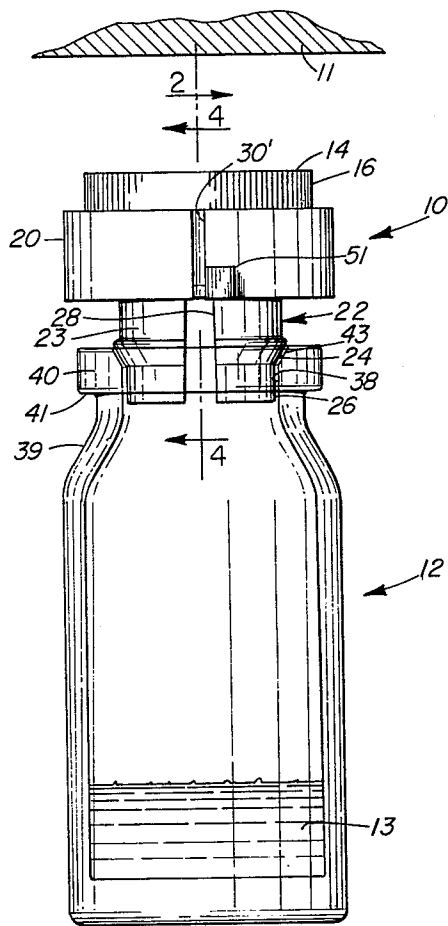


Fig. 1

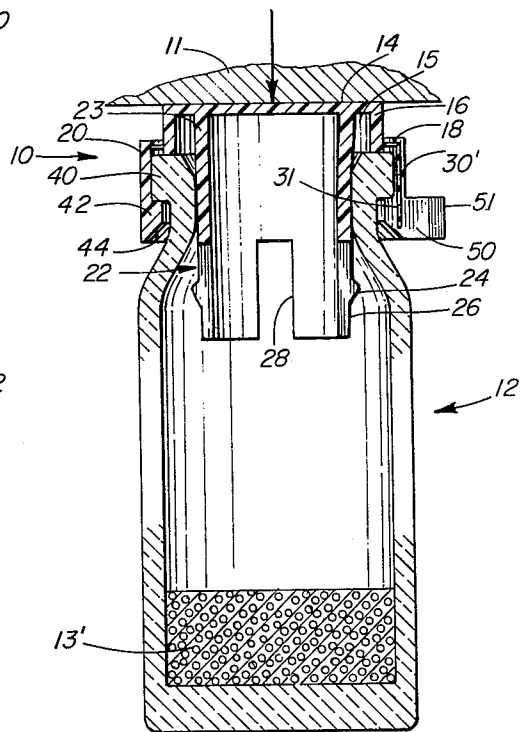


Fig. 2

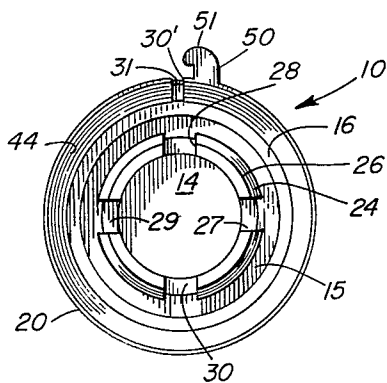


Fig. 3

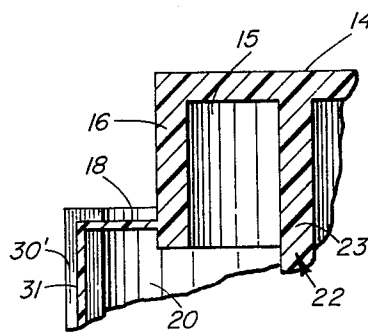


Fig. 4

CONTAINER CLOSURE FOR LYOPHILIZED PRODUCTS

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of U.S. Pat. application Ser. No. 308,096, filed Nov. 20, 1972 and now U.S. Pat. No. 3,834,571.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to closures for containers such as those used in the pharmaceutical industry. More particularly, the present invention relates to container closures for lyophilized products wherein the closures have a tear-away portion to permit initial removal of the closures from the containers.

2. Description of the Prior Art

Lyophilization, gelsiccation or freeze drying are used to describe a technique which has been known for many years. The technique is a valuable processing scheme for a pharmaceutical manufacturer, and has been used to dehydrate substances such as biologicals, serums, hormones, blood coagulation reagents and chemistry control reagents. The substances subjected to a lyophilization process are typically those which are destroyed or impaired at normal drying temperatures. Such substances are usually unstable when maintained in solution for a long period of time, and are generally required to be refrigerated to prevent spoilage.

A lyophilization process generally provides for freezing substances at or below -40°F. , and thereafter subjecting the substances to low absolute pressures. For example, at absolute pressures lower than 3 mm. of mercury, frozen water will pass from a solid to a gaseous state without becoming liquid (sublime).

It is known to use a two-piece closure for sealing a container after the products therein have been lyophilized. This known two-piece closure consists of a rubber stopper having a pair of vertical slots extending upwardly from the bottom of the stopper portion, and a metallic tear-off cap. The rubber stopper is partially inserted in the neck of a container with the slots extending above the neck for venting the container during the lyophilization process. After the process has been completed, the rubber stopper is fully inserted in the container such that the slots are sealed from a surrounding environment. Thereafter, the container is removed from the lyophilization apparatus and fed to an apparatus for securing the metallic cap about the upper end of the rubber stopper and the neck of the container. U.S. Pat. No. 3,480,171 discloses a similar two-piece container closure, but without the vertical slots in the stopper portion.

The two-piece closure of U.S. Pat. No. 3,480,171 requires a separate apparatus for installing the tear-off metallic cap on the container. Further, removal of such tear-off metallic caps presents a risk of injury to the user.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a one-piece closure for a lyophilized product container wherein the closure functions for venting the container during lyophilization, and functions as a tamperproof closure after lyophilization.

Another object of the present invention is to provide a closure for lyophilized product containers which may be removed easily and quickly without risk of injury to a user.

Still another object of the invention is to provide a closure for a lyophilized product container which is economical to manufacture, and relatively simple to install on a container.

In accordance with the present invention, there is provided an integrally formed closure for a lyophilized product container wherein the container comprises a neck, an upwardly facing opening in the neck having a predetermined diameter and an external radial bead on the neck. The closure comprises a top wall, and a stopper portion extending downwardly from the top wall. The stopper portion comprises an upper cylindrical section having an outer diameter greater than the predetermined diameter, a bottom cylindrical section having an outer diameter less than the predetermined diameter, an annular beveled section interconnecting the upper and bottom sections, and port means for venting the container during a lyophilization process. The beveled section has an upper outer diameter greater than the outer diameter of the upper section, and provides means for seating the closure in the neck during the lyophilization process with the port means positioned at least in part above the opening. The closure further comprises a tear-away skirt portion extending downwardly from the top wall, and the tear-away skirt portion includes means for engaging the bevel when the closure is seated in a second position in the neck with the port means positioned below the opening to prevent venting the container.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevation view of a closure and container embodiment of the present invention with the closure positioned for venting the container during a lyophilization process;

FIG. 2 is a cross-sectional view taken along line 2—2 of FIG. 1, but showing the closure fully seated in the neck of the container after the lyophilization process;

FIG. 3 is a bottom plan view of the closure shown in FIG. 1; and

FIG. 4 is a cross-section of a portion of the closure of FIG. 1.

DESCRIPTION OF SPECIFIC EMBODIMENTS

With reference to the drawings, there is shown a container closure 10 associated with a container embodied as a glass bottle 12. The bottle 12 has a reduced neck 39 and an external radial bead or flange 40 adjacent to an opening at the top of the neck 39. The bead 40 has an annular sharply angled shoulder 41 spaced downwardly from the opening in the neck 39.

The closure 10 has a top wall 14, and a hollow cylindrical stopper portion 22 extending downwardly from the central region of the top wall 14. The stopper portion 22 has an annular beveled section or seat 24, and a bottom section or end 26 of reduced outer diameter extending downwardly from the seat 24. Four slots 27—30 extend vertically through the lower end 26, the seat 24 and into the upper section of main body 23 of the stopper portion 22.

Generally, bottle openings have a beveled position at the upper ends thereof as shown at 43 of the bottle 12. Bottles and closures may be manufactured with a di-

mensional tolerance range. When the bottle opening 38 is at the outer limit of a tolerance range and the outer diameter of the upper section 23 of the stopper portion 22 is at the inner limit of a tolerance range there is a possibility that the closure 10 may undesirably be seated relatively low in the beveled portion 43 and thus limit the amount of the slots 27-30 exposed to the surrounding environment during a lyophilization process. To avoid the possibility of this undesirable condition, the upper part of the beveled seat 24 has an outer diameter greater than the outer diameter of the upper section 23 and thereby insures that at least a predetermined portion of each slot 27-30 is situated above the opening during the process. The outer diameter of the upper section 23 is greater than a predetermined diameter defined by the neck opening 38 to provide a fluid seal when the closure 10 is in the position shown in FIG. 2.

An outer wall 16 extends downwardly from the top wall 14 to complete a top wall portion of the closure 10. The outer wall 16 is concentrically aligned with the stopper portion 22 and is spaced therefrom to form an annulus 15. A tear-away skirt portion 20 is concentrically aligned with the outer wall 16 of the top wall portion, and is joined to the lower end of the outer wall 16 by a thin horizontal annular section 18 (FIG. 2). As shown in FIG. 2, the tear-away skirt portion extends downwardly about the bead 40, and has an internal circular rib 42 for abutting engagement with the shoulder 41 of the bead 40. The rib 42 preferably has a sharply angled or square upper corner to provide a tight-fitting interlock with the angular shoulder 41. The rib 42 is shown with a rounded or beveled bottom corner 44 for cooperation with the outer surface of the bead 40 to guide the closure 10 over the bead 40 during assembly of the closure 10 to the bottle 12 as shown in FIG. 2.

A groove 30' extends vertically along the outer surface of the skirt portion 20, and another vertical groove 32 extends along the inner surface of the skirt portion 20 through the rib 42 to provide a thin frangible or tearable section 31. A pull tab 51 is joined to the lower end of the skirt portion 20 by a member 50.

The closure 10 is integrally formed of flexible and resilient material which, when stretched or otherwise deformed, tends to return to an original shape so that the closure 10 can be made to engage the internal and external portions of the bottle 12 in fluid tight contact. One such suitable material is polyethylene which, in the molded state, provides the necessary degree of strength and firmness.

As shown in FIG. 1, the closure 10 is seated in a first position in the neck 39 of the bottle 12 with the annular beveled seat 24 in abutting contact with the inner surface of the neck 29 defining the neck opening 38. In this position, the slots 27-30 extend above the opening in the neck 39 for venting the interior of the bottle 12 during the lyophilization process on a liquid 13 in the bottle 12. After the lyophilization process is completed, a movable member 11 is moved into abutting contact with the outer surface of the top wall 14 and applies a force to the top wall 14 to seat the closure 10 in a second position shown in FIG. 2 wherein the ports or vertical slots 27-30 are positioned below the opening in the neck 39, and the closure 10 provides a fluid seal for the lyophilized product 13' in the bottle 12.

As noted above, the beveled or rounded corner 44 at the lower end of the skirt portion 20 guides the skirt

portion 20 over the bead 40 while the closure 10 is moved from the first position shown in FIG. 1 to the second position shown in FIG. 2. In the position shown in FIG. 2, the angular upper surface of the rib 42 is snap-locked into abutting engagement under the angular shoulder 41 of the bead 40. When thus positioned on the bottle 12, the closure 10 is effectively tamper-proof because any attempt to move the angular rib 42 over the angular shoulder 41 of the bead 40 will produce visible damage.

An outward force applied by a user to the pull tab 51 readily removes the tear-away skirt portion 20 by a tearing action upwardly along the vertical tearable section 31 and around the annular thin section 18.

What is claimed is:

1. An integrally formed closure for a lyophilized product container; wherein said container comprises a neck, an upwardly facing circular opening in said neck and an external radial bead on said neck, said opening having a predetermined diameter; said closure comprising:

a top wall portion;

a stopper portion extending downwardly from said top wall portion;

said stopper portion comprising an upper cylindrical section having an outer diameter greater than said predetermined diameter, a bottom cylindrical section having an outer diameter less than said predetermined diameter, an annular beveled section interconnecting said upper and bottom sections, and port means for venting said container during a lyophilization process;

said beveled section having an upper outer diameter greater than the outer diameter of said upper cylindrical section and providing means for seating said closure in a first position in said neck during the lyophilization process with said port means positioned at least in part above said opening; and

a tear-away skirt portion extending downwardly from said top wall portion, and including means for engaging said bead when said closure is seated in a second position in said neck with said port means positioned below said opening to prevent venting said container.

2. The closure of claim 1 wherein said stopper portion is hollow, and wherein said port means comprises a plurality of slots extending upwardly through said bottom section, said beveled section and to a level above said beveled section.

3. The closure of claim 1 wherein said skirt portion is joined to said top wall portion by a thin annular horizontal section; and wherein said skirt portion further includes another thin section extending downwardly from said horizontal section to the bottom edge of said skirt portion, and a pull tab adjacent to said downwardly extending section.

4. The closure of claim 3 wherein said bead engaging means comprises an inwardly projecting circular rib.

5. The closure of claim 4 wherein said top wall portion is in abutting contact with the uppermost surface of said neck when said closure is in said second position.

6. The closure of claim 5 wherein the lower surface of said bead is angularly formed, and wherein the upper surface of said rib is angularly formed for interlocking engagement with the lower surface of said bead when said closure is in said second position.

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