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STERILE CAP FOR A FREEZE-DRYING CONTAINER AND METHOD OF
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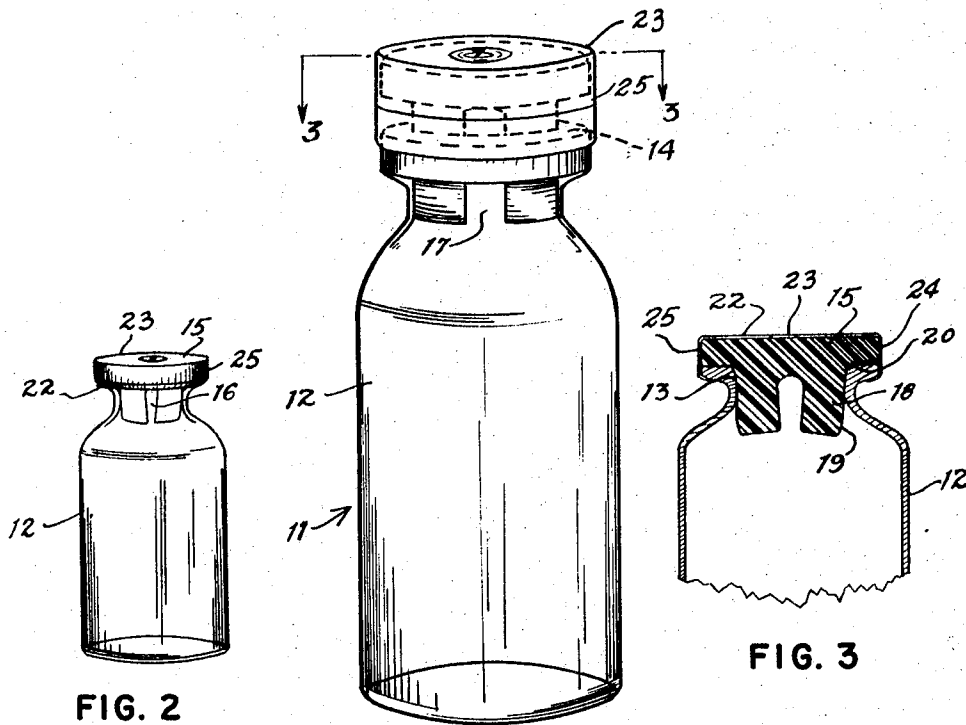


FIG. 2

FIG. 1

FIG. 3

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STERILE CAP FOR A FREEZE-DRYING CONTAINER AND METHOD OF FREEZE-DRYING MATERIALS UNDER STERILE CONDITIONS

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1 Claim

ABSTRACT OF THE DISCLOSURE

A cap and stopper assembly to maintain a sterile condition in a container during freeze-drying and stoppering.

This invention relates to a sterile cap for a freeze-drying container and a method of freeze-drying materials under sterile conditions.

The freeze-drying technique has been applied successfully to the freeze-drying of various biological materials such as, for example, vaccines and the like.

In freeze-drying material of this nature it is, of course, necessary to conduct the process under sterile conditions. If foreign bacteria should enter the container and contaminate the product the biological consequences would be, of course, extremely serious. The freeze-dried vaccines and the like are injected into a patient's body under sterile conditions.

Prior to the instant invention it was a rather difficult procedure to freeze-dry such materials under sterile conditions. The freeze-drying process had to be carried out in a completely sterile room. Such conditions are difficult to maintain. Furthermore the packaging of the material also had to be carried out in such a completely sterile room. As a result, while it was heretofore successfully possible to conduct freeze-drying of biological materials under such sterile conditions the techniques involved were costly, time consuming, and expensive.

Peculiarly, in contamination of products, bacteria do not contaminate unless they fall directly into the product. Bacteria are, of course, principally airborne. Hence, unless there are foreign conditions agitating the air, such as wind or the like, bacteria will not contaminate a container if the top of the container is covered.

The instant invention involves a structure which permits freeze-drying of biological material under conditions wherein total sterility of the room need not be obtained. The invention involves both the method of carrying out such process and apparatus for accomplishing the same.

The above constitutes a brief description of the instant invention and some of the objects and advantages thereof. Other objects and advantages of this invention will become apparent to the reader of this specification as the description proceeds.

The invention will now be described by reference to the accompanying drawings which are made a part of this specification.

FIG. 1 is a perspective view showing a container which is utilized for the freeze-drying of biological material. The closure means which are used to maintain sterility after the container is capped are shown in the partially open position that said means assume while freeze-drying is taking place.

FIG. 2 is a view similar to that of FIG. 1 but showing the closure means closing the mouth of the container and with the cap portion crimped over the container so that sterility is maintained until the material is to be used.

FIG. 3 is a cross-sectional view taken along lines 3—3 of FIG. 1.

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The invention will now be further described by reference to the specific form thereof shown in the accompanying drawings. In this connection, however, the reader is cautioned to note that the specific form of this invention as set forth in the instant specification is for illustrative purposes and for purposes of example only. Various changes and modifications may obviously be made within the spirit and scope of this invention and would occur to those skilled in this art.

Now referring to the specific form of the instant invention as set forth in the drawings a freeze-drying container assembly 11 comprises a receptacle portion 12 which is provided with a circular mouth 13 thereupon and a circumferential outwardly extending flange 14 carried by the mouth. A resilient stopper 15 is selectively disposable within mouth 13 of portion 12 either in stoppered (FIG. 2) relationship or partially stoppered (FIG. 1) relationship. A plurality of longitudinal grooves 16 and 17 are provided within stopper 15. Stopper 15 includes an outwardly and upwardly tapered body portion 18 having a smallest diameter 19 and a largest diameter 20. The smallest diameter 19 is no greater than the diameter of mouth 13 and the greatest diameter is greater than the diameter of mouth 13. Thus the body portion of stopper 15 can firmly close the mouth of the container.

A holding portion 22 is provided on stopper 15 which is carried by the body portion thereof and is adapted to overlie mouth 13 of receptacle portion 12.

A cap 23 is provided with an interior perimetral recess 24 within which holding portion 22 of stopper 15 is supported. Cap 23 is also formed with a perimetally disposed downwardly depending portion 25 which is adapted to overlie and embrace mouth 13 of receptacle 12. Downwardly depending portion 25 is also adapted to be crimped under flange 14 as shown in FIG. 2.

With the foregoing specific description the operation of this invention may now be explained.

Biological material 30 is placed within receptacle 12 under sterile conditions. The stopper is placed within the mouth of the freeze-drying receptacle in the position shown in FIG. 1 and the device is attached to a freeze-drying apparatus of conventional type. At this point sterile conditions need no longer be maintained since the cap portion of the stopper overlies the container and prevents further contamination. The freeze-drying process is now continued until the biological material within the container is freeze-dried. At that point the stopper is placed in the position shown in FIG. 2, the cap is crimped beneath the flange, and the container may then be sold. Sterile conditions will be maintained until the biological material within the container is actually used.

The foregoing sets forth the manner in which the objects of this invention are achieved.

We claim:

1. A sterile closure arrangement particularly adapted for use in maintaining sterility of a container contents during freeze-drying thereof, said closure arrangement comprising a resilient stopper having a tapered body portion adapted for selective disposition in the mouth of a container, said body portion having a diametrically disposed slot extending axially of said body portion and being operative to permit communication with the interior of the container when said stopper is partially inserted in the mouth thereof, said stopper including a flange of greater diameter than said body portion and adapted to overlie the mouth of said container to assist in sealing said container when said body portion is completely inserted in said mouth, and a sterile cap covering said flange on said body portion, said sterile cap including a top and a perimetally disposed, downwardly depending skirt, and means in said cap to embrace and retain said flange on said body portion to provide a sterile shield

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during freeze-drying of the contents and stoppering of
said container.

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JOSEPH R. LECLAIR, *Primary Examiner.*

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