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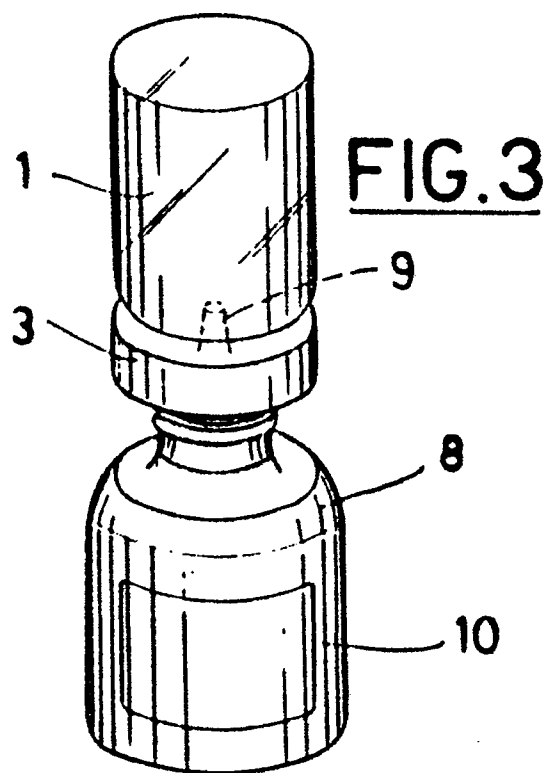
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54 Containers for lyophilized pharmaceutical products.

57 Containers for lyophilized pharmaceutical products to be administrated in drops, consist of two bottles (1, 8). The first one (1), that initially contains the lyophilized product (2), is made of rigid material and is provided with a hermetically sealed cap (3) that can be partially ripped open and with a rubber stopper (7) interposed between the cap (3) and its own open edge. The second bottle (8), that is designed for containing initially the solvent (10) is made of compressible material and is provided with a spout (9). The first bottle (1) has a hole (6) in the stopper (7) designed for receiving the spout (9).



EP 0 459 182 A2

This invention is referred to containers for lyophilized pharmaceutical products to be administered in drops, such as eye drops.

The packages of these pharmaceutical products usually consist of a dropper and a couple of bottles that contain respectively the lyophilized product and the solvent.

Extemporaneous prepared lyophilized eye drops are a kind of product that has to be used in a relatively short time, once it is prepared so as to prevent decay.

For the purpose of giving the user a product the expiration date of which starts from the day of the reconstitution of the eye drops, the pharmaceutical product has to be prepared extemporaneously following the instructions that are written on the ticket that is enclosed with the product.

The instructions reported on most of these products prescribe to tear the metallic crown cap of the glass bottle containing the lyophilized product and remove the rubber stopper or garnishing. Then, the solvent has to be poured out from the plastic container into said glass bottle, and in this way the solution is obtained by solving the lyophilized product that is contained therein. Finally the dropper is fitted onto the glass bottle that has to be shaken until the solution is completed.

After this, the user can instill the eye drops by squeezing the body of the plastic dropper applied on the glass bottle, after removing the top's cap. After the use, the cap has to be put on again and the bottle put away.

These operations have a few drawbacks.

First of all a problem occurs regarding the lack of sterility of the medicine when it has to be used: the solvent is actually poured out with no protection into the glass bottle containing the lyophilized product.

Thus eventual impurities or bacteric polluting agents coming from the external environment can infiltrate inside the glass bottle.

The main defect of the prior art lies in the fact that the product has to be instilled by squeezing the body of a plastic dropper that is fixed on the glass bottle very weakly. This operation has to be carried out very delicately as the dropper has an elongated shape. Consequently, a weak couple of forces acting with respect to the dropper's connection on the bottle is enough to displace the dropper from its seat.

Thus a device that eliminates the above drawbacks is required.

It is an object of this invention to limit the possibilities of bacteric pollution occurring when the user prepares the medicine and to guarantee better hygienic conditions by avoiding any direct contact between the medicine and the external environment.

It is another object of the invention to simplify the operations for preparing the medicine, and to achieve a higher degree of practicalness and safety for the containers.

For these and three objects that will appear more clearly by reading the following description, this invention proposes to realize containers for lyophilized pharmaceutical products to be administered in drops, characterized in that they consist of two bottles of which the first one, initially containing the lyophilized product is made of rigid material and provided with a hermetically sealed cap that can be partially ripped open and with a rubber stopper interposed between the cap and its own open edge; the second bottle being designed for containing initially the solvent made of compressible material and being provided with a spout; the first bottle having a hole in the stopper designed for receiving the spout; the first bottle having a hole in the stopper designed for receiving the spout of the second bottle.

The containers for pharmaceutical products according to this invention are going to be described referring to the enclosed drawings, in which:

fig. 1 shows a first bottle hermetically sealed with the lyophilized product in it;

fig. 2 shows the bottle of fig. 1 once opened and ready to receive the solvent;

fig. 3 shows the two containers according to this invention joined during the phase of preparation (reconstitution) of the eye drops;

fig. 4 shows a detail of the bottle of figs. 1 and 2;

fig. 5 shows the bottle containing the solvent; and

fig. 6 shows an embodiment different from the one of fig. 1.

Referring to fig. 1, a bottle 1, usually made of glass, contains the lyophilized product 2 and it is hermetically sealed by a cap 3, the centre of which is punched to the end of a tang or lever 4 for tearing it open.

For the use it is necessary to lift the tang 4. This movement causes the removal of the tang 4 which pulls a circular portion of cap 3 with it, uncovering a circular hole 5 (see fig. 2). A small hole 6 is obtained in the centre of a stopper 7 in correspondence of hole 5 in cap 3. The stopper 7 is usually located in these containers between the upper edge of the container and the closing cap.

A different embodiment is shown in fig. 6. This differs from the sample of fig. 1 for the presence of a further cap 11, preferably made of plastic material, that covers cap 3 superiorly and that substitutes the tang 4 for opening the bottle. Cap 11 has a larger diameter than that of cap 3 on which it is centrally punched, so the user can easily push

the protruding edge of cap 11 upwards. Cap 11 will rip off the central part of cap 3 uncovering in this way the hole 5 in a similar way as previously described and illustrated in figs. 1 and 2.

The stopper 7 can also consist of a simple rubber washer as shown in fig. 4, or of a traditional rubber stopper, or otherwise it can be of the "stoppering" kind, that is already used in particular for lyophilized products.

Referring to fig. 5, the spout 9 of a plastic bottle 8 that originally contains the solvent 10 has to be introduced into the hole 6. Then, the two bottles be turned upside-down as a whole, with bottle 1 on top and bottle 8 underneath.

At this point the lateral surface of bottle 8 has got to be pressed so that the solvent 10 will spray upwards, penetrating inside bottle 1 through spout 9 and solving the lyophilized contents therein and forming therefore the solution in doing so.

As soon as the sides of bottle 8 (that is still turned upside-down with the spout 9 inserted in hole 6 of bottle 1) are released, the newly formed liquid solution of eye drops will be resucked downwards under the effect of the force of gravity and of the depression caused by bottle 8 that is decompressed and recovers its own original shape immediately.

The bottle 8 is finally filled with the eye drop solution; bottle 1 can be taken off of bottle 8 and the product is ready to be used.

As it can be understood, this invention has several advantages. First of all the dropper that was present for the known eye drops containers has been eliminated together with its paper coverings for preserving the sterility.

It should be noticed that the process through which the lyophilized product is solved is highly aseptic with respect to the prior technique, as the solvent does not contact the external environment in any way.

The diameter of hole 6 of the stopper 7 is designed so as to let the solvent be sprayed inside the bottle with a thin and quite vigorous jet that creates a considerable turbulence that facilitates the solving of the lyophilized product. Moreover, a further re-mixing takes place as the solution passes back into bottle 8 from bottle 1.

Another improvement with respect to the prior devices is given by the fact that the eye drops are contained inside bottle 8 which is made of plastic. This can be provided with a child proof cap 12 ensuring a perfect seal against any accidental opening.

Claims

1. Containers for lyophilized pharmaceutical products to be administrated in drops, character-

ized in that they consist of two bottles (1, 8), of which the first one (1), initially containing the lyophilized product (2) is made of rigid material and provided with a hermetically sealed cap (3) that can be partially ripped open and with a rubber stopper (7) interposed between the cap (3) and its own open edge; the second bottle (8) being designed for containing initially the solvent (10) made of compressible material and being provided with a spout (9); the first bottle (1) having a hole (6) in the stopper (7) designed for receiving the spout (9); the first bottle (1) having a hole (6) in the stopper (7) designed for receiving the spout (9) of the second bottle (8).

2. Dropping bottles according to claim 1 wherein a substantially circular hole (5) is formed in the sealed cap (3) when this is ripped open; the hole (5) being located in correspondence of the hole (6) obtained in the stopper (7) underneath the sealed cap (3).
3. Dropping bottles according to claims 1 and 2 wherein the hermetically sealed cap (3) is partially openable by means of a tang (4) that is centrally punched onto said cap (3).
4. Dropping bottles according to claims 1 and 2 wherein the bottle (1) is provided with a further cap (11), preferably made of plastic material, having a larger diameter with respect to the hermetically sealed cap (3) which it is centrally punched.
5. Dropping bottles according to claim 1 wherein the bottle (8) provided with a spout (9) has a cap (12).
6. Dropping bottles according to claim 5 wherein the cap (12) is a child-proof cap.

FIG.1

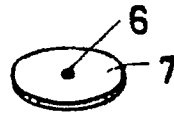
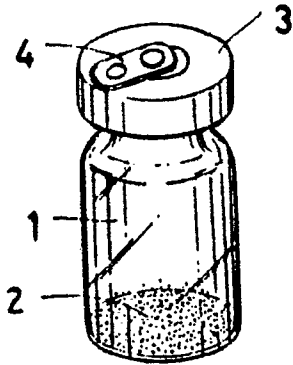


FIG.4

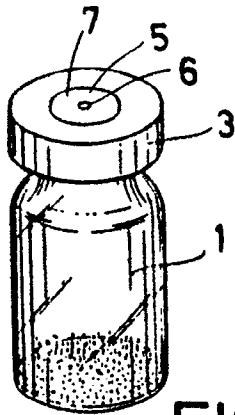


FIG.2

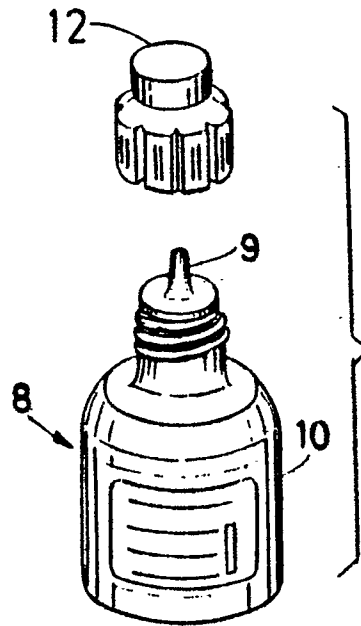


FIG.5

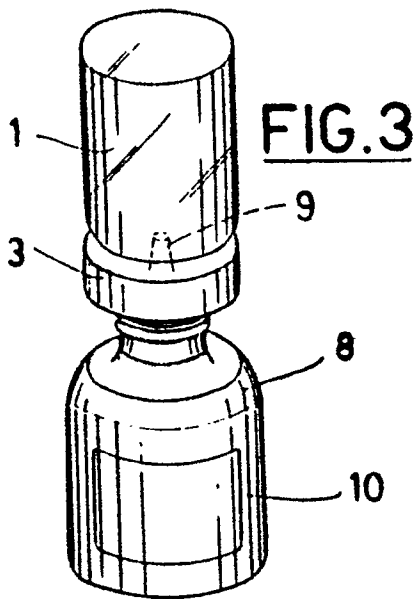


FIG.3

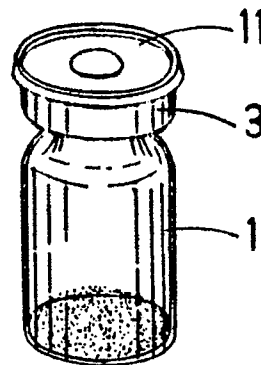


FIG.6