April 11, 1939. P. G. HEINEMAN 2,153,981

MEDICINAL CONTAINER

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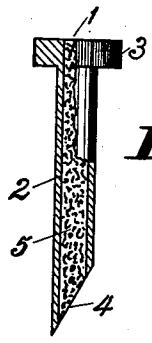


Fig. 1

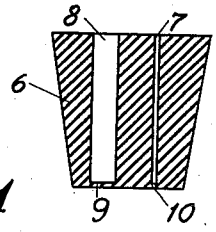


Fig. 2

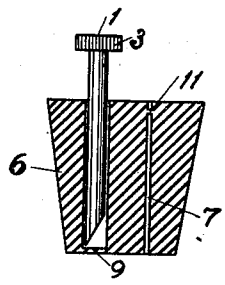


Fig. 3

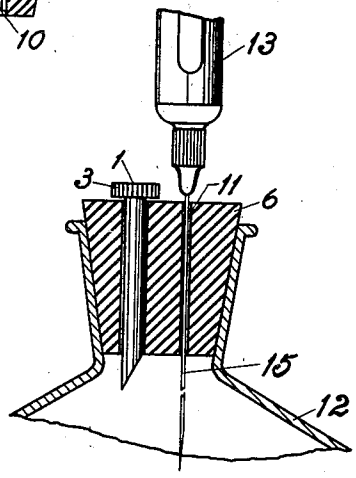
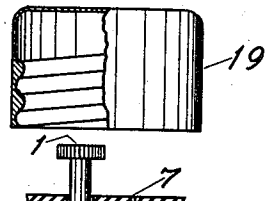


Fig. 3a



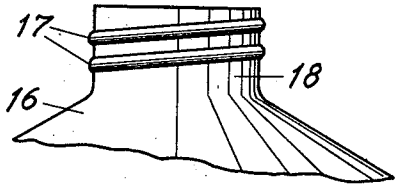


Fig. 4

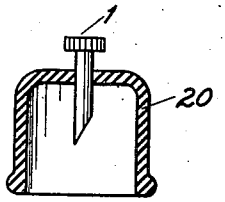


Fig. 5

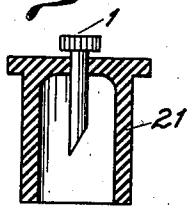


Fig. 6

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MEDICINAL CONTAINER

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Application April 3, 1936, Serial No. 72,522

1 Claim. (Cl. 215—47)

The object of this invention is a novel type of closed medicinal container which will enable the physician, or dentist, or veterinarian, to withdraw from it into a hypodermic syringe, an accurate amount of its liquid contents, without difficulty and without risk of microbial contamination of the liquid from the air.

Medicinal containers are usually made of glass and they are commonly closed with rubber stoppers or rubber caps. When filling the syringe, the operator must either remove the stopper or cap, or he must puncture it with the hypodermic needle attached to the syringe. If the closure is removed, communication with the air cannot be avoided. If it is not removed, difficulty arises in aspirating the solution into the syringe through the needle, because during removal of the liquid a partial vacuum is created in the closed container. The larger the amount to be withdrawn, the greater is the suction caused by partial vacuum. Accuracy of dosage, therefore, is impaired.

The above disadvantages are particularly noticeable with "multiple dose containers" which in contrast to now commonly used single dose ampules hold two or more charges of medicament. Upon repeated use, the risk of contamination or inconvenient operation through creation of a vacuum has so far rendered this type of ampule unserviceable. My invention is intended to remedy this situation. Production of "multiple dose containers" is obviously less expensive in every respect than that of single dose ampules.

Some practitioners draw air into the sterilized syringe before puncturing the stopper. This air is then injected into the air space of the container creating internal pressure. The risk of contamination during this procedure is obvious. Some manufacturers incorporate germicidal compounds into the medicinal solutions, in order to destroy the germs which gain access with the air. However, in order to accomplish real antisepsis, the germicide must be present in sufficient quantity to be effective. Such quantities of antiseptics may cause irritation to the patient. An ideal medicament should contain no ingredient which is therapeutically unnecessary and which may bring discomfort to the patient.

My novel type of container is designed to overcome these drawbacks. For that purpose it is closed with a closure provided with an air filter which permits equalization of pressure between the outside and the air space of the container upon aspiration of the solution into the hypodermic syringe while avoiding the risk of contamination.

The elements of this combination which impart to it the aforementioned functions are illustrated in the accompanying sheet of drawings in which

Fig. 1 is a view, partly in section, of an air filter;

Fig. 2 is a cross-sectional view of a stopper in accordance with my invention;

Figs. 3 and 3*a* are the same, but illustrating the working of the air filter in cooperation with the stopper 6 (Fig. 3); and with a container in aspirating the solution into the syringe (Fig. 3*a*);

Fig. 4 illustrates a combination of the stopper in Fig. 3 with a screw cap container.

Figs. 5 and 6 demonstrate two modifications of a cap as a closure in accordance with my invention.

In Fig. 1, the air filter 1 consists of a tube 2 made of a suitable material, such as chromium plated steel, stainless steel, brass or nickel; also Bakelite, hard rubber or any similar substance may be used. The tube 2 is equipped with a thumb-rest 3 and a beveled aperture 4; in its central cylinder 1 it contains a cotton filter 5.

The closure may be practically any style of stopper or cap. Three examples appear in the subsequent illustrations.

Fig. 2 shows a stopper 6, provided with two holes 7 and 8. The large hole 8 will accommodate the air filter 1; it is closed by the diaphragm 9. A fine hole 7 reaches from the top of stopper 6 to the diaphragm 10 at the lower end, or the hole is interrupted by a diaphragm 11, as in Fig. 3.

Figs. 3 and 3*a* exemplify the working of the air filter 1 in combination with the stopper 6 and the container 12 in aspirating a solution into the syringe 13. In inoperative position, the filter is inserted into the large hole 8 to such depth as to barely touch the diaphragm 9 without penetrating it. The small depression 11 in Fig. 3 indicates the location of the fine hole 7 and serves as a guide for the needle 15 of a hypodermic syringe 13.

A container 12 tightly closed with this stopper 6 is operated by pushing the air filter 1 down until the thumb-rest 3 contacts with the surface of the stopper. The beveled aperture 4 then enters the air space in the container 12. The fine hole 7 guides the needle 15 of the hypodermic syringe 13 which penetrates the rubber diaphragm 10 or 11, and then permits withdrawal of the medicament.

Fig. 4 illustrates a combination of the stopper in Figs. 3 and 3*a* with a screw-cap container. A bottle 16 with a screw-thread 17 on the neck 18

is fitted with the stopper 6 equipped with the air filter 1 and the needle hole 7. A screw-cap 19 can then be attached in such manner as to cover the stopper.

Optional embodiments of a combined air filter and stopper are shown in Figs. 5 and 6.

Fig. 5 illustrates a rubber cap 20 which may be slipped over the neck of a bottle in obvious manner. Upon using the outfit, the operator moistens the surface of the rubber cap 20 with a 2% phenol solution or any other aqueous germicide, and pushes filter 1 through the cap near its center.

The germicidal solution preserves sterility and facilitates penetration of the rubber by the filter point. There is no necessity for a needle hole in this type, because the needle punctures the rubber easily in any place.

Fig. 6 shows another style of stopper 21 which in principle is like that of Fig. 5, except that the skirt 21 of the closure member is longer and of lesser diameter.

In regard to the style of bottle, it has been found that a bottle with a cylindrical neck and without lip is most suitable when rubber caps are used. For solid stoppers any kind of neck is satisfactory. For small quantities of medicament up to one ounce there is no difficulty in using the medicament to the last drop. For larger amounts than one ounce, a flat bottle with a neck near one side permits usage of the whole amount of the solution by tipping the bottle when the amount of medicament contained therein is small.

The tube 2 in the air filter 1 is filled with a column 5 of non-absorbent cotton. The cotton is preferably of long fiber quality. Being non-absorbent, accidental contact with the solution in the container will not interfere with its efficiency as a filter. When the solution is withdrawn from the bottle in the manner indicated, air filters in germ-free condition into the air space of the bottle, equalizing pressure.

It will be noted that the rubber diaphragms 10 and 11 or the rubber cap 20 or 21 may be punctured many times with a hypodermic needle without risk of admitting unfiltered air, and they will close automatically after withdrawal of the needle due to the elasticity of the rubber.

Furthermore, after the air filter is properly placed, it remains in the same position as long as is necessary to use up the whole contents of the container. There is no filing of necks as with ampules and no exposure whatever to air contamination. Manipulation of my device is simple and safe.

It will be obvious from the above that the thumb-rest 3 of the air filter 1 may be made of different diameter according to the size of the stopper to which it is fitted.

In practical application, the container 12 may be shipped with the air filter 1 in the stopper 6, or the air filter in a separate package, according to the style of the stopper.

A salt in dry form may be placed in the containers and the solvents may be injected through a hypodermic needle connected with a syringe. The air filter works in both directions and relieves the air pressure caused by injection of solvent.

Three series of bacteriological tests were made with these types of closures. These tests have shown that the air, after having been filtered by the device described herein, is actually germ-free. The detailed report of these tests is as follows:

EFFICIENCY TESTS WITH RUBBER STOPPERS EQUIPPED WITH AIR FILTERS

First series, Figs 2 and 3

Two bottles—one of one ounce and one of two ounces capacity—are filled with National Institute of Health broth. They are stoppered with cotton and sterilized in an autoclave. Two stoppers are equipped with air filters and a fine hole is made in the stopper to reach nearly to the lower end, thus leaving a diaphragm of rubber of about 2 m/m. thickness. The two stoppers are wrapped in paper and sterilized in an autoclave. After sterilization, the cotton plugs are removed from the bottles and the stoppers are placed in the necks with aseptic precaution.

Varying amounts of the broth are removed daily—on several occasions twice daily—by means of a sterilized Luer syringe. The needle is passed through the fine hole in the rubber stopper. Each amount of broth thus removed is planted in a fermentation tube containing about 30 cubic centimeters of National Institute of Health broth and these fermentation tubes are incubated at 37° C. for seven days. The experiment terminated when the contents of the bottles were exhausted. A total of 20 withdrawals were made from the two-ounce bottle, and 10 from the one-ounce bottle. One of the bottles during the term of the experiment was kept at room temperature and the other one at 37° C. in the incubator. Thus contamination of the contents of either bottle would become evident both in the bottles and in the cultures made from the contents.

There was not a single fermentation tube showing contamination. The severity of the test is emphasized when it is considered that solutions for parenteral administration in the majority of cases do not contain substances which are favorable for bacterial growth. On the other hand, the broth of the National Institute of Health is one of the best culture media known.

There was not the slightest air resistance when the broth was drawn up in the syringe. It was proved that air passes readily through the filter when the bottle is placed flat on a table so that the end of the air filter was submerged. As soon as the syringe piston is moved up, air bubbles rise in the fluid.

This rubber stopper with the air filter makes possible the withdrawing of the solution without air resistance; it preserves sterility of the solution for an indefinite period of time; and it makes possible the placing of a number of doses in one container without danger of contaminating the solution when a dose is withdrawn.

Second series, see Fig. 3a

This series was made exactly as the first series, excepting that in the first series the needle hole in the stopper was made from the top to near the bottom, while this second series was made with a stopper having a needle hole from the bottom to the top, leaving a diaphragm of rubber at the top.

The results were as satisfactory as with the first series.

Third series, see Figs. 5 and 6

This third series of tests was made with a rubber cap instead of a stopper (see Fig. 5). In this

case the filter is inserted near the center of the cap. There is no needle hole in the cap. Instead, the cap is punctured by the sterilized needle in any suitable place. The tests were repeated daily up to a time when about one-half of the volume of broth remained in the bottle.

For the last test the bottle is laid on a table at such an angle that the broth covers the aperture of the filter. A needle, attached to a hypodermic syringe is then inserted through the rubber cap and about two cubic centimeters of broth are drawn into the syringe. These two cubic centimeters are planted in fermentation tubes containing National Institute of Health broth. The end of the filter being submerged in the broth, discharges the filtered air into the broth and it is thus possible to watch the air bubbles pass rapidly through the broth.

A fermentation tube is inoculated with the contents of the syringe and the bottle containing the remainder of the broth is incubated, to determine whether it is contaminated by the air bubbles.

No growth was observed in any one of the subcultures and no growth occurred in the broth which had been exposed to the bubbles of the air. This severe test proves the efficiency of the air filter.

This third series was made before an open window.

The operation of my device has above been described with respect to air as a contaminating agent. It is understood that other gaseous media as they may be used in medicinal practice, such as nitrogen or carbon dioxide, are within the scope of my invention and are intended to be within the purview of the appended claim.

What I claim is:

A medicinal container comprising in combination, a necked bottle and a stopper tightly sealing the same, a system of openings provided in said stopper which consists of channels traversing substantially the entire length of the stopper, and an air filter arranged in one of said channels to disinfect atmospheric air prior to entering the space of the container by operation of the system of openings, which filter comprises in combination, a hollow, sharply beveled, tube-like body, filled in its hollow space with a column of non-absorbent disinfecting cotton.

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