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STERILE PACKAGING

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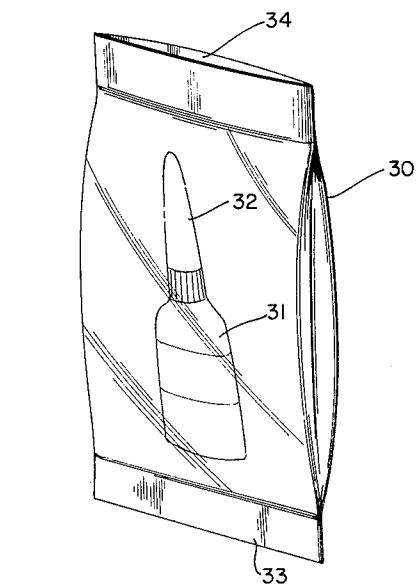
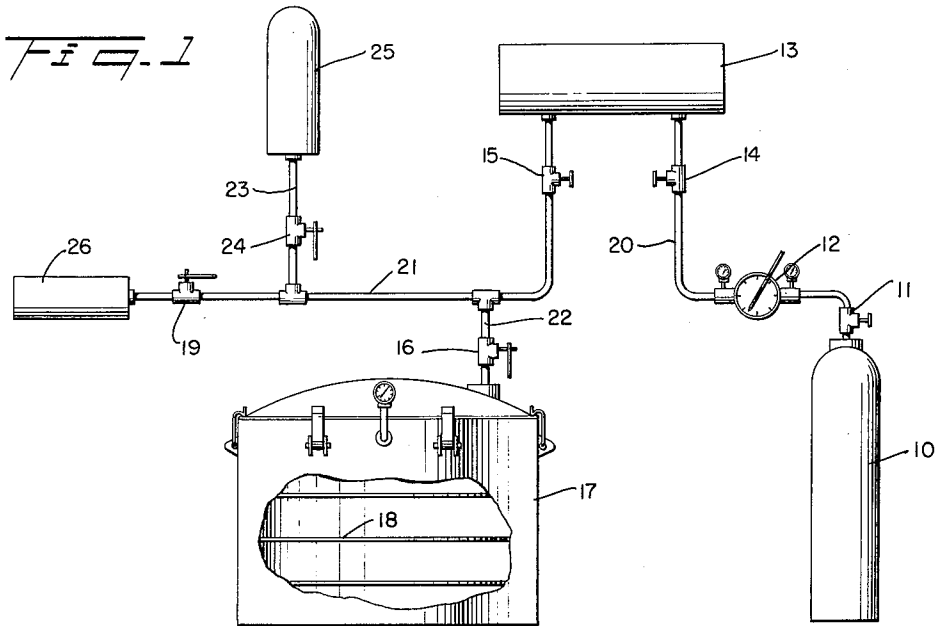
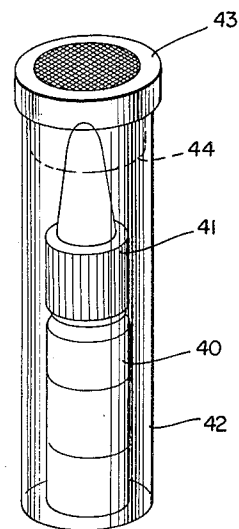


Fig. 3



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This invention relates to sterile packaging. It has particular relation to the sterile packaging of pharmaceuticals and will be described in that connection, but it is to be understood that it is equally useful in the sterile packaging of any material, object or substance.

The medical profession has need of sterile ampoules, sterile surgical instruments, and the like, which can be used once, without preliminary sterilization and attendant handling, in the doctor's office or in the hospital. It is an object of this invention to provide sterile packaging. An illustrative example is in the profession of ophthalmology, wherein ampoules are used to inject medications into the eyes of patients, and this invention will be described in connection with that particular problem.

Another object of the invention is to provide novel sterile packages for the preservation and protection of contents.

The above and further objects and novel features of the present invention will more fully appear from the following detailed description when the same is read in connection with the accompanying drawings. It is to be expressly understood, however, that the drawings are for the purpose of illustration only and are not intended as a definition of the limits of the invention. Reference for this latter purpose is had primarily to the appended claims.

In the drawings, wherein like reference characters refer to like parts throughout the several views,

FIG. 1 is a schematic diagram of an apparatus for carrying out the process;

FIG. 2 is an elevational view of a novel package according to the invention;

FIG. 3 is an elevational view of another novel package conforming to the invention.

In FIG. 1 the numeral 10 indicates a container holding ethylene oxide under pressure, diluted with an inert gas such as CO₂. Ethylene oxide has sterilizing properties which I use in this invention. Its sterilizing power against molds and bacteria is marked and is adequate for all normal purposes in a concentration of 10% in CO₂. It is possible to decrease the concentration until an inordinately long time is required to achieve sterility, or to increase it until the mixture becomes wasteful or may make a combustible mixture when released and mixed with the air, but the intelligent operative will avoid such extremes. Even under such extreme conditions the ethylene oxide retains its sterilizing properties, although excessively diluted on the one hand and wastefully concentrated on the other. Any other inert gas may be used as a diluent, but CO₂ is available, cheap and satisfactory.

Other alkylene oxide gases which are gaseous at ordinary temperature may also be used for sterilization but are more costly and not more efficient.

The sterilizing gas from compressed gas cylinder 10 passes through valve 11 to a pressure regulator of some standard type 12, by which the pressure in the sterilizing tank may be selected. The gas from regulator 12 passes through valve 14 to expansion chamber 13, from whence it passes through valve 15 to valve 16 and autoclave 17, which is provided with racks 18 on which packages such as those of FIGS. 2 and 3 are supported. Valves 11, 12, 14 are on pipe 20, and valves 15, 19 are on pipe 21, to which vat 17 is attached by pipe 22. Pipe 23 also branches off pipe 21 and contains valve 24. Bacterio-

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logical filter 25 is connected to pipe 23; such filters are frequently ceramic having porosity not over .5 micron. A vacuum pump 26 serves to exhaust the system when desired.

In operation the cover of autoclave 17 is opened, the racks 18 are stocked with the objects to be sterilized, valves 14, 15, 16, 19, 22, 24 are opened, the cover of the autoclave is replaced, the vacuum pump 26 is started and the system is exhausted of air up to valve 11, which remains closed. The pressure regulator 12 is set at 25 pounds and valves 19, 24 are closed. Valve 11 is now opened and the gas from cylinder 10 fills the system, including the autoclave, with a CO₂ and ethylene oxide atmosphere, containing e.g. 90% CO₂ and 10% ethylene oxide. The pressure is illustrative. Pressures of any value insufficient to damage the particular object being sterilized may be used. Atmospheric pressure is also useful. Pressures less than atmospheric tend to have less efficient penetration of crevices in objects than super-atmospheric pressures.

In an efficient operation the valves 11, 14, 15, 16, 19 were closed when the pressure in the system was 20 pounds, and the autoclave was allowed to rest under pressure for 6 hours. At the end of that time valves 16, 19 were opened and the autoclave was exhausted by pump 26. The valve 24 was opened to equalize the pressure with filtered air, and the autoclave was opened. This system provides effective sterilization and is applicable to another and very important part of the invention.

Referring now to FIGS. 2 and 3, a polyethylene sack 30, sealed at one end 33 but open at the other 34, contains a flexible tube 31, which may, e.g., hold a medicament. The tube has a long dropper-type spout covered by a cap 32. In FIG. 3 a cylindrical bottle 40 with cap 41 is enclosed within a cylindrical container 42 having a snug fitting cap 43 with an extension 44 extending tightly within the barrel of the container 42. The container 42 is made of polyethylene, which is substantially impermeable to bacteria and molds but somewhat permeable to ethylene oxide. This discovery is the basis of a valuable part of the invention.

A container 30 receives another container 31 which holds a medicament. The package, end 34 open, is put in the autoclave and sterilized, withdrawn and aseptically sealed, retaining some of the sterilizing gas. Sealing can be by hot clamps, which seal the lips of the sack together autogenously, by folding and clamping, or by any known method of sealing polyethylene. Aseptic conditions as known to the pharmacist are employed.

In FIG. 3 the containers are rigid but the outer is polyethylene and permeable to ethylene oxide.

The process can also be carried out by placing sealed packages in the autoclave although this method requires a materially longer time to achieve sterility as the sterilizing gas can only enter the outer container by passing through it.

Sterilization of the tip of the ampoule can be achieved by making the cap 32 of polyethylene, and sterilization of the contents will proceed if the inner container is also made of polyethylene.

The following examples were carried out under the conditions stated:

Plastic polyethylene vials similar to that of FIG. 2 were enclosed in individual sacks, both the vial and the sack being made of polyethylene, although the vial was much thicker than the sack, which was pellicular. The vial contained 1% atropisol. The sacks were left open at one end and the packages were sterilized, as above described, for 6 hours in a gas containing 10% ethylene oxide and 90% CO₂. The ends of the sacks were heat-sealed under aseptic conditions, four were

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immersed in liquid thioglycollate medium for bacteria, and four were immersed in liquid Sabaraud's medium for molds. They were incubated for 14 days at standard incubating temperature. Thereafter the contents of the vials, the caps, and the external surfaces of the vials were tested for sterility. The results were as follows:

LIQUID THIOGLYCOLLATE MEDIUM FOR BACTERIA

Contents

- (1) No growth in 14 days
- (2) No growth in 14 days
- (3) No growth in 14 days
- (4) No growth in 14 days

Entire Tube

- (1) No growth in 14 days
- (2) No growth in 14 days
- (3) No growth in 14 days
- (4) No growth in 14 days

LIQUID SABAURAU'S MEDIUM FOR MOLDS

Contents

- (1) No growth in 14 days
- (2) No growth in 14 days
- (3) No growth in 14 days
- (4) No growth in 14 days

Entire Tube

- (1) No growth in 14 days
- (2) No growth in 14 days
- (3) No growth in 14 days
- (4) No growth in 14 days

The advantages of the invention are very great. The physician receives a sterile container containing an assured medicament. No sterilization is required to be done in his office. The handling of the outer container does not cause contamination of the inner container. Apparently the ethylene oxide inside the sealed outer container prevents the growth of bacteria or molds on the outside of that container. In the thicker packages it is not impossible that the polyethylene absorbs and retains some of the ethylene oxide. However, whatever may be the explanation, the invention is successful and very useful. It can be used to package surgical knives, dressings and sutures. Indeed, the field of its usefulness is as wide as the nature of things that are improved by sterilization, embracing packaging, for professional and for lay use.

I have named polyethylene as the preferred material but other polyalkylenes are also useful although more expensive. In addition, glassine paper is permeable to ethylene oxide and impermeable to bacteria and molds. It can also be sealed satisfactorily. In all cases, the outer package is maintained in a sterile condition by the slow leakage of ethylene oxide through it.

What is claimed is:

1. The method of providing a thing of medicinal, surgical, and pharmaceutical type with a sterile package having external protection against molds and bacteria that comprises covering the thing with a container having inner and outer walls, the outer of which is slightly permeable to a sterilizing gas but impermeable at atmospheric temperature to molds, bacteria, and air, sterilizing the inner and outer walls of the container and filling the space between the walls with a sterilizing gas, and sealing the container with a content of the sterilizing gas,

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thereby providing the package with exterior protection by slow seepage of sterilizing gas through the outer walls.

2. The method of claim 1 in which the double walls of the container are polyethylene, and the sterilizing gas is ethylene oxide.

3. The method of claim 1 in which the outer wall of the container is polyethylene, the inner wall is impervious to ethylene oxide, and the sterilizing gas is ethylene oxide.

4. The method of claim 1 in which the outer wall is composed of glassine paper and the sterilizing gas is ethylene oxide.

5. The method of claim 1 in which the outer wall is permeable to an alkylene oxide gas and the sterilizing gas is an alkylene oxide gas.

6. A sterile package comprising a supply of surgical and medical type, inner and outer containers composed of bacteria and mold impermeable material, of which the outer is permeable to alkylene oxide gas, contains an atmosphere comprising an alkylene oxide, and is maintained sterile to bacteria and molds by seepage of the alkylene oxide from within.

7. A sterile package comprising inner and outer containers of which the outer is permeable to ethylene oxide and is impermeable to bacteria, air, and mold, and contains an atmosphere of ethylene oxide.

8. A sterile package comprising inner and outer containers of which the outer is composed of polyethylene and contains an atmosphere comprising ethylene oxide in sterilizing concentration.

9. A sterile package comprising inner and outer containers of which the outer is glassine impermeable to air, bacteria, and mold and contains an atmosphere of ethylene oxide to which it is slowly permeable.

10. The package of claim 6 in which the supply of surgical and medical type is a pharmaceutical contained in the inner container, which inner container is at least in part composed of a material permeable to the alkylene oxide gas and impermeable to the pharmaceutical.

11. The package of claim 10 in which the inner and outer containers are composed of polyethylene.

12. The method of providing a thing of medicinal, surgical, and pharmaceutical type with a sterile package having external protection against molds and bacteria that comprises covering the thing with a container having inner and outer walls, the outer of which is slightly permeable to a sterilizing gas but impermeable at atmospheric temperature to molds, bacteria, and air, sealing the container and subjecting the sealed container to sterilizing gas under pressure until the gas has penetrated the inner and outer walls of the container and sterilized the contents.

References Cited in the file of this patent

UNITED STATES PATENTS

1,962,900	Hirsch	June 12, 1934
2,281,473	Brewer	Apr. 28, 1942
2,358,570	Goldberg	Sept. 19, 1944
2,572,669	Sarge et al.	Oct. 23, 1951
2,634,856	Perkins	Apr. 14, 1953
2,738,059	Elson	Mar. 13, 1956

FOREIGN PATENTS

1,079,798	Fance	May 26, 1954
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OTHER REFERENCES

Reddish: "Antiseptics," pp. 647-651, 1954. (Div. 43.)