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STERILE SIFTER PACKAGE FOR PHARMACEUTICALS
WHICH MAY BE INJURED BY HEAT
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FIG. 1

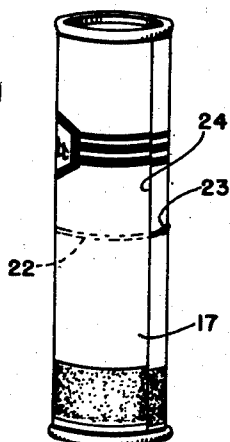


FIG. 2

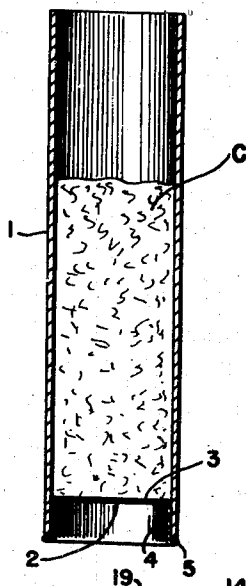


FIG. 3

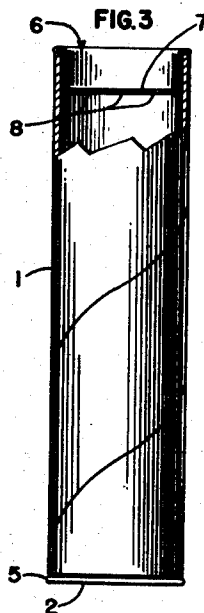


FIG. 4

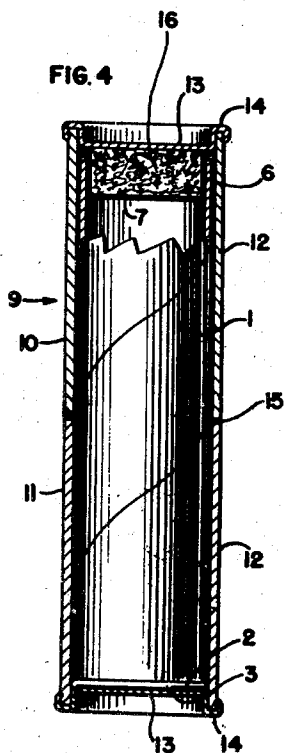
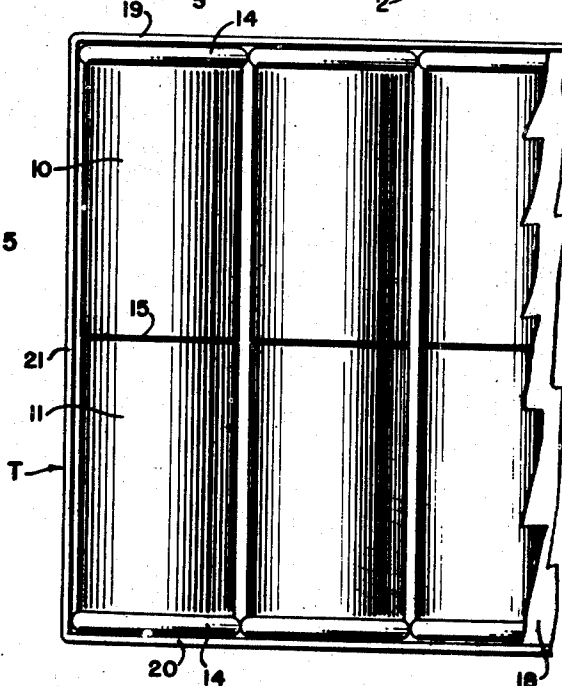


FIG. 5



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STERILE SIFTER PACKAGE FOR PHARMACEUTICALS WHICH MAY BE INJURED BY HEAT

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3 Claims. (Cl. 206—47)

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This invention relates to a pharmaceutical package and to the method of preparing the same. It has particular reference to the production of a sterile package containing pharmaceutical material which may be aseptically produced but which may not, as a practical matter, be subjected to sterilizing heat.

Many pharmaceutical preparations such as various sulpha products may be sterilized by heat before packaging without impairing the material. However, other pharmaceutical preparations, for example penicillin, are damaged by heat and cannot be sterilized by known heat treating processes. It may, however, be produced aseptically so that if carefully handled it may be packaged under aseptic conditions so that the resulting package is a sterile package, that is to say, it is free from contaminating material and organisms which would prohibit its use for human medical treatment.

The main object of the present invention is to provide a package structure and method of packaging pharmaceutical and like products which embody materials such as penicillin which may not be sterilized; to provide a package for materials such as indicated which when completed will constitute a sterile package and which will be effective to maintain sterility of the packaged material for an extended period of time; to provide a package of the character indicated which may be easily and economically produced and which may be easily opened by the physician or other person who wishes to make use of the packaged material; and, in general, it is the object of the invention to provide an improved package and method of producing the same for pharmaceutical materials of the character referred to.

The foregoing objects are attained in this instance by means of a double canister arrangement designed to be sterilized before final filling and sealed aseptically by means of compression fitted end closures.

Other objects and advantages of the invention will be understood by reference to the following specification and accompanying drawing in which there is illustrated a selected embodiment of the improved package and the preferred method of producing the same.

In the drawing,

Fig. 1 is a perspective illustrating the completed package;

Fig. 2 is a longitudinal sectional view through an inner container portion of the package and illustrating the first step in preparing the same.

Fig. 3 is a side elevation of the inner container

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portion of the package in which an end portion is illustrated in section and a further step in method revealed;

Fig. 4 illustrates the package ready for application of a label and opening device; and

Fig. 5 is a fragmentary plan showing a step in the method of handling the containers preparatory to the application of the wrappers or labels thereto.

The improved package illustrated comprises an inner container 1 which is preferably in the form of an elongated cardboard tube, preferably of the spiral rolled construction indicated in Fig. 3. One end of the tube 1 is closed by an end member 2 of metal, the same being of cup-shape to provide a transverse end wall 3 and a cylindrical side wall 4, the free edge of which is rolled on itself to form an outwardly projecting end bead or rim 5. The end closure 2 is preferably of such cylindrical form and size as to fit snugly within the end portion of the cylindrical body tube 1, insertion of the end closure being, of course, limited by engagement of its rim 5 with the end of the body 2. The frictional fit should be such that once the end member is pressed into place, it will not readily come out.

The open-ended inner container as illustrated in Fig. 2 is now ready to receive its charge of material which may be penicillin or a mixture of penicillin and some other product such as a sulpha drug or the like, such charge being represented at C. The remaining open end of the inner container is then closed by another cup-shaped end closure 6 which is of substantially the same form as the end closure 2 except that its transverse wall 7 is preferably provided with dispensing sifter openings 8 through which the packaged material 6 may be sifted and dispensed. The sifting end closure 6, like the end closure 2, is made a snug frictional fit in the end of the body tube 1 so that it will not be dislodged incident to the dispensing of the material through the said sifter openings.

The inner container 1 is enclosed in an outer container 9 which comprises a pair of sections 10 and 11 which may conveniently be of exactly like form, in other words, two like sections are employed in cooperation with each other to constitute an outer container for the charged inner container 1. Each of said sections comprises a cylindrical body wall 12 of paper or fiber board and a metallic end closure 13 having a rim portion 14 embracing a marginal end portion of the tube and crimped thereon. Said body tube sections 12 are of such length that when their re-

spective end walls 13 engage the opposite end closures of the inner container, the adjacent ends of the tube sections will meet as indicated at 15 midway between the ends of the inner container. It is not important that the joint 15 be located midway between the ends of the inner container but this arrangement is quite satisfactory and requires the production of only one size of out container section.

The inner container elements comprising the body tube 1 and its end closures 2 and 6, and the outer container sections 12 and their end closures 13, may be sterilized by a heat treatment in a conventional manner before the inner container is filled. A desirable procedure is to initially assemble the inner tube 1 with its bottom cap 2 in place with the bottom half 11 of the outer shell for sterilization as one unit. The cotton closure or other closure material 16 may be inserted in the upper portion 10 of the outer shell and these elements sterilized as one unit. The perforated or sifter cap 6 may be sterilized independently of the other parts. Any sterilizable material which is to be embodied in the fill of the inner container may also be sterilized by any suitable or conventional heat treatment process.

The elements entering into the package are assembled in suitable sterile containers in a room in which all equipment and the air itself is maintained in a sterile condition and into which the aseptically produced product such as penicillin is delivered while remaining in an aseptic condition. The aseptic material may then be mixed under aseptic conditions with the sterile material and introduced into the sterile inner container through its one open end (before or after insertion in the lower section of the outer shell) after which the sifter end closure 6 is inserted, this being readily accomplished manually or with relatively light apparatus which may easily be maintained in a sterile condition. The outer container section 10 may then be applied, its end closure 13 serving to press and hold the wad 16 against the perforated transverse portion 7 of the end member 6 thereby effectively to close the perforations therein and prevent the sifting of material from the inner container so long as it remains within the outer container and so long as the outer container sections are maintained in their closed position as illustrated in Fig. 4.

The outer container sections 10 and 11 may advantageously be secured in their closed position by the application of a wrapper or label 17 (Fig. 1) to the outer surface of the outer container, such wrapper lapping over both sections and being adhesively secured thereto so that the sections cannot move apart or be turned relative to each other. Such wrappers or labels could, of course, be manually applied to the outer container under aseptic conditions but such application would be slow and costly and otherwise objectionable. This operation may be more advantageously done by automatic machinery but it is considered impracticable, although not impossible, to maintain such automatic wrapping machinery in a sterile condition.

I have found that the container structure illustrated in Fig. 4 may be removed from aseptic surroundings for wrapping purposes without impairing the sterility of the inner container and its content, provided that the sections of the outer container are maintained in their closed position. To facilitate transfer of the container structure as shown in Fig. 4 to a wrapping or labeling machine in another room or department

where the atmosphere and equipment is not necessarily in an aseptic or sterile condition, a tray such as partially represented at T may be employed. Such tray has a bottom 18, opposite side walls 19 and 20, and opposite end walls, one of which is represented at 21. The distance between the opposite side walls 19 and 20 is such that the assembled container structure represented in Fig. 4 will fit snugly between them and the two sections thereby held in their closed positions relative to each other. The tray may be of such length between its opposite end walls as to accommodate any desired number of containers. Such trays are sterilized before being brought into the room where the containers are prepared so as to prevent any contaminating material from being brought into the room. The trays may be of such form as to deliver the containers directly to the wrapping mechanism without further manual handling although this is not essential. However, the wrapping machine should receive the containers in the closed condition in which they are brought to the machine in the trays so as to prevent any contaminating material from reaching the inner container.

In connection with the label applying step, a tear-string 22 may be positioned in the line of the joint 15 and under the wrapper, a short end portion 23 of such tear-string being caused to project beyond the edge 24 of the wrapper 17. Such accessible end portion of the tear-string may be readily grasped when the container is to be opened and pulled from around the container to thereby sever the label or wrapper 17 in registry with the joint 15 between the outer container sections. Thereupon the section 10 may be removed so as to cause the upper portion of the sterile inner container to project above the remaining outer container section 11. In that exposed and projecting condition, the inner container may be grasped between the fingers at a point spaced from its sifter end and removed from the remaining outer container section, thereby avoiding any contamination of the inner container. The wadding 6 will fall out when freed from the restraining effect of the outer container end member or it may be removed with a tweezer or sterile instrument so as to avoid any possibility of contaminating the dispensing end of the container. As a practical matter, when the described container is to be opened in an operating room, normal procedure would be that a nurse or other attendant would initially handle the sealed container, the outer surface of which may be presumed to be non-sterile or contaminated. Such nurse would first split the label by means of the pull string and remove the top section 10 of the outer container without touching any part of the inner container. The upper portion of the sterile inner container is then accessible for aseptic handling by the surgeon.

Various changes in the described structure may be made without departing from the invention.

I claim:

1. A pharmaceutical package comprising a sterilized cylindrical inner container embodying a fiber board tube and metal end closures therefor, said end closures being in the form of cup-shaped members having transverse end wall portions and cylindrical side wall portions frictionally fitting within the end portions of said body tube with said end wall portions at the inner ends of said side wall portions so as to provide recessed ends of the inner container, the end wall of one of said metal end closures being perforated

to permit material to be dispensed from the container, sterile siftable pharmaceutical material in said sterile inner container, a sterilized outer container enclosing said inner container and comprising a pair of cylindrical body sections respectively having one end closure, said sections being respectively telescoped over the opposite end portions of said inner container and being of such combined internal length as to receive and enclose the entire length of said inner container, a wad in the recessed dispensing end of said inner container to close said dispensing end wall, said wad being held in place by the adjacent end of said outer container, and a wrapper secured to said outer container in overlapping relationship to both of the sections thereof to thereby seal the same in closed condition, said sterilized outer container serving to preserve the sterile condition of the inner container and its content while permitting the application of said wrapper under non-sterile conditions.

2. A pharmaceutical package comprising a sterilized cylindrical inner container embodying a fiber board body tube and metal end closure therefor, said end closures being in the form of cup-shaped members having transverse end wall portions and cylindrical side wall portions frictionally fitting within the end portions of said body tube with said end wall portions at the inner ends of said side wall portions so as to provide recessed ends on the inner container, the end wall of one of said metal end closures being perforated to permit material to be dispensed from the container, a content of sterile, siftable pharmaceutical material in said sterile inner container, a sterilized outer container enclosing said inner container and comprising a pair of cylindrical body sections respectively having one end closure, said sections being respectively telescoped over the opposite end portions of said inner container and being of such combined internal length as to receive and enclose the entire length of said inner container, a wad in the recessed dispensing end of said inner container to close said dispensing end wall, said wad being held in place by the adjacent end of said outer container, and a wrapper secured to said outer container in overlapping relationship to both of the sections thereof to thereby seal the same in closed condition, said sterilized outer container serving to preserve the sterile condition of the inner container and its content while permitting the application of said wrapper under non-sterile conditions, and a wrapper tear-string under said wrapper intermediate the adjacent ends of said outer container sections, an end portion of said

tear-string projecting beyond said wrapper so as to be readily accessible to facilitate tearing of said wrapper in registry with said adjacent ends to thereby facilitate opening of said outer container.

3. A package comprising an inner container having a content of pharmaceutical material which must be protected against contamination while in the package and during the process of making the package, and an outer container enclosing said inner container, said inner container having a tubular body, closures for the opposite ends of said body, one end closure being provided with a dispensing opening for permitting discharge of the material from the container, and one end closure being frictionally engaged with said tubular body so as to be manually applicable thereto after introduction of the content into said inner container, said outer container comprising a pair of sections respectively enclosing the opposite end portions of said inner container, said sections each being of substantially less length than the length of said inner container and having adjacent, proximate ends located intermediate the ends of said inner container and each having an end wall overlying an end of said inner container, a plug of compressible material between the end wall of one of said sections and the inner container end closure having said dispensing opening, said plug being compressed against said end closure and serving to close said dispensing opening, and a wrapper around and adhered to the mutually adjacent end portions of said outer container sections so as to hold the same in assembled relation over said inner container, said wrapper being severable intermediate said proximate ends of the outer container sections so as to permit removal of one of said sections to expose a portion of the length of said inner container.

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