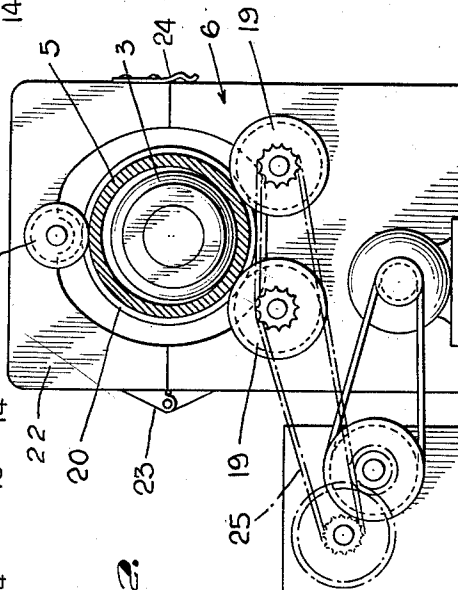
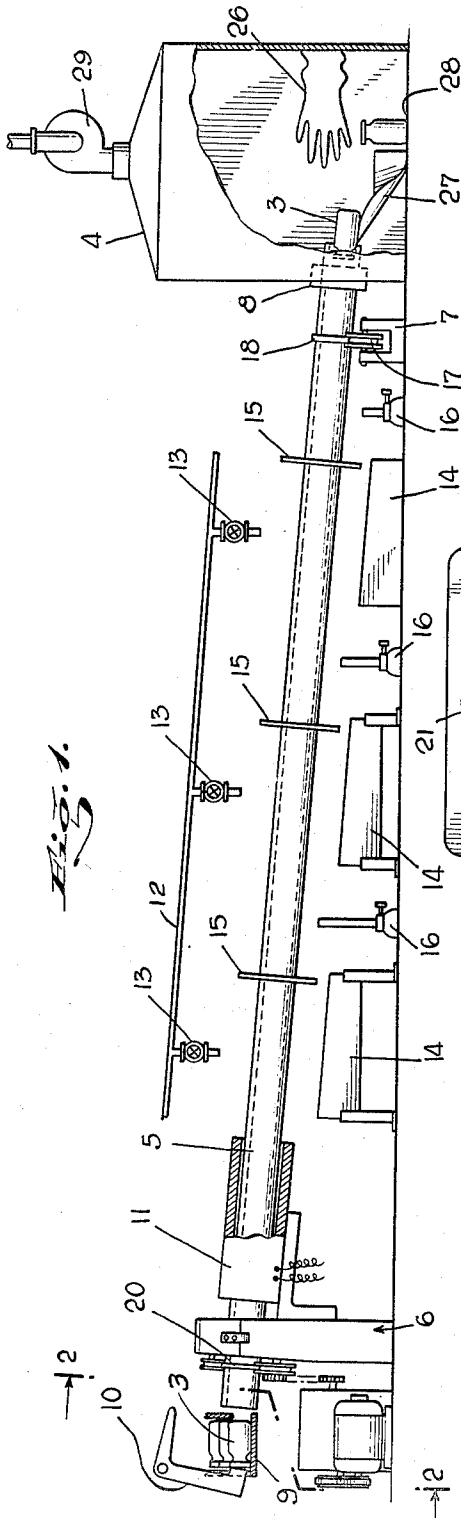


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STERILIZING APPARATUS AND METHOD

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## STERILIZING APPARATUS AND METHOD

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This invention relates to the heat treatment of articles of essentially cylindrical contour and, particularly, to an improved method and apparatus for the handling of essentially cylindrical articles in heat treatment thereof in a manner to permit relatively rapid temperature changes without damage to the articles. More particularly, the invention relates to an improved method and apparatus for the rapid sterilization of vials, ampules and other containers of the type generally employed in the sterile packaging of pharmaceutical preparations and the like.

It is of primary importance in the packaging of many pharmaceutical preparations, particularly those intended for parenteral injection, that the vials, ampules, or other containers employed be thoroughly sterilized prior to carrying out sterile packaging operations. In the past, it has been customary to sterilize such containers by arranging them in covered trays and heating the trays and containers in an oven at a temperature of 250° C. for about two hours, generally with a number of trays assembled together in a suitable supporting rack. At the end of this time, the racks with the still-covered pans are removed to an air-conditioned, dust-free room and allowed to cool to room temperature, a step often requiring as long as six hours. The long cooling time is necessary because of the slow dissipation of heat from the containers within the covered pans, yet it is of primary importance that the pans remain covered since the sterility of the vials or containers would otherwise be impaired.

In addition to the objectionably long time required in the foregoing sterilization procedure, it will be evident that there still remains the problem of maintaining the vials or containers in a sterile condition when transferring them from the pans to sterile cubicles or other enclosures in which filling operations are carried out. Even when the greatest precautions are taken, there is considerable risk of contamination during this transfer.

An object of the present invention is to provide a new method and apparatus which will permit the sterilization time to be reduced from the usual period of about eight hours to a period of a few minutes; a further object being to provide a method and apparatus for the continuous rapid sterilization of vials or containers as a final step in delivering the same to sterile packaging cubicles whereby the sterilized containers are deposited directly within the cubicles.

These and other objects of the invention will

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be more readily understood from a consideration of the following specification and accompanying drawing in which the various parts of the apparatus are identified by suitable reference characteristics in each of the views and in which:

Figure 1 is a side elevation of one form of our apparatus with part of the structure broken away and in section and with portions of the assemblage diagrammatically shown;

Figure 2 is an enlarged view substantially on the broken line 2—2 of Figure 1.

Regarded in certain of its broader aspects the novel method and apparatus for heat treating or sterilizing essentially cylindrical articles such as vials, ampules, or other containers involves successively feeding articles to be heat treated to one end of an elongated cylindrical tube or chamber while continuously rotating the same on its axis, applying heat to a portion of the tube or chamber adjacent the feed end thereof, and applying a cooling medium to the remainder of the chamber, and so regulating the feeding of articles to the chamber and the application of heat and cooling medium thereto as to provide for discharge of articles from the remote end of the tube or chamber in an essentially cool and thoroughly sterile condition.

One embodiment of the invention is disclosed in the drawing showing the apparatus set up in a conveyor line for delivering vials or ampules 3 to a sterile packaging cubicle 4, and including an elongated cylindrical tube or chamber 5 rotatably supported at the feed end thereof by a drive unit 6 and at the discharge end thereof by a roller support unit 7. The tube 5 is preferably formed of stainless steel, but other heat resistant materials having good thermal conductivity can also be employed. The discharge end of the tube 5 extends into the cubicle 4, and between the tube and cubicle is provided an essentially gas-tight seal diagrammatically indicated at 8.

Adjacent the feed end of the tube 5, we have shown a guide member 9 adapted to receive the vials or ampules 3 from a suitable conveyor and align the same with the opening in the tube 5, and means is provided as diagrammatically indicated by the bell crank feed arm 10 for advancing vials or ampules 3 from the guide member 9 into the tube 5. Means is also provided, as indicated by the enlarged lower end of the feed arm 10, for preventing movement of vials into the guide 9 during the forward feed motion of the arm 10.

The inside diameter of the tube 5 should be sufficiently larger than the outside diameter of

the vials or ampules 3 to permit free rotation of the vials or ampules on the inner wall of the tube as the tube rotates about its axis. At the same time, it is preferable to provide a minimum amount of clearance between the vials and tube in order to facilitate rapid heat transfer therebetween. A ratio of about 8 to 9 between the outside diameter of the vials and inside diameter of the tube has been found to be satisfactory. It should be noted in this connection that the rotary motion of the vials with respect to the tube prevents any extended period of contact between any one point on the vial and the tube, thus minimizing the danger of breakage in the vials or ampules due to excessive localized heating or cooling.

In the adaptation shown in the drawing, the tube 5 is arranged in an inclined position, and when thus arranged it will be apparent that the rotation of the tube and the rotation of the vials within the tube operates to continuously and slowly advance the vials toward the discharge end of the tube. In this adaptation of the apparatus, it will thus be apparent that the feed arm 10 serves merely to deliver vials to the tube. It is possible, however, to arrange the tube 5 in a horizontal position in which event the feed arm 10 would serve not only to deliver vials to the tube but also to advance the column of vials there-through.

Adjacent the feed end of the tube 5 and circumferentially enveloping said tube in closely spaced relation thereto is a heating unit 11 which is preferably an electrical unit of either the resistance or inductance type. The size and heat range of the unit 11 will, of course, depend upon the particular heat treating or sterilizing operation to be performed. In the sterilizing of vials of the type shown in the drawing, it is desirable to employ a heating unit which will raise the vials to a temperature of about 700° F. in two to three minutes. It is found that this rapid elevation in temperature of the vials can be effected without any danger of breakage when the vials are continuously rotated in the tube 5 in the manner previously described.

Means is provided along the remainder of the tube 5 as indicated diagrammatically by the feed line 12 and valves 13 therein for applying water or other cooling medium to the outside of the tube 5. Suitable receptacles 14 are provided below the tube 5 to catch the cooling medium, and the tube is preferably provided with spaced flanges 15 for limiting movement of the cooling medium longitudinally of the tube and facilitating collection of the medium by feed receptacles. A plurality of valves 13 are preferably employed to provide a degree of flexibility in control of the rate of cooling of the tube and vials arranged therein. It will, of course, be apparent that cooling may be effected by means of a cooling coil or jacket integral with the tube itself, and it is to be understood that the cooling means shown in the drawing is intended to represent diagrammatically any suitable cooling means.

As it becomes necessary from time to time to clean the tube 5, it is advisable to provide means as indicated by the spaced heater units or burners 16 for heating the entire length of the tube 5 for sterilization thereof after cleaning. It will, of course, be understood that any arrangement of a heating element or elements longitudinally of the tube can be employed for this purpose, and it is to be understood that the burners 16 are intended

merely as a diagrammatic indication of any suitable heating means.

Since intermittent cleaning of the tube 5 requires that the tube be easily removed from the apparatus, we preferably employ in the roller support unit 7 merely a pair of rollers 17 grooved to engage a collar or flange 18 on the tube 5. The drive unit 6 as more clearly shown in Figure 2 of the drawing employs a pair of drive rollers 19 grooved to engage a collar or flange 20 on the tube 5. In order to ensure positive engagement between the drive rollers and the tube, we provide a third grooved roller 21 supported in a bracket or housing 22 hinged, as at 23, to the body of the drive unit 6, and having a locking engagement as at 24 with said drive unit to facilitate easy release of the tube 5 for removal thereof from the apparatus. Any suitable drive means such, for example, as a chain 25 may be employed for driving the rollers 19. It should be noted in this connection that when employing the apparatus for the sterilization of vials or ampules in the manner shown, it is generally desirable in practice to employ a number of sterilizing tubes with one or more of such tubes registering with each of a number of cubicles 4. In such a set-up, it will be apparent that a central drive can be employed to actuate the feed rollers of all of the units. Alternatively, of course, each unit can be provided with an individual electrical motor or other source of power. In sterilizing vials or ampules with the apparatus disclosed, it has been found that rotation of the tube 5 at a rate of about 13 R. P. M. produces satisfactory results when arranged on an incline of about 1 inch per foot and that elevation of temperature of the vials to 700° F. within about two to three minutes and cooling to room temperature within about six minutes renders the vials thoroughly sterile and pyrogen-free.

As evidence of the reliability of the apparatus in handling and sterilizing vials without damage, continuous rotation of vials within a tube for a period of thirty minutes (more than three times the normal time that a vial will remain in the tube) gave no indication whatever of damage due to abrasion. In no instance has there been evidence of breakage of vials or ampules due to the rapid heating and cooling as might be expected if the vials were rapidly heated and cooled in stationary contact with a supporting element.

The cubicle 4 may be of any conventional type such as those normally used in the packaging of pharmaceutical products, and is preferably provided with flexible hand insert members 26 for receiving the hands of an operator. Vials or ampules 3 may be picked up by the operator as they emerge from the tube 5 or may be deposited in a suitable conveyor such as the inclined trough 27 for carrying the same to a storage area 28 within the cubicle.

It is, of course, to be understood that every effort is made to ensure sterile conditions within the cubicle, and in this connection it will be evident that any air entering the cubicle through the tube 5 is automatically sterilized in passing through the zone heated by the element 11. If a positive pressure is desired within the cubicle, however, means may be provided as indicated by the blower 29 for introducing sterile air to the cubicle. In practice, it is found that best results are obtained when the pressure within and without the cubicle is essentially the same.

With a tube 5 of particular length and diameter, it is possible by appropriate regulation of

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the speed of rotation of the tube, rate of advance of articles through the tube, and amount of heat and cooling medium applied to heat treat or sterilize a number of different sizes of vials, ampules or other cylindrical articles. For best results, however, the diameter and length of the tube should be selected to meet the requirements of the particular size article to be treated.

Throughout the disclosure, special emphasis has been placed on the adaptation of our apparatus for the sterilization of vials, ampules, and the like, but it is to be understood that it is equally adapted for tempering, annealing, and other heat treating operations in which rapid controlled heating followed by rapid controlled cooling of articles is desired.

Various changes and modifications in the apparatus herein disclosed will occur to those skilled in the art, and to the effect that such changes and modifications are embraced by the appended claims, they are understood to constitute part of our invention.

We claim:

1. The method of delivering cylindrical containers in a sterile condition to a sterile filling and sealing zone that comprises advancing a co-axially arranged series of cylindrical containers successively through a heating zone and a cooling zone registering with said sterile filling and sealing zone while providing support for each of said articles along a line of contact extending longitudinally thereof which is continuously

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shifting about the cylindrical periphery of said article.

2. An apparatus for delivering essentially cylindrical containers to a sterile filling and sealing cubicle while simultaneously sterilizing said containers, said apparatus comprising conveyor means for advancing cylindrical containers in end to end relationship, in combination with a sterilizing unit comprising an elongated and rotatably supported tube having one end registering with said conveyor means and the other end disposed within said sterile cubicle, means for heating said tube adjacent the first named end thereof, means for applying a cooling medium to other portions of said tube, and the inner surface of said tube having a smooth and uninterrupted cylindrical contour of uniform diameter throughout the length of said tube, whereby the rotation of said tube causes the cylindrical containers passing therethrough to roll continuously and circumferentially with respect to the inner surface of said tube.

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