3,467,097  DUAL MEDICINAL VIAL

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5 Claims

ABSTRACT OF THE DISCLOSURE

This patent describes a novel medicament vial comprising a container having an open end and a closed end; the walls of the container being restricted intermediate the ends thereof by a restriction having a substantially V-shaped cross section terminating in a substantially sharp small V point; a resilient stopper in said container having an outer extreme width greater than the width of said container, the stopper having portions of lesser width than the width of said container, and having its outward perimeter provided with a sharp small V pointed in cross section indentation adapted when positioned over the restriction to seal upon both walls and the point of the restriction. A second stopper is inserted in the open end of the vial. This patent further describes a generally cylindirical first casing adapted to fit over a portion of the vial and a second generally cylindrical casing adapted to fit over the other end of the vial, the casing forming a closed housing for the vial and the second casing having at its closed end a reentrant portion with a closed end wall. The second casing is adapted after removal of both of the casings from the vial to be replaced over the vial in place of the first casing with the closed end of the reentrant portion engaging the top of a stopper positioned at the top open end of the vial.

This invention relates to a medicament vial and more particularly to a vial having a pair of compartments, one of which may contain a medicament in the form of a dry lyophilized powder and the other of which may contain a diluent for the same. Such two compartment medicament vials are known but it is the primary purpose of this invention to provide such a vial in which the lyophilization may take place within the medicament in one compartment of the vial and this compartment then sealed in the absence of air whether sterilized or not or any inert gas or other aeroform fluid such as nitrogen. A number of injectable medicaments are stable for but short periods of time, once they are in solution. Such medications are normally supplied to the physician in a dry form which he reconstitutes by adding a diluent to same immediately preceding injection of same. In recent years, the drug manufacturers have adopted a procedure wherein a drug unstable in solution is first reduced to a solution for the purpose of sterilizing same, and then returned to a dry state by a process of quick freezing and vacuum evacuation of the liquid, commonly referred to in the drug trade as lyophilization. Some injectable medications, such as rabies, are very difficult to process, as no air should come in contact, even though sterile, with the dried product. Current two-compartment devices widely marketed, though providing for an effective two-compartment system, nevertheless necessitate their removal from the vacuum chambers in order to set the rubber plugs commonly used to divide the dry and liquid compartments.

This invention has as a primary feature thereof a two-compartment vial wherein the solution to be lyophilized can be put in one compartment. A resilient plug intended to seal and separate the dry compartment from its diluent chamber is also set in said vial immediately above a center sealing ring so that the entire unit may be placed within the freeze dry and vacuum cabinet. However, due to the fact that the diameter of this sealing center disk is at points greater than the diameter of the vial itself in its largest portion, it at all times maintains a fixed position, yet intermediate to these points, its diameter is less than the largest diameter of the vial, and permits complete evacuation of the liquid in the lyophilization cycle. At the termination of this cycle the resilient plug is set in its sealing position by rods within the lyophillizer without necessitating removal of the vial prior to such sealing. These and other objects, features and advantages will be apparent from the annexed specification in which:

FIGURE 1 is a vertical section of the vial of this invention as it is placed in the lyophillizer;
FIGURE 2 is an enlarged vertical section of the completed vial with the lyophilized material sealed therein as well as the diluent and in which the entire vial is encapsulated in outer package;
FIGURE 3 is a section similar to FIGURE 2 showing the condition of the invention as the diluent is introduced into the section containing a lyophilized powder;
FIGURE 4 is a section of the vial of this invention in its condition to be filled with a conventional syringe;
FIGURE 5 is a plan view of the center plug; and
FIGURE 6 is a side view of the center plug used in connection with this invention.

Referring now more particularly to the drawings, 10 indicates a vial preferably of glass but which in many instances may be of any of the well known glass materials and which is generally cylindrical in form being closed at the bottom 11 and having an open top 12. A plug 13 formed of a resilient material is utilized and is particularly illustrated in FIGURES 5 and 6. This plug has an exterior diameter indicated at 14 which is larger than the interior diameter indicated at 15 of the vial at any point thereof. The plug 13, however, has a plurality of portions 16 wherein the diameter is reduced for purposes hereinafter indicated.

Referring now more particularly to FIGURE 6 it will be noted that the plug 13 has an upper portion 17 and a lower portion 18 which are substantially mirror images of each other. Midway of the two portions 17 and 18 is a point 19 which, if practical, would come to a sharp V-shaped point but due to manufacturing difficulties is actually a very short cylindrical section bordered by tapered walls 20 and 21. The outwardly extending portions 22 which extend the full diameter of the plug are arcuate in shape on the edge toward the center line as indicated while the spaces 23 between the portions 22 are of reduced diameter which diameter is nevertheless greater than the diameter 19. The result is that the entire V-shaped or tapered portions 19 and 20 extend inward around the plug 13. Intermediate its ends the vial 10 has an indentation 24 which forces the glass inwardly in a generally V-shaped cross section 25. This indentation is formed while the vial 10 is in a formable state such as heated glass and the indentation 24 is formed by applying a sharp pointed blade to the perimeter of the vial with a purpose of having a sharp pointed end 26 on the indentation. However, as indicated a perfectly sharp point is not generally obtained due to the difficulties of manufacture but the point 26 thereof though rounded is intended to have substantially no longitudinal length.

A second plug 27 of resilient material is provided as a closure for the open end 12 and normally has a central bore 28 extending only part-way therethrough and a pair of rings 29 and 30 formed thereon. The rings 29 and 30 in their extended state are of greater diameter than the interior diameter 15 of the vial so as to be received in
the vial with a press-fit which nevertheless permits the plug 27 to have a sliding movement within the vial when the natural resistance thereto is overcome.

The package is completed by providing an outer casing 31 comprising a generally cylindrical upper portion 32 having an internally enlarged portion 33 forming a shoulder 34 and a generally cylindrical portion 35 having a portion 36 of reduced outward diameter so that the upper and lower portions 32 and 33 may be joined with a lapped joint as shown in FIGURE 2. The upper portion 32 is closed at the end wall as shown at 37. The lower portion 35 has an end wall 38 of annular shape connecting with an upstanding re-entrant cylindrical portion 39 which is closed by a circular portion 40 extending across the cylindrical portion 39.

In use the device of this invention is filled with a medicament 41 of the type which is to be lyophilized. This generally includes mixing the medicament 41 with a liquid such as water. The plug 13 is inserted in the vial as is shown in FIGURE 1 in which condition it is not seated upon the indentation 24 so that communication through the openings 16 into the interior of the vial is maintained. Thus, the medicine in FIGURE 1 having been placed in the lyophilizer it may be freeze dry removing all of the liquid and freezing the powder and presenting a vacuum. Thereafter a proper tool may be inserted to depress the plug 13 so as to seat the same on the indentation 24, which is the condition shown in FIGURE 2. It will be noted that the beveled edges 20 and 21 conform to the inwardly beveled edges of the indentation 24 and that the hardy perceptible section 19 conforms to the tip of the indentation 24 thus forming a three-point seal between the plug 13 and the indentation 24 which securely seals the medicament in the bottom of the vial and prevents the entrance of any air. In fact, if the medicament does not entirely fill the space the space 40 may very well be a vacuum. Thereafter the device is removed from the lyophilizer, a diluent 41 is inserted into the vial and plug 27 placed therein to contain the diluent. The casing 31 is then placed around the vial with the parts 32 and 33 joined together as shown in FIGURE 2. FIGURE 2 therefore represents the condition in which this invention, after filling, is shipped or stored.

When it is desired to use the device of this invention, the casing 31 is entirely removed and the upper portion 32 is discarded while the lower portion 35 is reversed and placed upon the top as shown in FIGURE 3 in which case the wall 40 engages the top of the plug 27. Downward pressure on the portion 35 will be thus communicated to the plug 27 and to the fluid 41, which pressure is sufficient to force the plug 13 over the indentation 24 into the position shown in FIGURE 3. This, of course, permits the liquid 41 to mix with the powder. After the liquid and powder have been thoroughly mixed the device is inverted as shown in FIGURE 4 and a syringe 50 having needle 51 is utilized. The needle 51 pierces the thin wall of plug 27 and permits withdrawal of the mixed diluent fluid and powder into the syringe as shown at 52 in FIGURE 4. When the syringe is thus properly loaded it will be removed from the vial and is in condition for the contents to be injected into the patient.

It will be noted that when the syringe needle 51 pierces the thin wall of plug 27 and the plunger of the syringe is withdrawn the plug 27, because of its sliding fit within the vial 10 will pass upwardly in the vial as shown in FIGURE 4 withdrawing the fluid into the syringe as indicated at 52 without the introduction of any air into the vial 10. This is a feature which this invention has in common with my copending United States patent application Ser. No. 467,858, filed June 29, 1965, now United States Patent No. 3,302,283, May 23, 1967.

While there has been described what is at present cons-

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