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Cohen

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[54] **SYRINGE FOR INJECTION OF FRESHLY MIXED LIQUID-POWDER**

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[52] **U.S. Cl.** ..... **128/218 M,** 128/234, 128/272

[51] **Int. Cl.** **A61m 5/22**

[58] **Field of Search** ..... 128/218 R, 218 M, 128/218 NV, 216, 220, 224, 234, 272

[56] **References Cited**

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[57] **ABSTRACT**

A syringe formed of an inner tubular member adapted to contain a liquid carrier and an outer tubular member adapted to contain a dry medicament to be taken up with the carrier for injection whereby the materials are freshly mixed immediately prior to injection and wherein the dry medicament and liquid carrier are separably maintained in sealed relation one from the other until admixed immediately prior to injection, whereby the sealing means between said inner and outer tubular members comprises a sealing ring of flexible material within said inner tubular member in sliding engagement with the inner walls thereof and a needle assembly supported at the forward end of the inner tubular member, the forward end of the needle of the needle assembly terminating a short distance from the sealing ring prior to admixture and the needle piercing through said sealing ring when in position of admixture.

12 Claims, 8 Drawing Figures

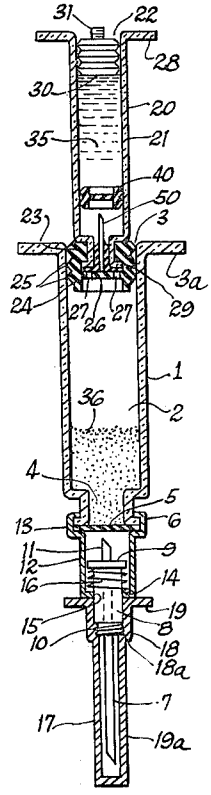


FIG. 1

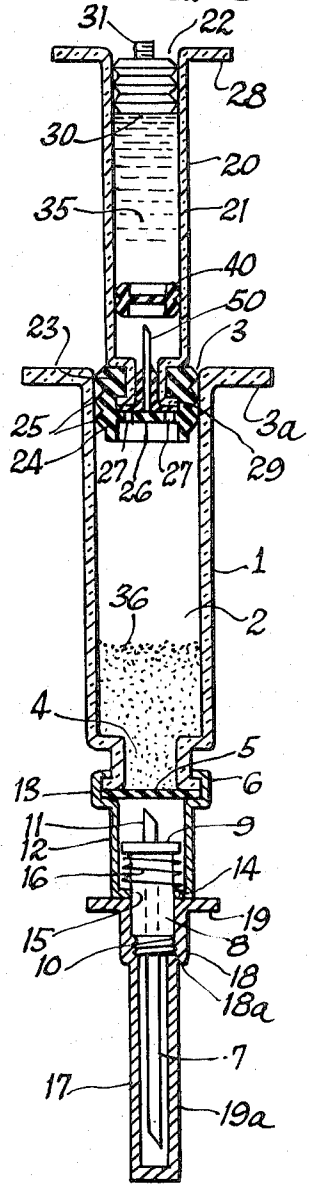


FIG. 2

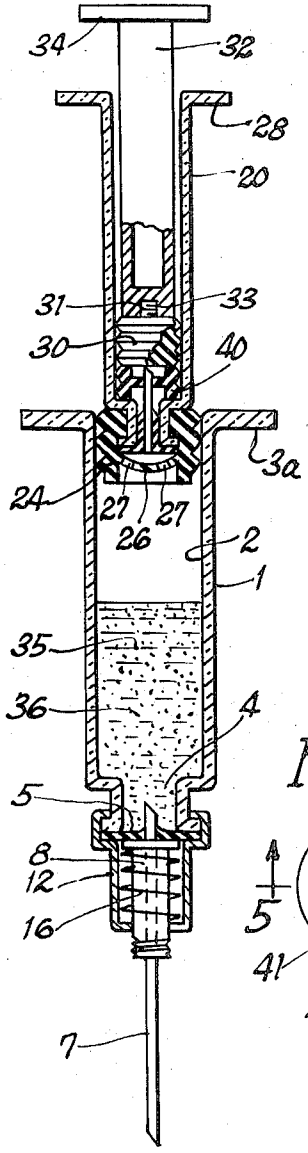


FIG. 3

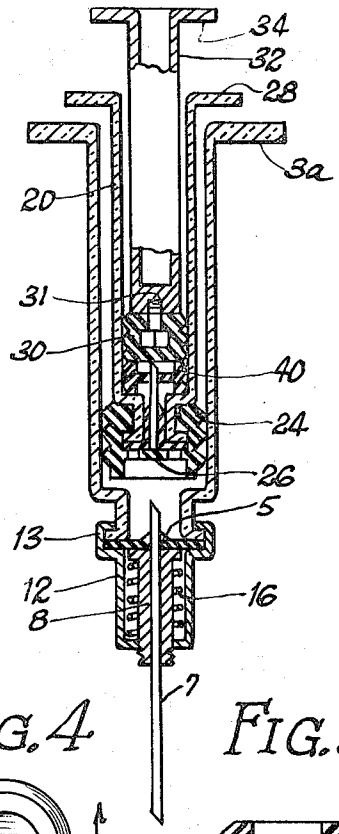


FIG. 4

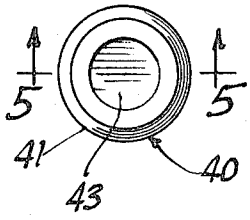


FIG. 5

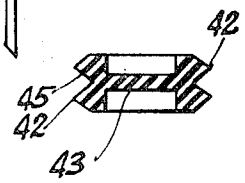


FIG. 6

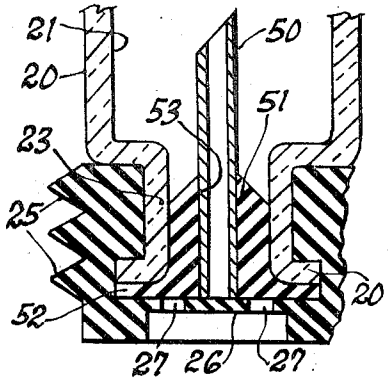


FIG. 7

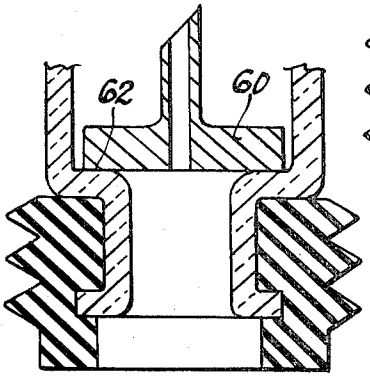
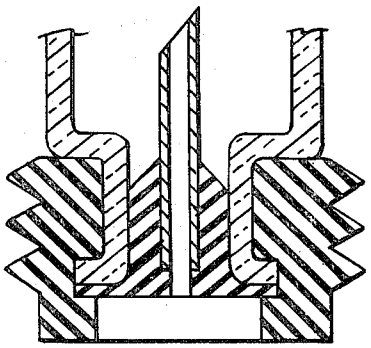


FIG. 8



SYRINGE FOR INJECTION OF FRESHLY MIXED LIQUID-POWDER

This invention relates to a device for injection of solutions or dispersions of a medicament in a liquid carrier and more particularly to a hypodermic syringe adapted to contain one component of the medicament separate and apart from a carrier or component in liquid form. Immediately prior to administration, the liquid is caused to flow into the compartment containing the one component material for injection of the solution or mixture formed thereof.

The invention will be described with reference to a syringe in which the one component is a medicament in dry solid form while the other component or carrier separated therefrom is a liquid carrier which takes up the solid material by solution or dispersion when admixed therewith for injection immediately after admixture. It will be understood that the one component, instead of being a medicament in dry solid form, can be a liquid medicament which is adapted to be maintained separate and apart from another compound or carrier in liquid form until immediately prior to injection.

A syringe of the type described is disclosed in my issued U.S. Pat. No. 3,557,7,787 and an improvement thereof in my copending application Ser. No. 864,376, filed Oct. 7, 1969, and entitled "A Syringe for Injection of Freshly Mixed Liquid-Powder." As described in my aforesaid copending application, the syringe assembly comprises inner and outer tubes with the inner tube having an outer wall-to-wall dimension less than the inner wall-to-wall dimension of the outer tube to enable the inner tube to be telescoped for relative axial movement within the outer tube member, a sealing ring of flexible material at the forward end of the inner tube and a piston plug within the inner tube in sealing relationship therewith and actuable by an elongate actuator attached thereto, a needle assembly sealing the forward end of the outer tube, and sealing means between the inner and outer tube comprising a flexible closure sealed on the forward end of the inner tube with passages through said portions of said inner tube for abutment to effect a sealing relation when in seated position and to define passages therethrough communicating with the interior of the tube when the flexible closure is unseated, and a sealing ring of flexible material within said inner tube between said piston plug and sealing closure and being in a sealing slidable relationship with the inner walls of the inner tube. This sealing closure has a passage in the form of a slit which opens when the piston plug is actuated and the fluid inside the inner tube is under pressure. The fluid then unseals the flexible closure and enters the outer tube containing the dry medicament, thus giving the desired mixture or solution for injection.

By reason of the passages through the flexible sealing member as well as through the slidable piston member within the inner tubular member, it is possible for fluid or vapors to leak through to the outer tubular member to cause caking of the material in the outer tubular member to to cause deterioration thereof whereby the prepackaged syringe becomes unsuitable for use. It is desirable to provide a separation between the materials housed in the separate tubular members which is an absolute barrier to the transmission of fluids or vapors from one tubular member to the other until the desired admixture of fluid from the inner tubular member into the outer tubular member for admisture immediately prior to use.

It is an object of this invention to provide a disposable syringe adapted to house the liquid and solids or liquid in separated compartments which are sealed one from the other to prevent the flow of vapors or fluid from one compartment to the other but which enable passage of that liquid from one compartment to the other for admixture immediately prior to use.

Other objects and advantages of this invention will hereinafter appear and for purposes of illustration, but not of limitation, an embodiment of the invention is shown in the accompanying drawing in which:

FIG. 1 is a sectional elevational view of a syringe embodying the features of this invention with the elements illustrated in position prior to use;

FIG. 2 is a sectional elevational view of the syringe shown in FIG. 1 with the syringe partially actuated to effect displacement of the liquid carrier from the liquid compartment to the solid compartment for solution or admixture therewith;

FIG. 3 is a sectional elevational view of the syringe shown in FIGS. 1 and 2 with the syringe in fully actuated position to effect displacement of the freshly prepared solution from the solids compartment for injection;

FIG. 4 is a top plan view of the floating piston seal embodied in the liquid chamber;

FIG. 5 is a sectional view taken along the line 5—5 of FIG. 4;

FIG. 6 is a sectional elevational view of the unsealing needle assembly at the forward end of the inner tube.

FIG. 7 is a sectional view similar to that of FIG. 6 showing a modification in the means for mounting the piercing needle; and

FIG. 8 is a sectional view similar to that of FIG. 6 in which the flexible sealing member has been deleted.

With reference to the drawings, the syringe embodying the features of this invention comprises an outer casing 1 in the form of an elongate tubular member, formed of glass, plastics or the like, having a bore 2 extending continuously therethrough from an open rearward end 3 to a forward openended neck portion 4. The forward open end is adapted to be sealed by means of a sealing disc member 5 dimensioned to be greater than the opening at the forward end and to abut the outwardly extending annular lip 6 on the end of the neck portion. The rearward end of the tubular member is formed with an outwardly extending flange 3*a* which serves as a finger grip.

The hypodermic needle 7 is mounted in a needle hub 8, in the form of a cylindrical member, having an outwardly extending flange portion 9 at its rearward end and a threaded portion 10 in the peripheral surface at the forward end.

Means are provided to secure the sealing disc member 5 in sealing relation onto the open end of the casing 1 and to mount the needle hub 8 for axial displacement in the direction toward and away from the casing 1 with the rearward end 11 of the needle 7 in endwise alignement with the sealing disc member 5 and forwardly thereof, when in normal retracted position, and to pierce the disc member 5 and extend into the interior of the casing 1 when in operated position. Such means is illustrated as comprising a cup-shaped cap member 12 having a rearward end portion 13 which is crimped about the outwardly extending lip 6 with the sealing

disc 5 thereon securely to position the disc in sealing relationship across the open end of the casing. The body portion of the cup-shaped member, having a diameter greater than the flanged portion 8, extends forwardly for a distance and then is formed with an inwardly turned portion 14 at its forward end to define an opening 15 corresponding to the cross-sectional dimension of the needle hub 8 to enable relative sliding movement therein. The needle hub 8 and the supported needle 7 are continuously urged towards operated position by means of a compression spring, in the form of a coil spring 16 which surrounds the needle hub, with one end abutting the shelf 14 while the other end abuts the annular flange 9 on the rearward end of the needle hub 8.

The needle hub is held in its normal retracted position with the rearward end 11 of the needle 7 within the cup immediately in advance of the sealing disc 5, as by means of a needle cover 17 having a cupped rearward end portion 18 dimensioned to correspond with the ccross-section of the needle hub and flanged portion 19 extending outwardly from the rearward end thereof, and a tubular portion 19*a* dimensioned to receive the end portion of the needle 7 extending forwardly beyond the needle hub in protection thereof. The internal wall of the cup portion 18 is formed with a threaded portion 18a for threaded engagement with the forward end portion of the needle hub whereby the needle cover is threaded onto the threaded end of the needle hub by an amount to bring the flanged portion 19 into engagement with the cap 12 whereby the needle hub is retained in retracted position with the rearward end of the needle adjacent the front wall of the sealing disc and with the compression spring 16 in relation such that, when the cover is removed, the needle hub is released for axial displacement. Thus the coil spring 16 becomes effective to displace the needle hub in the rearward direction automatically to project the end of the needle 7 through the sealing disc 5 and into the interior of the casing 10.

A second tubular member 20 of glass, plastic or the like material is dimensioned to have an outer wall-to-wall dimension which is less than the inner wall-to-wall dimension of the tubular member 1 to enable the former to be telescoped through the interior of the outer tubular member 1. The second tubular member is similarly formed with a passage 21 extending from the open rearward end 22 through a neck portion 23 of smaller cross-section at the forward end. The forward neck end portion of the second tubular member is fitted with a rubber stopper 24 including an outer ribbed piston ring portion 25 fitted in gripping relationship about the neck and extending laterally beyond the walls of the second tubular member for a distance to effect sealing engagement with the inner walls of the outer tubular member 1 whereby the second tubular member is capable of the function of a piston movable axially relative the outer tubular member 1 thereby to provide a piston and cylinder arrangement between the two tubular members.

A cylinder-like member 51 formed of glass, plastic, rubber or the like has a diameter approximately equal to or slightly less than the inner diameter of said neck portion 23, extending partly therethrough and having an outwardly extending flanged portion 52 for abutment to the flanged lip 29 of the second tubular member. A needle-like member 50, formed of glass, metal or hard plastic or the like extends through a bore 53 in said cylinder-like member 57 into the passage 21 of the inner tubular member for a short distance beyond the neck.

The rubber stopper in the form of a flexible closure 24 has a disc portion 26 which normally spans the flanged end of the cylinder-like member to seal the tubular member. It is further formed with one or more openings 27 in the lateral portions beyond the needle opening whereby the openings 27 abut the stopper or flange to prevent communication therethrough when the flexible closure 24 is in relaxed position but in which the flexible closure is unseated to unblock the openings 27 when the flexible closure is subjected to fluid under pressure from the inner tubular member to enable flow of liquid from the second tubular member through the needle with the first tubular member when the sealing disc 26 is flexed for displacement from sealing engagement with the flanged portion 52 of the cylinder-like member.

Again, the rearward end portion of the second tubular member is formed with an outwardly extending flanged portion 28 for use as a finger grip, as will hereinafter be described. The rearward end of the passage 21 is sealed with a rubber plug 30 mounted for axial displacement through the passage 21 as a piston within the cylinder defined by the second tubular member. Means, such as a threaded stud 31, is provided on the rearward end of the plug type piston for connection of an actuator 32 for displacement of the piston relative the cylinder. In the illustrated modification, the actuator 32 is in the form of a third elongate tubular member dimensioned to have a cross-section less than the cross-section of the passage 21 through the second tubular member and formed at one end with an internally threaded female portion 33 for threaded engagement onto the threaded plug 31. The rearward end of the actuator is formed with an outwardly extending flanged portion 34, for use as a finger grip.

In accordance with the practice of this invention, use is made of a sealing member in the form of a piston plug 40 of rubber, plastic or the like sealing material having an outer sealing rib 41 or sealing ribs 41, 42 slidably engaging the inner walls of the inner tubular member in sealing relation. Instead of forming the crosswise connecting body portion 43 with one or more slits which provide openings for the passage of liquid therethrough upon flexure in response to fluid pressure, as described in my aforementioned copending application, the crosswise extending disc member or body portion 43 is provided to be free of any such passages or slits whereby a positive sealing relation is provided by the axially movable piston seal.

Instead, the piston seal 40 is located between the fluid 35 in the inner tubular member and the end portion of the inner tubular member adjacent the outer tubular member but beyond the end of the piercing needle so that the piston seal 40 constitutes a complete barrier to the passage of fluid or vapors from the inner tubular member to the interior of the outer tubular member.

In response to actuation of the piston plug 30 for displacement axially towards the outlet end of the inner tubular member for displacement of liquid 35 from the inner tubular member into the outer tubular member, the column of liquid in the inner tubular member is displaced axially in the direction toward the outlet end

and the piston seal 40 is axially displaced therewith and forced into engagement with the end of the hollow needle 50 for penetration through the central body portion 43 of the piston seal whereby communication is established between the fluid in the inner tubular member and the outlet end of the inner tubular member and through the flexible closure 26 and openings 27 with the interior of the outer tubular member for flow of liquid from the inner tubular member through the hollow needle into the outer tubular member.

In the specific embodiment illustrated, the sealing member is formed of parallel, spaced sealing ribs 41 and 42 connected by a tubular section 45 of smaller dimension with a crosswise extending penetratable member 43 midway between the ends of the tubular member.

In the assembled relation, illustrated in FIG. 1, a fluid 35 is housed in sealing relationship within the second tubular member with the floating sealing disc 40 near the forward end portion thereof while dry medicament 36 is housed in sealing relationship within the first tubular member 1. The loaded device can be shipped and stored for extended periods of time without deterioration of the ingredients and without exposure of the elements to non-sanitary conditions. The double seal effected by the sealing disc 26 and the floating disc 40 operates to maintain complete separation between the two chambers whereby the dry medicament material is not exposed to the fluid or moisture of the liquid contained in the second tubular member.

In use, the device is held with the two middle fingers under the flanged member 28 of the second tubular member and the actuator 32 is pressed by the thumb to effect displacement of the plug 30 through the cylindrical passage 21. This operates to place the liquid 35 under pressure which first moves the piston seal 40 to the end of the inner tubular member whereby the middle part 43 of the piston seal is pierced by the needle like member 50 enabling the liquid to flow to the resilient closure disc 26 to cause flexure sufficient to unseat the disc and establish communication between the chambers 21 and 2 through the openings 27 to enable flow of fluid under pressure from the chamber 21 in the second tubular member into the chamber 2 of the first tubular member for admixture with the dry medicament 36. This intermediate portion is illustrated in FIG. 2. The liquid takes the medicament into solution or suspension, with shaking when necessary, to provide a freshly prepared fluid system ready for administration by injection.

Thereafter or before, the needle cover 17 is removed to expose the needle 7 and to free the compression spring 16 which operates automatically to effect rearward displacement of the needle hub and needle whereby the rearward end portion 11 of the needle is projected through the sealing disc 5 into communication with the chamber 2 containing the mixture of fluid and medicament in the freshly dispersed or dissolved state.

Administration is made without change of devices and without exposure of the freshly prepared solution or suspension by inserting the needle into the vessel or tissue. For this purpose, the outer casing may be grasped with one hand with the middle fingers beneath the flanged portion 3a. The needle is inserted and the thumb is pressed down onto the actuator which, at the end of its travel in the second tubular member, causes displacement of the second tubular member for movement as a piston through the cylindrical passage 2 of the first tubular member thereby forcibly to displace the freshly prepared fluid system from the interior of the first tubular member through the needle end into the tissue.

It will be apparent that the sealing effect which is achieved by the sealing disc 40 is sufficient without the flexible seal 26 to effect positive separation to prevent escape of liquid fluids or vapors from the interior of the inner tubular member into the interior of the outer tubular member whereby complete separation can be maintained between the materials housed in the tubular members. As a result, the flexible sealing disc 26 and 27 can be dispensed with, as illustrated in FIG. 7 whereby reliance is had on the sealing disc 40 to establish the sealing relation between components until immediately prior to use.

By way of further modification, as illustrated in FIG. 7, the hollow needle 50 can be supported at the outlet end of the inner tubular member by a holder 60 dimensioned to have a cross-section less than the inner wall-to-wall dimension of the inner tubular member but greater than the passage through the neck of the inner tubular member so that the needle holder will rest on the flange 62 for support of the needle in position to penetrate the sealing disc. This arrangement provides more positive support for the needle in resistance to the forces which become effective when the sealing disc is forced into positive engagement with the hollow needle and the forces which exist as the liquid is forced from the inner tubular member into the outer tubular member.

It will be understood that changes may be made in the details of construction, arrangement and operation without departing from the spirit of the invention, in that the sealing means between inner and outer tubular members may be used in connection with other devices where a sealed relationship has to be maintained between an inner tube and an outer tube or other outer space until use, as defined in the following claims.

I claim:

1. In a hypodermic syringe having a rigid inner tubular member having a forward end and a rearward end and a rigid outer tubular member having a forward end and a rearward end with the inner tubular member having an outer diameter less than the inner diameter of the outer tubular member to enable axial movement of the inner tubular member in telescoping relation within the outer tubular member, a piston ring member on the forward end of the inner tubular member dimensioned slidably to engage the inner walls of the outer tubular member in sealing relation, a hypodermic needle on the forward end of the outer tubular member, a piston plug slidable axially in the inner tubular member and means for actuating the piston plug for axial displacement within the inner tubular member, the improvement which comprises sealing means in the inner tubular member for sealing the portion of the inner tubular member beyond the sealing means from the outer tubular member and means for establishing communication through said sealing means between the outer portion of the inner tubular member and the outer tubular member, comprising a hollow penetrating needle pointed at one end and mounted in the forward end portion of the inner tubular member with the end of the hollow penetrating needle extending axially a short dis-

tance into the interior of the inner tubular member, and a piston plug extending continuously crosswise of the inner walls of the inner tubular member and having an outer sealing rib in sealing engagement with the inner walls of the inner tubular member and slidable axially within the inner tubular member between a normal position rearwardly of the hollow penetrating needle point and an operated position forwardly of the hollow penetrating needle point whereby the needle penetrates the sealing disc and communicates with the interior of the inner casing beyond the sealing disc, in which the rib portion of the piston plug is dimensioned to have a greater width than the central portion in endwise alignment with the hollow penetrating needle.

2. A hypodermic syringe as claimed in claim **1** which includes a rupturable closure sealing the forward end of the outer tubular member and a holder mounted on the forward end portion of the outer tubular member for supporting the hypodermic needle for movement between extended and retracted position, with the rearward end of the needle terminating a short distance forwardly of the rupturable closure when in extended position and penetrating through the rupturable closure when displaced to retracted position.

3. A hypodermic syringe as claimed in claim **1** which includes a flexible closure on the forward end of the inner tubular member with passages through the flexible closure in endwise alignment with the end portion of the inner tubular member for abutment to plug the passages when in normal sealed position and to free the passages responsive to pressure from within the inner tubular member to unseat the closure.

4. A hypodermic syringe as claimed in claim **1** in which the penetrating needle is mounted on the forward end of the inner tubular member.

5. A hypodermic syringe as claimed in claim **1** in which the inner tubular member is formed with a neck portion at the forward end and which includes a holder for the penetrating needle dimensioned to have a cross-section less than the cross-section of the inner tubular member but greater than the neck portion whereby the holder for the penetrating needle rests upon the shoulder of the inner tubular member formed between the neck portion and the inner walls of said inner tubular member.

6. A hypodermic syringe as claimed in claim **1** in which the sealing disc is formed of an elastomeric material.

7. A hypodermic syringe as claimed in claim **1** in which the inner tubular member is adapted to contain a fluid and in which the outer tubular member is adapted to contain a dry material to be taken up by the fluid when the latter is caused to flow from the inner tubular member to the outer tubular member responsive to movement of the piston ring member axially within the inner tubular member.

8. A hypodermic syringe as claimed in claim **1** in which the sealing disc within the inner tubular member is formed of rubber-like material having annular axially spaced ribs dimensioned to extend into sealing engagement with the inner walls of the inner tubular member.

9. A hypodermic syringe as claimed in claim **1** in which the sealing disc comprises a pair of axially spaced rim portions, a tubular portion joining the inner areas of said rim portions and a thin disc portion spanning the tubular portion and rupturable by the penetrating needle.

10. A sealing means for sealing the interior of a tubular member from the outside comprising a hollow penetrating needle extending axially into the inner tubular member and a support fixed on the end of the inner tubular member for mounting the penetrating needle with the end portion of the needle extending a short distance axially into the inner tubular member, a sealing ring of flexible material within said inner tubular member dimensioned slidably to engage the inner walls of the tubular member in sealing relationship and mounted for axial movement between sealing position beyond the end of the penetrating needle and unsealing position forwardly of the end of the penetrating needle whereby the needle penetrates through the sealing disc for communication with the interior of the tubular member.

11. A sealing means as claimed in claim **10** in which the support for the hollow needle is fixed to the forward end of the tubular member.

12. A sealing means as claimed in claim **10** in which the tubular member is formed with a neck portion of smaller cross-section than the remainder to provide a shoulder portion therebetween and in which the support for the hollow needle is dimensioned to have a cross-section less than the cross-section of the tubular member but greater than the neck portion whereby the needle support rests on the shoulder in position of use.

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