

[72]	Inventor	Herbert C. Snyder Brockway, Pennsylvania
[21]	Appl. No.	807,570
[22]	Filed	March 17, 1969
[45]	Patented	Sept. 8, 1970
[73]	Assignee	Brockway Glass Company, Inc. Brockway, Pennsylvania

FOREIGN PATENTS

920,604 3/1963 Great Britain..... 128/218(M)UX

Primary Examiner—Samuel Koren
Assistant Examiner—James H. Czerwonky
Attorney—Christel and Bean

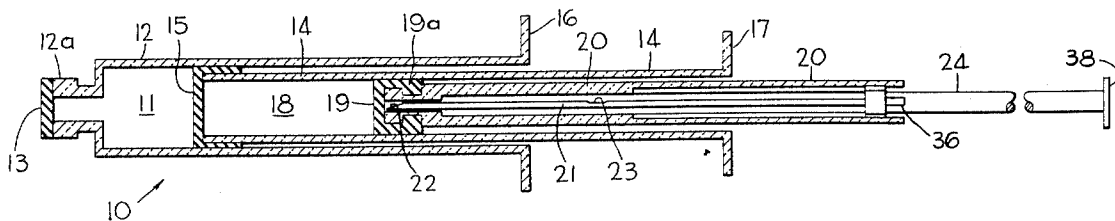
[54] **HYPODERMIC SYRINGE ASSEMBLY**
10 Claims, 8 Drawing Figs.

[52]	U.S. Cl.	128/218, 128/220, 128/221
[51]	Int. Cl.	A61m 5/22, A61m 5/32
[50]	Field of Search	128/218, 218(N), 218(M), 220, 218.2, 221, 215, 218.1

[56] **References Cited**
UNITED STATES PATENTS

1,767,304	6/1930	Morton	128/220
2,193,322	3/1940	Lozier et al.....	128/218(M)UX
2,489,600	11/1949	Tydings et al.....	128/218.1
2,567,001	9/1951	Watson	128/218(M)UX
3,370,754	2/1968	Cook et al.	128/218(M)UX

ABSTRACT: A hypodermic syringe assembly including two axially-spaced compartments or chambers for storing drug and solvent prior to use. The needle is contained within the assembly but isolated from the chambers prior to mixing. Mixing occurs when the needle is moved axially through a penetrable seal by a push rod to a position where the piercing end thereof is in one chamber and an intermediate port or opening in the needle is in the other chamber. The needle functions as a conduit and both chambers are variable in axial length to facilitate transferring of the contents of one to the other. When mixing is completed the needle is moved further axially by the push rod, in the same direction, through another penetrable seal whereby the piercing end is exposed externally of the syringe assembly for injection and the needle opening is in the chamber containing the mixture.



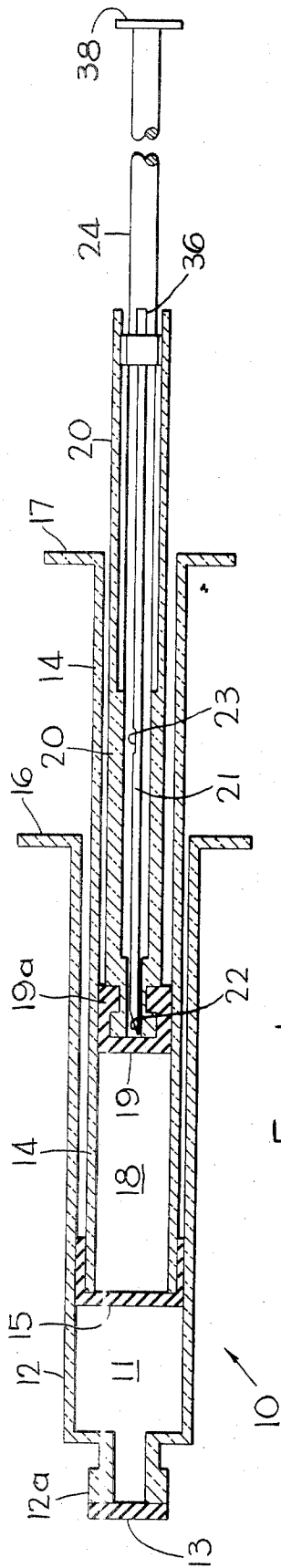


FIG. 1.

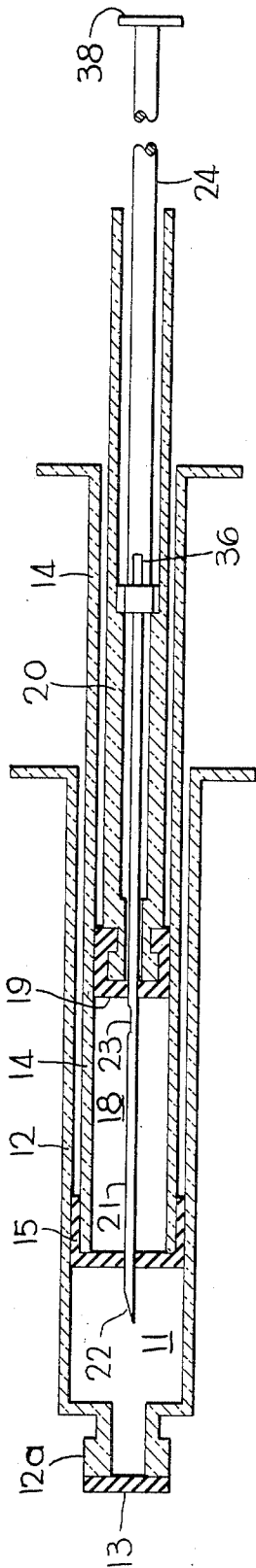


FIG. 2.

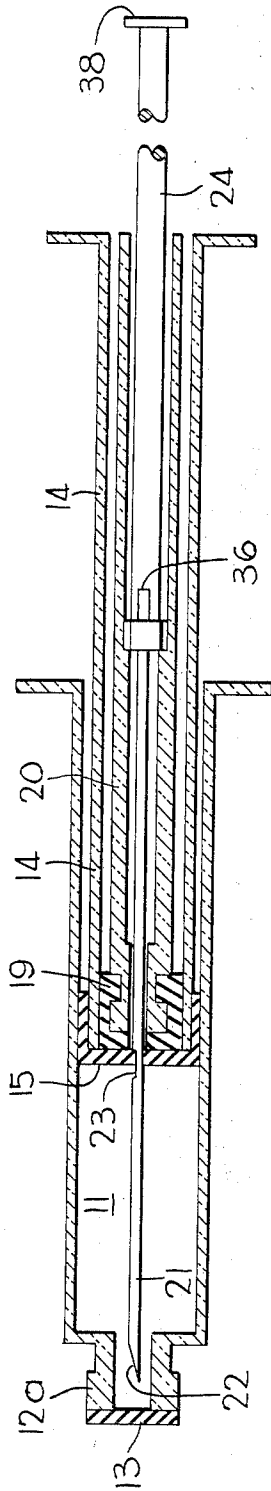


FIG. 3.

INVENTOR.
HERBERT C. SNYDER
BY
Christel + Bean
ATTORNEYS

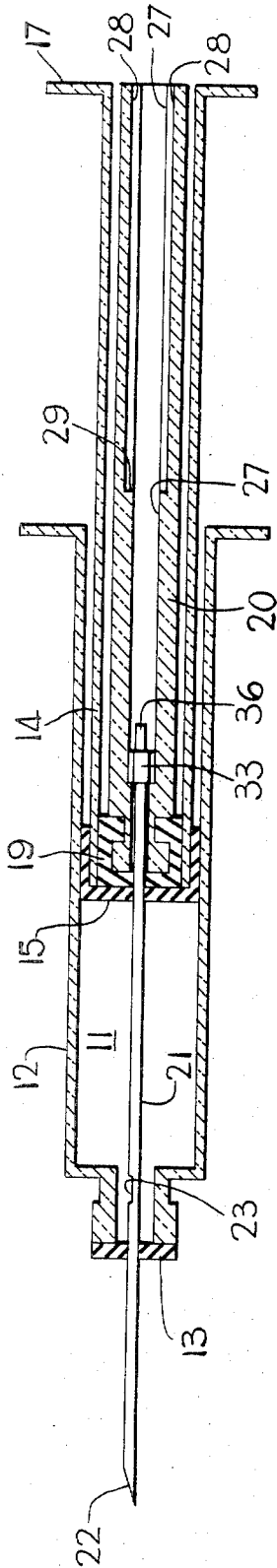


FIG. 4.

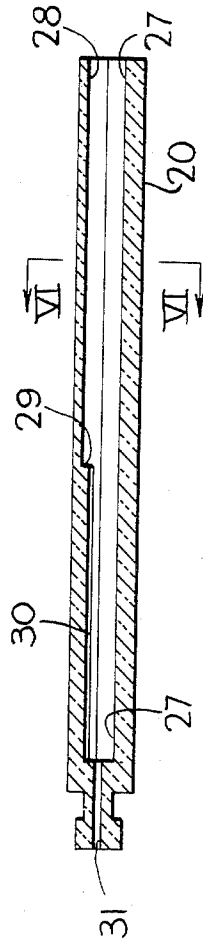


FIG. 5.

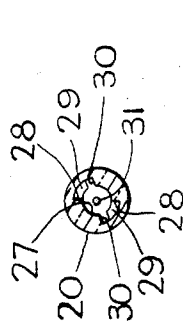


FIG. 6.

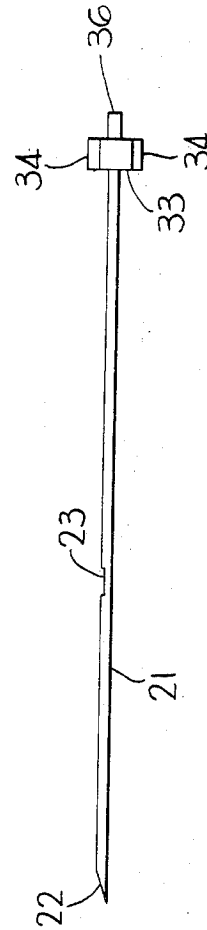


FIG. 7.

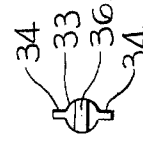


FIG. 8.

INVENTOR.
HERBERT C. SNYDER
BY

Christel & Bean
ATTORNEYS

HYPODERMIC SYRINGE ASSEMBLY

BACKGROUND OF THE INVENTION

This invention relates to hypodermic syringes and, more particularly, to a novel pre-filled syringe adapted to contain two substances in isolation from each other until it is desired to use the syringe.

In recent times, unit dose dispensing of drugs has received increased attention because of concern for patient welfare and for the rising costs of medical care. Prepackaging of a drug can provide positive identification, precise dosage, greater assurance of sterility, avoidance of contamination with other drugs which otherwise might result, for example, from the use of inadequately cleaned syringes, and less chance of drug deterioration because the expiration date and storage conditions can be indicated clearly on the package. The advantages of storing many medications in the dry or lyophilized form are numerous, and the number of medications prepared and stored in this manner are increasing. For example, many antibiotics which when in solution are highly unstable and maintain their specified potency for only a few hours, in dry form as by freeze drying or lyophilization process have a "shelf-life" several years. These dry medications are mixed with the proper diluent just prior to injection.

It thus would be highly desirable to provide a unit dose syringe having a drug, in dry or lyophilized form if desired, in one compartment separated from a solvent in a second compartment, which syringe would enable mixing of drug and solvent just prior to injection. The syringe must be of simple construction both for ease of operation and to afford economical manufacture, which permits throw-away use.

SUMMARY OF THE INVENTION

The present invention provides a novel syringe assembly including two axially-spaced compartments or chambers for storing drug and solvent prior to use. Mixing occurs when a needle, stored in the assembly, is moved axially through a penetrable seal to a position where the piercing end is in one compartment and an opening provided in the needle intermediate the ends thereof is in the other compartment. The needle functions as a conduit and both chambers are variable in axial length to force the transfer of the contents of one to the other. When mixing is completed the needle is moved further axially, in the same direction, through another penetrable seal whereby the piercing end is exposed externally of the syringe assembly for injection and the intermediate needle opening is in the chamber containing the mixture.

While a single specific embodiment of the principles of the present invention is illustrated in the accompanying drawing and described in detail in the following specification, it is to be understood that such embodiment is by way of example only and that various mechanical modifications may be made without departing from the spirit of the invention, the scope of which is defined in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal sectional view of one form of syringe assembly of the present invention with the parts in an initial position;

FIG. 2 is a similar view showing the parts in position for the mixing operation;

FIG. 3 is a similar view showing the completion of the mixing operation;

FIG. 4 is a similar view of the assembly ready for injection;

FIG. 5 is a longitudinal sectional view of one form of a needle supporting sleeve of the syringe of the present invention;

FIG. 6 is a cross-sectional view taken about on line 6-6 in FIG. 5;

FIG. 7 is an elevational view of one form of a needle included in the syringe assembly provided by the present invention; and

FIG. 8 is an end view of the needle of FIG. 7.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The syringe assembly provided by the present invention is designated 10 in FIG. 1 and includes a first chamber or compartment 11 defined by a first tubular member in the form of glass sleeve 12 which is provided with a penetrable seal 13 at one end thereof and open at the other end, and a second tubular member in the form of glass sleeve 14 movable within tubular member 12 and provided with a penetrable seal 15 at one end thereof and open at the other end.

Tubular members or sleeves 12, 14 preferably are made of glass but alternatively could be made of suitable plastic or other material. Each of the members 12, 14 is provided with a radially projecting flange, in particular flanges 16, 17, respectively. Tubular member 12 has a reduced diameter or neck portion 12a defining a relatively smaller diameter opening over which disc-shaped seal 13 is secured as by conventional adhesive bonding to the end surface of neck 12a. Seal 15 of tubular member 14 is generally cup-shaped with the base thereof closing the end of tubular member 14 and the wall or flange thereof circumferentially surrounding member 14 at that end and serving as a piston in tubular member 12. Both seals 13 and 15 advantageously may be moulded from silicone rubber.

The syringe assembly 10 also includes a second chamber or compartment 18 defined in part by means of tubular member 14 and seal 15. Chamber 18 is completed by a penetrable seal 19 provided at the end of a third tubular member or glass sleeve 20 which is movable within tubular member 14. Seal 19 also is advantageously moulded from silicone rubber and also serves as a piston in tubular member 14.

Seal 19 is provided with an annular rib portion 19a which fits snugly within a circumferential groove in the outer surface of tubular member 20 to provide a locking engagement therebetween. The structural details of tubular member 20 will presently be described.

The syringe assembly finally includes a conduit means in the form of a hollow needle 21 having a sharp or piercing end 22 and a lateral opening or port 23 provided intermediate the ends thereof. The needle is moved axially first from its initial storage position shown in FIG. 1 to its mixing position, shown in FIG. 2, and then to its exposed position for an injection by a motion transmitting means in the form of detachable push rod 24.

FIGS. 5 and 6 show in more detail the structure of tubular member 20. A constant diameter bore 27 extends through member 20 and terminates a short distance from the left hand end thereof. A pair of first longitudinal guide slots 28 provided in the interior wall of member 20 extend for approximately half the length of member 20 and terminate in a ledge 29. A second pair of longitudinal guide slots 30 are provided in the wall of member 20 along the remaining length of bore 27. As viewed in FIG. 6, the slots 30 are within the confines of slots 28. A relatively small diameter bore 31 is provided in the left hand end portion of member 20 and communicates with bore 27. This internal structure of member 20 facilitates guiding of needle 21 from its storage to its mixing and then to its exposed positions in a manner which presently will be described.

FIGS. 7 and 8 show in detail the combined conduit means and hollow needle 21, the sharp or piercing end 22 being provided by cutting the tip of needle 21 at an angle in a conventional manner.

The other end of needle 21 is provided with a cylindrical enlargement 33 having radially oppositely projecting lugs 34 of a thickness such that they may be received in the slots 30 in member 20. Enlargement 33 is also provided with an axially extending flat lug 36 for operative engagement with a slot in the end of push rod 24.

Push rod 24 is provided at the other end thereof with a radially extending flange 38 to facilitate hand operation thereof.

The syringe assembly would be pre-filled with drug and solvent which are isolated when the syringe is then assembled in

its storage position as shown in FIG. 1. For example, solvent can be stored in chamber 18 and drug, either in liquid or powder form, stored in chamber 11. Needle 21 is enclosed within tubular member 20 and seal 19 during storage, which protects needle 21 from contamination and damage, and, moreover, the needle is isolated within the assembly from the drug and solvent prior to mixing and injection. The assembly thus can be shipped and stored for considerably long periods with the contents of the two chambers or compartments in sealed isolation.

When it is desired to use the syringe the operator simply grasps the assembly and pushes the extending end of rod 24 with his finger in a direction toward the assembly. As the push rod 24 is moved in this forward direction, needle 21 also is moved and penetrates seal 19, enters chamber 18, then penetrates seal 15 so that the end 22 thereof is in chamber 11 and opening 23 is in chamber 18 and in proximity to seal 19 as shown in FIG. 2. During this forward travel of needle 21, lugs 34 are moved along slots 28 to the point where they abut ledge 29 within tubular member 20. Continued forward pressure applied to push rod 24 moves needle 21, seal 19 and tubular member 20 jointly in a forward direction within tubular member 14. The volume of chamber 18 thus is decreased causing fluid to flow from it through opening 23 and through needle 21 into chamber 11. Mixing thus occurs, and the resultant hydraulic pressure causes an increase in the volume of chamber 11 by relative axial movement between the tubular member 12 and 14 to accommodate the mixture. When complete displacement has occurred the parts are in the position shown in FIG. 3. With the mixing operation completed, the syringe assembly is next readied for an injection. This is accomplished by turning push rod 24 in a clockwise direction so that lugs 34 on needle 21 are aligned with the slots 30. Rod 24 may then be pushed forward to its fully inserted position shown in FIG. 4 causing needle 21 to penetrate seal 13 so that the piercing end 22 thereof is exposed and opening 23 is in chamber 11. The push rod 24 may then be withdrawn from the assembly and discarded. The syringe assembly then is operated to perform an injection in a conventional manner as by applying the thumb to the end of tubular member 14 on flange 17 and by placing the index and third fingers under flange 16 to grasp member 12. Pressing tubular member 14 in a forward direction decreases the volume of chamber 11 to evacuate the contents thereof through needle 21. If the frictional engagement of needle 21 in the assembly is not sufficient to hold it firmly in place, a small collet chuck can be attached over the seal 13. After injection the entire assembly may be discarded.

The distance between the piercing end 22 of needle 21 and opening 23 therein must be sufficient to insure that when further forward movement of needle 21 and push rod 24 within tubular member 20 is stopped at the beginning of the mixing operation, opening 23 will be in chamber 18 just ahead of seal 19. Having opening 23 in this position insures that the entire contents of chamber 18 will be transmitted through needle 21 to chamber 11 as the needle 21, seal 19 and member 20 are moved together in a forward direction. Moreover, opening 23 must be spaced from end 22 a distance sufficient to insure that opening 23 will be in chamber 11 when needle 21 is in its fully exposed position as shown in FIG. 4.

The syringe assembly provided by the present invention thus advantageously is operated in a simple manner to perform mixing and prepare the assembly for injection. No rearrangement of the syringe assembly components is required during mixing and in preparation for injection, but rather the hand manipulation required conforms with standard and accepted hypodermic injection practices. In particular, two forward movements of push rod 24 separated by a slight rotation thereof accomplish both mixing of the previously separated syringe contents and placing of the syringe components in a position for injection. This simple operative procedure not only enhances the ease with which the syringe assembly is

used but also eliminates the danger of contamination which is present when several steps including rearrangement of syringe parts are required.

The simple structure of the syringe assembly renders it economical both from the standpoint of original manufacturing cost and disposability after a single use. Only a few parts are needed in addition to those required in a conventional, non-mixing syringe. The parts are of simple structure and easy to manufacture.

The syringe assembly can be used equally well with a dry powder and its proper diluent or with two liquids. It is intended to be pre-filled with a unit dose and disposed of subsequent to the single use. Patient discomfort thus is minimized because each injection is made with a fresh, sharp needle. Moreover, patient safety is maximized because there is no possibility of cross-infection through improperly cleaned syringe or needle and because there is provided, in effect, a "closed system" from pharmaceutical filling line to patient. In addition, the syringe saves nursing time in the preparation and administration of parenteral medication and saves pharmacists' time in dispensing unit dose quantities.

I claim:

1. A hypodermic syringe assembly comprising:

- a. means defining a first chamber of variable axial length and adapted for containing injectable material;
- b. means defining a second chamber of variable axial length axially adjacent to said first chamber and adapted for containing injectable material;
- c. a hypodermic needle having a penetrating point at one end and a lateral opening intermediate the ends thereof;
- d. means adapted to support said needle for axial movement in said assembly and to store said needle in an inoperative position; and
- e. means for moving said needle axially from said inoperative position to a fluid transferring position where said pointed end is in one of said chambers and said lateral opening is in the other and thence to an injecting position where said pointed end is exposed externally of said assembly and said lateral opening is in the chamber to which fluid was transferred.

2. The hypodermic syringe defined in claim 1 including:

- a. a first tubular member provided with a penetrable seal at one end thereof and open at the other end thereof; and
- b. a second tubular member movable within said first tubular member and provided with a penetrable seal at the end thereof which is toward the first penetrable seal; whereby said first chamber defining means comprises said first tubular member and said two penetrable seals.

3. The hypodermic syringe defined in claim 2 including a third tubular member movable within said second tubular member and provided with a third penetrable seal at the end thereof directed toward said first and second penetrable seals and open at the other end thereof, said second chamber defining means comprising said second tubular member and said second and third penetrable seals.

4. The hypodermic syringe defined in claim 3 wherein said needle in inoperative position is entirely contained within said third tubular member and disposed so that the pointed end thereof is toward said seals.

5. The hypodermic syringe defined in claim 4 wherein said needle moving means comprises a rod movable within said third tubular member and adapted to engage said needle at the end opposite the pointed end thereof.

6. The hypodermic syringe defined in claim 1 wherein said needle support means has a stop for temporarily arresting said needle when it reaches the fluid transferring position, and a guideway for movement of said needle beyond said stop to the injecting position.

7. The hypodermic syringe defined in claim 6 wherein said stop comprises a ledge defined by the end of a first longitudinal slot and said guideway comprises a second longitudinal slot of narrower width and communicating with said first slot at said ledge.

8. The hypodermic syringe defined in claim 7 wherein said needle is provided with a guide member adapted to be moved along said slots.

9. A hypodermic syringe assembly comprising:

- a. a first tubular member provided with a penetrable seal at one end thereof and open at its other end;
- b. a second tubular member movable within said first tubular member and provided with a penetrable seal at one end thereof and open at its other end;
- c. a third tubular member movable within said second tubular member and provided with a penetrable seal at one end thereof and open at the other end;
- d. a hollow needle contained and axially movable within said third tubular member and disposed so that the piercing end thereof is toward said penetrable seals, said needle being provided with a lateral opening intermediate the ends thereof;
- e. a member movable within said third tubular member and engaging said needle at the end opposite said piercing end

whereby said needle may be moved axially relative to the assembly and independently of the movement of said first, second and third tubular members; and

- f. said third tubular member having a stop for temporarily arresting said needle after penetration of the penetrable seals of said second and third tubular members, and a guideway for movement of said needle beyond said stop for piercing the penetrable seal of said first tubular member and disposing said needle for injection use.

10. The hypodermic syringe defined in claim 9 wherein said needle is so proportioned that when the needle is arrested by said stop the piercing end thereof is within said first tubular member and the lateral opening is within the second tubular member whereby subsequent movement of said third tubular member toward said second tubular member transfers material from within said second tubular member to within said first tubular member through said needle.

20

25

30

35

40

45

50

55

60

65

70

75