ABSTRACT

A syringe has a floating barrier seal located at approximately the middle of the syringe chamber, thereby forming (at least) two different chambers on opposite sides of the barrier to provide separate storage space for (at least) two different medicines. A hypodermic needle projects inwardly into the adjacent one of the chambers, far enough to pierce the floating barrier after the first medicine has been substantially all dispensed. The needle passes through the barrier to dispense the second medicine on the other side of the barrier, at which time there is a relief of back pressure which otherwise would result from a compression of the first medicine. At this time, the barrier seals the first medicine away from the needle so that it cannot mix with or contaminate the second medicine. A catch may be provided to prevent the barrier from raising and thereby allows the first medicine to reach the needle after the second medication has begun to flow.

17 Claims, 13 Drawing Figures
MULTI-CHAMBER SYRINGE

This is a continuation-in-part of my earlier filed, co-pending application Ser. No. 255,099, filed May 19, 1972, now abandoned.

This invention relates to syringes for giving multidose injections and, more particularly, to syringes which do not allow two or more medicines to mix prior to their sequential injection into a patient.

Syringes are used to inject medicine into the body of a human or an animal. Usually, the injected medication is a single fluid or a mixture, in which case the syringe has a single compartment and a single needle. Sometimes, the medication includes two chemicals or drugs which must be mixed immediately prior to the injection. Here, the syringe usually has two compartments separated by a barrier which either ruptures or opens at the time of injection so that the injected medicine is a single chemical mixture as it passes into the patient's body.

When it has been necessary to inject two separate and unmixed chemicals, the customary practice has been to use two separate syringes. This doubles the cost of preparing and administering the mixtures for injection, and it doubles the pain by requiring two punctures of the patient's skin.

A suggested alternative is to provide twin, rigidly interconnected syringes which does nothing for the cost, but supposedly gives a single sensation of pain since the two needles are physically too close together to be perceived as more than a single point of contact. Aside from the cost, this twin syringe requires greater skill on the part of the doctor or nurse administering the medication.

The foregoing assumes the syringe is being used for injection. However, syringes are also used for extraction by creating a vacuum in the chamber. In essence, by reversing the process of injection one is able to produce an extraction.

Accordingly, an object of this invention is to provide a syringe for administering two medications which are completely separate and unmixed at the time of injection. Here an object is to provide a syringe having substantially the same cost as a single medication syringe. In this connection, an object is to provide a disposable, double compartment syringe having such a low cost that it may be filled with two or more medications and prepackaged in a sterile container by a pharmaceutical company.

Another object is to enable the unimpeded flow of a second medication by precluding the back pressure which otherwise might build from the remaining portions of the first medication. This object is accomplished by having a point of evacuation in the first chamber which is effective after the second medication has begun to flow, thus enabling that chamber's residual medication to be released.

The object, furthermore, is to convert a multiple chamber syringe which may be used for an injection, into a single chamber syringe, which may be used for extraction. This object is accomplished by capturing the floating barrier dividing the two compartments at the base of the syringe chamber. In this way, the object of converting to a single chamber syringe is achieved.

Moreover, an object of the invention is to reduce the skill level required to administer a multi-medication injection. Here, an object is to reduce the patient's pain and psychological suffering in anticipation of and during the injection.

In keeping with an aspect of this invention, these and other objects of the invention are accomplished by a syringe having a floating barrier therein at approximately the middle of the syringe chamber. Two different chambers are thereby formed on opposite sides of the floating barrier to separate the two different medications. A single hypodermic needle projects inwardly into the bottom of a first of the chambers far enough to pierce the floating barrier after substantially all of the first medication has been dispensed. The needle passes through the barrier to thereafter dispense the second medication on the other side of the barrier. In this way, the barrier seals the first medication away from the needle so that it cannot mix with or contaminate the second medication. At this time, the residual medication is released through a point of evacuation of the first chamber, thus precluding back pressure from the second medication. Moreover, if desired, the floating barrier may be captured at the base of the chamber, thus enabling the syringe to be used for extraction.

The nature of a preferred embodiment of the invention may be understood best from an inspection of the attached drawings wherein:

FIG. 1 is an exploded view, in perspective, of the inventive syringe;
FIGS. 2–3 are stop motion views schematically showing how two medications are separately dispensed so that neither mixes with or contaminates the other prior to injection;
FIG. 6 schematically shows the first embodiment of evacuating the remainder of a first medication after it is no longer being injected into a patient;
FIG. 7 perspective shows a second embodiment of the needle assembly for evacuation of medication;
FIG. 8 shows perspective a third embodiment with absorbent material to accumulate escaping medication and prevent a dribbling of the first medication at the port;
FIG. 9 is a cross section view of a fourth embodiment utilizing the syringe tube as a point for a weakened rupture area;
FIG. 10 perspective shows a fifth embodiment with a weakened area in the needle assembly; and
FIGS. 11–13 are partly cross sectional and partly perspective views of several embodiments for capturing the floating barrier in order to enable the syringe to be used for evacuation.

This is a very sophisticated syringe into which many optional features can be easily incorporated. One such option provides an evacuation port which will preclude any buildup of back pressure. This port can be a weakened wall structure or a stationary outlet with any of various forms of peel off tabs. Due to the equal effectiveness of any such means, the manufacturer may select the one means which is suited to his manufacturing or processing procedure. Another easily incorporated option enables this syringe to be used for extraction as well as injection by either simply modifying the design of the needle or the inside wall of the chamber. Again this choice allows the use of the most economical means for the manufacturers facilities.

The inventive syringe 20 comprises a needle assembly 21, a cylinder 22, a floating barrier seal 23, and a plunger assembly 24. The needle is separated into first and second parts 26, 27, respectively. The first part 26

...
3,896,805

is sharpened and adapted to pierce the skin of a person or animal receiving the medication. The second part 27 of the needle projects into the cylinder 22 for a distance which is adequate to puncture the barrier 23 when it reaches the bottom of the cylinder. A preferably plastic collar 28 is firmly attached to the needle 21 at the junction point between the two parts 26, 27. The collar 28 includes two oppositely disposed ears 29, 30 which cooperate with internal threads in the syringe to attach the needle thereto.

The cylinder 22 is an elongated hollow tube of uniform cross section, terminated at the bottom in an internally threaded coupler 35. Concentrically positioned inside coupler 35 is a tube 36 having an axial opening therein to receive the needle 27 with a sufficiently tight seal to preclude leaking. The threads 37 inside the coupler 35 engage and receive the ears 29, 30 on the collar 28. Thus, as the assembly 28 is rotated, the two parts 28, 35 come together with a tight seal.

The upper end of the cylinder 22 has opposing tabs 38, 39 which are held by the index and middle fingers of the person administering the injection. The upper end 40 of the cylinder 22 is beveled to provide a conical entrance for guiding and directing the barrier 23 and plunger 24 members upon entrance into the cylinder. The entire unit is preferably made from low cost, this-walled, transparent plastic material so that the person administering the injection can watch the operation to be sure that the medications are properly fed into the patient.

According to one aspect of this invention, a floating barrier member 23 is provided for forming two separate chambers in the tube. Preferably, this barrier is a soft rubber plug which has two longitudinally displaced piston rings 41, 42 for making a good seal against the interior wall of the cylinder 22. The bottom 44 of the plug is somewhat conical to help guide it on its entrance into the cylinder 22. An axial bore 45 almost completely pierces the plug forming the floating barrier member 23. However, the bottom of the bore 45 does not quite extend through the bottom of the plug. Therefore, the bottom of the bore 45 is covered by a thin membrane 46 to prevent any fluid from passing through the barrier.

The plunger assembly 24 comprises a ram rod 50 having a soft rubber plug 51 attached to the bottom and a thumb pad 52 attached to the other end. The plugs 23 and 51 are almost identical, both slide inside the cylinder 22.

The method of its use is illustrated by the stop motion views of FIGS. 2–5. Preferably, a pharmaceutical manufacturer loads the inventive syringe in his laboratory or factory by depositing a first medicine 54 in the bottom of the cylinder 22. Then, the barrier 23 is placed in the tube and brought down into contact with the top of the medicine surface, to eliminate all entrapped air. One way of doing this is to invert the syringe, allowing the entrapped air to escape through a tube located intermediate the barrier 23 and cylinder 22, and then to seal the tube.

After the first medicine 54 is loaded into the first compartment, a second medicine 55 is loaded into the second compartment. Then the plunger assembly 24 is brought down into contact with the upper surface of the second medicine, and all entrapped air is withdrawn. One way to withdraw the entrapped air is to slip a small tube of hypodermic needle stock between the soft rubber plug 51 and the inside surface of the cylinder 22 and to vacuum pump the air from the upper chamber. The inventive syringe (FIG. 2) is now preloaded with two completely separated medications 54, 55, held securely apart, one from the other.

As the injection is given (FIG. 3), only the first medicine passes out of the chamber 22 and through the needle 26, into the patient. As the first medicine is exhausted, the floating barrier 23 engages and is pierced by the upper end 27 of the needle 21. It is easy to pierce the floating barrier since only the thin membrane 46 is present at this point. Thereafter, the needle end 27 is in the bore 45 which provides an unimpeded passage for the medicine in the upper chamber. The rubber-like material of the floating barrier surrounds and seals the outside of the needle 27 and prevents any more of the first medicine 54 from passing through the needle.

At this time (FIG. 4), the second medicine 55 passes through the needle 27 and into the patient receiving the injection. The second medicine is not mixed with or contaminated by the first medicine at any time before or during the injection.

At the bottom of the stroke (FIG. 5), the plug 51 reaches the top of the barrier 23 or the needle 27, where it terminates the flow of the medicine through the needle. The medicine is now exhausted, and the spent syringe is discarded.

It is apparent that the same principle may be extended to an administration of a larger number of medicines by increasing the number of floating barriers and, therefore, the number of separate compartments inside the cylinder 22. The membrane member 46 is thin enough and the rubber plug 23 is soft enough to admit the second medicine 55 to the needle. However, sometimes the first medicine 54 entrapped under the floating barrier 23 should be evacuated to relieve pressure and to allow the barrier 23 to settle further into the cylinder 22. This is especially true if there are two or more floating barriers. The first barrier must settle to allow the second barrier to be pierced by the needle 27.

Therefore, another aspect of this invention is to insure the flow of medication after the barrier reaches the needle top by relieving any possible back pressure in the first chamber. This is accomplished by incorporating a port for evacuation of the first chamber, into the design inventive syringe 20. There are several possibilities for both the placement of this port and a method of evacuation (FIGS. 6–10).

The first embodiment involves a weakening of cylinder 22 at a point 60 in the entrapped area 61. An adjacent chamber 62 is positioned to communicate with the entrapped area 61 when the weakened point 60 ruptures. As the first medicine 54 is ejected from the cylinder 22, the pressure does not exceed the rupture strength of the weakened area 60. However, when the medication 54 flow is blocked by the needle end 27 passing through the floating barrier, the fluid pressure builds in the entrapped area 61. Weakened area 60 ruptures under the augmented pressure, and the entrapped medication flows from area 61 into a closed and, perhaps, evacuated chamber 62. As the fluid flows from area 61, the barrier 23 settles further into cylinder 22 in order to enable the needle end 27 to properly perform its penetration function. There cannot be a reverse flow since the punctured membrane 46 of the floating barrier 23 seals itself around the outside pe-
riphery of the needle. Moreover, any pressure differential is such that the flow will be from the cylinder 22 into the chamber 62.

A second embodiment of a syringe device with an evacuation port (FIG. 7) has the location of the evacuation port 74 in collar 28 of the needle assembly 21. This evacuation port 74 has a flexible plastic peel off or otherwise removable tab 70. Preferably, an adhesive is applied to a portion of the removable tab 70 to form adhesive cover portion 71 which is large enough to cover the port 74. This tab is affixed to collar 28, over evacuation port 74, thus sealing it from premature evacuation of the first medication 54 during the injection thereof. The nonadhesive edge of the removable tab 70 forms tab grip 72. By holding tab grip 72 between index finger and thumb or by catching it with a fingernail, one can easily peel the adhesive cover 71 from collar 28. This procedure is used to release entrapped medication 54. After peeling the removable tab 70 from the collar 28, any entrapped medication 54 flows through the evacuation port 74, thus relieving back pressure.

Yet another embodiment for evacuation (FIG. 8) is a variation of the second embodiment (FIG. 7). This variation provides a means for accumulating or sponging up the first medication 54 after its release through evacuation point 74. Here the peel off tab 76 is somewhat in the nature of an adhesive bandage. A non-releasable adhesive binds the straight or vertical fastener portion 80, to the plastic collar 28. Bulge 78 holds a pad of absorbent material 82 in a position to catch the medication at port 74 when the syringe is in a generally vertical position. Therefore, when first medication 54 is released, by pushing back the tab portion 71, it is soaked up by absorbent material 82.

Still another embodiment for total evacuation (FIG. 9 and 10) is essentially the first embodiment (FIG. 6) without provision of an evacuation chamber 62. Here, weakened area 86 in the syringe ruptures when pressure builds from first medication 54 becoming entrapped under floating barrier 23. However, instead of utilizing an adjacent chamber, the entrapped medication simply flows from cylinder 22, thus enabling floating barrier 23 to settle. In FIG. 10, the location of the weakened wall structure 88 is in the collar 28 of the needle assembly. The choice of location, with comparable effectiveness, enables a manufacturer to choose the position best suited to its manufacturing techniques.

A further aspect of this invention is to provide a syringe which is not only capable of injecting, but also of extracting. Therefore, the multiple chamber inventive syringe 20 is made capable of converting itself into a single chamber syringe. This is accomplished by capturing the floating barrier 23 at the base of cylinder 22 thus enabling inventive syringe 20 to perform as if it were a single chambered device.

As shown in FIG. 12, a capture means is provided in the form of two or more bosses or knobs 92 and 94 which are molded on the inside surface walls of the cylinder 22. Their distance from the base of cylinder 22 is slightly greater than the height of floating barrier 23. These bosses or knobs 92 and 94 are small enough to enable the flexible material at piston rings 41 and 42 to slide over them during injection; yet large enough to trap floating barrier 23 at the base of cylinder 22 during extraction. The lower and upper edges of the bosses 92, 94 may be shaped to enable the barrier to be captured and yet to preclude any release thereof. The trapping of floating barrier 23 converts cylinder 22 into a single chamber and therefore enables the inventive syringe 20 to be used for extraction, after evacuation of second medicine 55.

In FIG. 11, the capture means is a cone 90 preferably made by an expansion of a hypodermic needle. It could also be a separate piece slipped on over the needle and dimpled in place. Cone 90 is positioned at the top of second part 27 at needle to trap floating barrier 23 at base of cylinder 22. The diameter of the base of cone 90 is formed relative to the diameter of the axial bore 45 for enabling it to trap floating barrier 23 after clearing the top of it. The soft rubber construction of floating barrier 23 affords little resistance as cone 90 passes through axial bore 45.

In the FIG. 13 modification, the design of the needle's second part 27 includes a barb-like capture means. Here, the tip of the second part 27 is bent back upon itself to form a hook 96. The top end of the hook may be sharpened to facilitate a penetration of the barrier. Hook 96 holds floating barrier 23 stationary after clearing the top of it. Since the materials of both the needle's second part 27 and floating barrier 23 are quite flexible, little resistance is encountered as hook 96 passes through axial bore 45.

The wall of the bent needle may be broken at the top or it may be left intact so that medication centers the needle at the barb end of the hook, which is pointing downward in FIG. 13. Due to the pressure of medication flowing around the needle, the medication may enter the barb end of this point as effectively as the end of a straight hypodermic needle. This enables manufacturers to simply use a bent section of conventional hypodermic needle stock, rather than to produce a special closed end.

It should be understood that modifications may be made without departing from the scope of the invention. Therefore, the appended claims should be construed to cover all equivalent structures.

I claim:

1. A multi-chamber syringe, comprising: a cylinder having a cavity, a plunger having one end received in the cavity, at least one floating barrier means in said cavity forming at least first and second fluid chambers first and second liquids in said first and second chambers, needle means communicating with the first chamber and projecting into said cavity a sufficient distance to puncture said barrier means and communicate with the second chamber when said barrier means nears the end of its travel as said syringe is emptied, openable port means for selectively relieving back pressure on said barrier means without mixing said liquids in said first and second chamber, whereby said barrier means may continue to settle after having relieved said pressure and means for selectively opening said port means.

2. The syringe of claim 1 wherein said floating barrier means comprises a soft plug having at least one integrally formed circumferential piston ring and an axial bore closed by a membrane.

3. The syringe of claim 1 wherein said port means comprises an evacuation port in a wall of said cylinder.

4. The syringe of claim 3 wherein said evacuation port comprises an opening having a tab associated therewith for opening said port, and absorbent means
adjacent the opening for accumulating at least some of the liquid passing through said opening.

5. The syringe of claim 3 wherein said evacuation port comprises an opening having a peel off closing tub associated therewith for opening said port.

6. The syringe of claim 3 including means associated with said port for accumulating at least some of the liquid after relief of said back pressure.

7. The syringe of claim 1 including means for capturing said barrier means after said puncture whereby the second chamber may be used for extraction.

8. The syringe of claim 7 wherein said capture means comprises means associated with the internal wall of said cylinder.

9. The syringe of claim 7 wherein said capture means comprises means associated with the end of said needle means which punctures said barrier means.

10. The syringe of claim 7 wherein said capture means comprises an enlarged portion of the needle means adjacent its puncture end.

11. A syringe comprising a cylinder having a floating barrier therein, a piston having one end received in the cylinder, a needle extending into said cylinder to pierce said barrier with an end of the needle at a predetermined point in the stroke of said piston, means for capturing said barrier when punctured, whereby said syringe may be used for injection before capture of the barrier or for extraction after capture means for relieving pressure in the syringe at least prior to complete passage of the needle through the barrier.

12. A syringe assembly, comprising:
   a cylinder having a fluid receiving cavity:
   a plunger having one end received in one end of the cavity:
   a floating barrier means received in the cavity and defining first and second chambers, said second chamber being located intermediate the barrier means and the plunger:
   needle means adjacent the other end of the cavity, said needle means projecting into and communicating with said first chamber, said needle means puncturing the barrier means and communicating with the second chamber when the barrier means is moved toward the needle means responsive to movement of the plunger into the cavity;
   means for capturing the barrier means adjacent the other end of the cavity with the needle means communicating with the second chamber, whereby the plunger may be withdrawn for subsequent use of the second chamber in pumping fluid means for relieving pressure in the first chamber at least prior to complete passage of the needle through the barrier means.

13. The syringe assembly of claim 12 wherein the capturing means comprises, an enlarged portion of the needle means for retaining the barrier means after the needle means punctures the barrier means.

14. The syringe assembly of claim 13 wherein the enlarged portion of the needle means comprises a cone adjacent the puncturing end of the needle means.

15. The syringe assembly of claim 13 wherein the enlarged portion of the needle means comprises a barb adjacent the puncturing end of the needle means.

16. The syringe assembly of claim 12 wherein the capturing means comprises, an enlarged portion on the inner surface of the cylinder and located adjacent the barrier means in the second chamber after the barrier means is punctured by the needle means.

17. The syringe assembly of claim 16 wherein the enlarged portion comprises a plurality of bosses on the inner surface of the cylinder.

* * * * *