A method of filling pharmaceutical syringes with fluid in a machine having a reservoir, vacuum source, pump an actuator that holds a vacuum adapter, sealing element and filling needle over a syringe. The method includes drawing a vacuum during a critical step while maintaining a constant fluid level in the filling needle to avoid overfilling or under filling.
VACUUM FILLING OF SYRINGE LIQUIDS WITH OUTGASSING COMPENSATION STROKE

FIELD OF THE INVENTION

This invention relates to a method of filling a syringe with a pharmaceutical product wherein the method uses a vacuum and a compensating vacuum pumping stroke to avoid undesirable explosive discharge of fluid during the subsequent stopper injection process when air rises out of the syringe injection needle. The process also provides a more accurate syringe needle fill volume.

BACKGROUND OF THE INVENTION

Machinery for filling and closing pharmaceutical syringes must comply with the FDA cleanliness and volume accuracy guidelines. In addition they need to be fast to provide a product that is competitive in the marketplace. To meet these requirements the industry has developed machines that can fill and close syringes at a rate of 50 syringes per minute or more and other machines that can fill volumes with an accuracy of 0.05%. The filling ranges possible are between 0.15 and 100 milliliters. To fill the small volumes it therefore becomes important to be extremely accurate for the fill volume due the high price of the filling fluid which can approach $1200 or more for each syringe fill. One syringe tray would be worth $1800000 alone. A preferred method is one that minimizes volumetric error by avoiding splashing and wetting of a filling needle which is injecting the fluid. It is the purpose of this invention to disclose the apparatus and method of filling syringes that provides this careful and precise method. This method also provides a procedure that insures filling of the syringe injection needle that has a very narrow cross section that can entrap air.

SUMMARY OF THE INVENTION

The machine to perform this method consists typically of a filling apparatus and a closing (stoppering) apparatus. The invention consists of the filling apparatus method. This apparatus comprises an actuator arm that supports a vacuum adapter, filling needle and a sealing element above the syringe. Connecting by flexible hose to the vacuum adapter is a rotatable piston pump and a reservoir that connects to the pump suction. The rotatable piston in the pump, in one position opens a port to the reservoir to draw in fluid while the piston raises. In a second rotated position the pump piston uncovers a port to the vacuum adapter to allow the lowering piston to inject fluid into the syringe when the adapter is lowered to engage the sealing element with the top of the syringe. The careful sequencing of critical steps using this pump and the use of a vacuum source create a method that provides a closely controlled volume of fluid in a syringe. The method can be used in a machine that fills multiple syringes simultaneously or one or two syringes simultaneously. The method will be described for a single syringe filling apparatus.

The apparatus to perform this method consists of a reservoir of fluid, a vacuum source, a rotatable piston pump, and a movable actuator arm that supports a vacuum adapter, syringe sealing element and fluid filling needle over a syringe. The method comprises:

a) filling the pump with fluid by raising the pump piston;

b) rotating the piston to open a flow path from pump to fill needle;

c) drawing a vacuum on the vacuum adapter and syringe from the vacuum source and simultaneously raising the piston thereby maintaining a constant fluid level in the filling needle and removing air from the syringe injection needle;

d) lowering the piston and discharging fluid into the syringe and syringe needle;

e) releasing the vacuum and continuing the discharge of fluid into the syringe; and

f) raising the actuator arm and vacuum adapter as the liquid level rises in the syringe until the proper volume has been filled in the syringe and the cycle is completed. This method eliminates air from the syringe injection needle and avoids fill needle undesirable drips into the syringe upsetting control of the fill volume.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side view showing the volume of the apparatus used to fill a syringe showing the rotatable piston pump, vacuum adapter and syringe of the present invention. FIG. 2 is a view of the apparatus at the start of a fill cycle. FIG. 3 is a view showing the apparatus at the start of a fill cycle. FIG. 4 is a view showing the pump piston rotation. FIG. 5 is a view showing the pump compensation stroke. FIG. 6 is a view showing the fluid injection stroke. FIG. 7 is a view showing the continued injection and release of vacuum.

DETAILED DESCRIPTION OF THE INVENTION

The invention will be first described by referring to the apparatus illustrated in FIG. 1. The syringe 10 shown as partially filled with fluid 12 is held in position below the vacuum adapter 14 which holds the filling needle 16 and the sealing element 18. Injection needle 19 is attached at the bottom of syringe 10. The vacuum adapter 14 is raised and lowered by actuator arm 20. A vacuum port 22 is connected to a sequentially controlled vacuum source (not shown). The flexible filling tube 24 connects to the discharge of pump 26 which has both vertical motion as shown at arrow 28 and rotary motion as shown at arrow 30 depending on the programmed action of pumping, changing ports or drawing a vacuum. Connecting to the inlet side of the pump is a reservoir 32 containing the pharmaceutical fluid 12. In a typical machine for filling syringes there can be multiple apparatus like FIG. 1 that operate in unison to fill multiple syringes simultaneously. The following operation will be described for only one device by referring to FIGS. 2-7. The cycle starts at FIG. 2. The pump piston 34 is rising to draw by vacuum, fluid 12 from reservoir 32. At this point the piston 34 has sealed the opening at the filling tube 24 at pump discharge 36. The air surrounding the device at P1 and within the syringe 10 at P2 is at normal atmospheric pressure and the actuating arm 20 has lowered the vacuum adapter 14 so the sealing element 18 seals against the top of the syringe 10.

In FIG. 3 the pump piston 34 has reached an upper position and the pump is filled with fluid 12. At this point the
piston 34 rotates 180 degrees closing the suction 38 and opening the pump discharge 36. The filling needle 16 has remained in the same position as in FIG. 2 and the pressures remain the same.

[0020] FIG. 4 illustrates the important step incorporating the “outgassing compensation stroke”. A vacuum source connected at vacuum port 22 creates a vacuum P2 within the syringe 10 thereby causing air in injection needle 19 to expand and be discharged from the top of needle 19. At the same time the pump piston 34 rises creating a vacuum in the pump discharge 36 so as to maintain a constant fluid level 40 within the filling needle 16 while air is evacuated at vacuum port 22. It is this air evacuation step with the outgassing compensation stroke that eliminates a loss of fluid from the fill needle 16 that would otherwise upset the control of volume in the syringe 10, i.e. too much fluid.

[0021] In FIG. 5 once the proper vacuum is obtained in the syringe at P2 and air is removed from the injection needle 19, the piston 34 starts down discharging the fluid 12 into the syringe 10 which is still maintained at a vacuum compared to atmospheric pressure P1. This step fills the injection needle 19 as shown by fluid 12 since the vacuum has been maintained.

[0022] In FIG. 6 the piston 34 continues down discharging fluid 12 and the vacuum is released at port 22 and the pressure at P2 is equal to atmospheric pressure P1 so that the fluid 12 does not start to boil.

[0023] Once equal pressures are reached when P1 equals P2 in FIG. 7 the filling needle 16 moves continuously up as the fluid level in the syringe 10 rises due to the downward motion of piston 34. The piston 34 is now at it’s lowest position and the filling cycle is complete. The fill needle 16 and vacuum adapter 14 are now raised so that the syringe can pass on to the next station for stopper insertion. The fill cycle is completed.

[0024] The critical evacuation step as shown in FIG. 4 has eliminated a possible air bubble from remaining in the injection needle 19 and it’s subsequent discharge during a later stopper injection step. Additionally, this step includes the upward compensation stroke that maintains a constant level in fill needle 16 thereby preventing loss of fluid from that needle and consequent incorrect measure of fluid volume on completion of the filling process.

We claim:
1. A method of filling syringes with fluid in a machine having a reservoir, vacuum source, rotatable piston pump, and actuator arm that holds a vacuum adapter, sealing element and filling needle, the method comprising:
   A) filling the pump with fluid by raising the pump piston;
   B) rotating the piston thereby opening a flow path from pump to fill needle;
   C) drawing a vacuum on the vacuum adapter and syringe from the vacuum source and simultaneously raising the piston thereby maintaining a constant fluid level in the filling needle and removing air from the syringe needle;
   D) lowering the piston thereby discharging fluid into syringe and syringe needle;
   E) releasing the vacuum and continuing the discharge of fluid into the syringe; and
   F) raising the actuator arm and vacuum adapter as the liquid level rises in the syringe until the proper volume has been filled in the syringe, thereby completing the cycle.
2. The method of claim 1 wherein there are multiple actuator arms, vacuum adapters, sealing elements and filling needles that fill multiple syringes simultaneously.
3. The method of claim 2 wherein the method can be used in a machine having between 1 and 10 fill needles.

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