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(54) VACUUM FILLING OF SYRINGE LIQUIDS WITH OUTGASSING COMPENSATION STROKE

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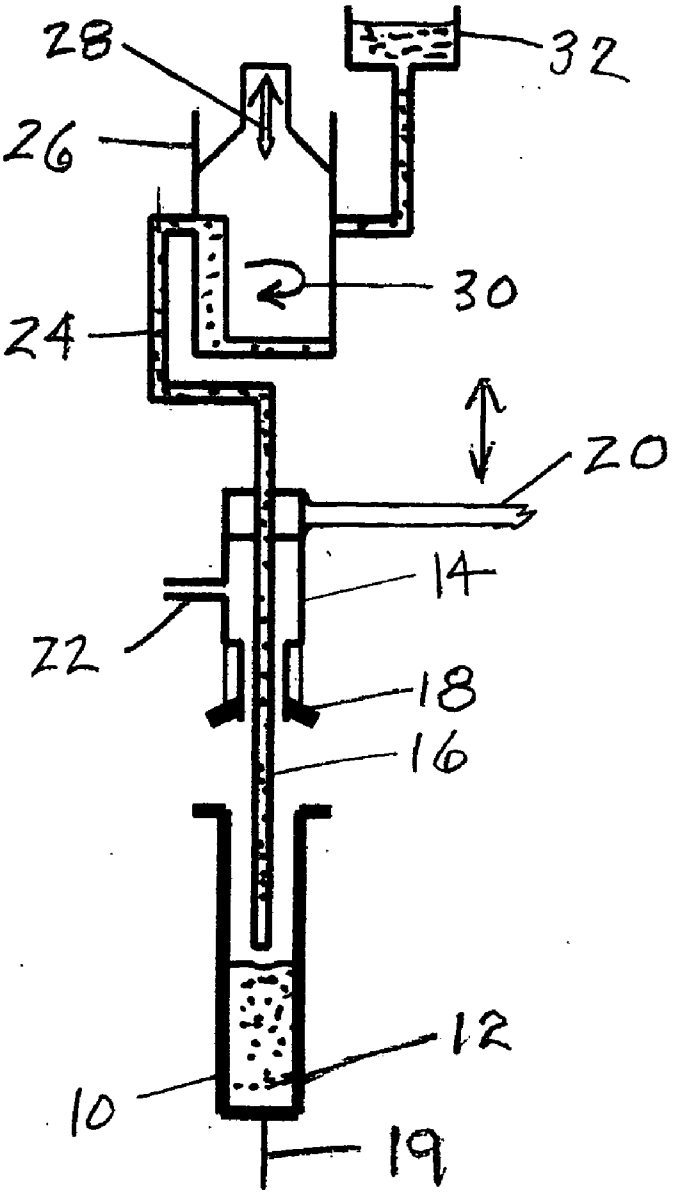
(57) **ABSTRACT**

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.



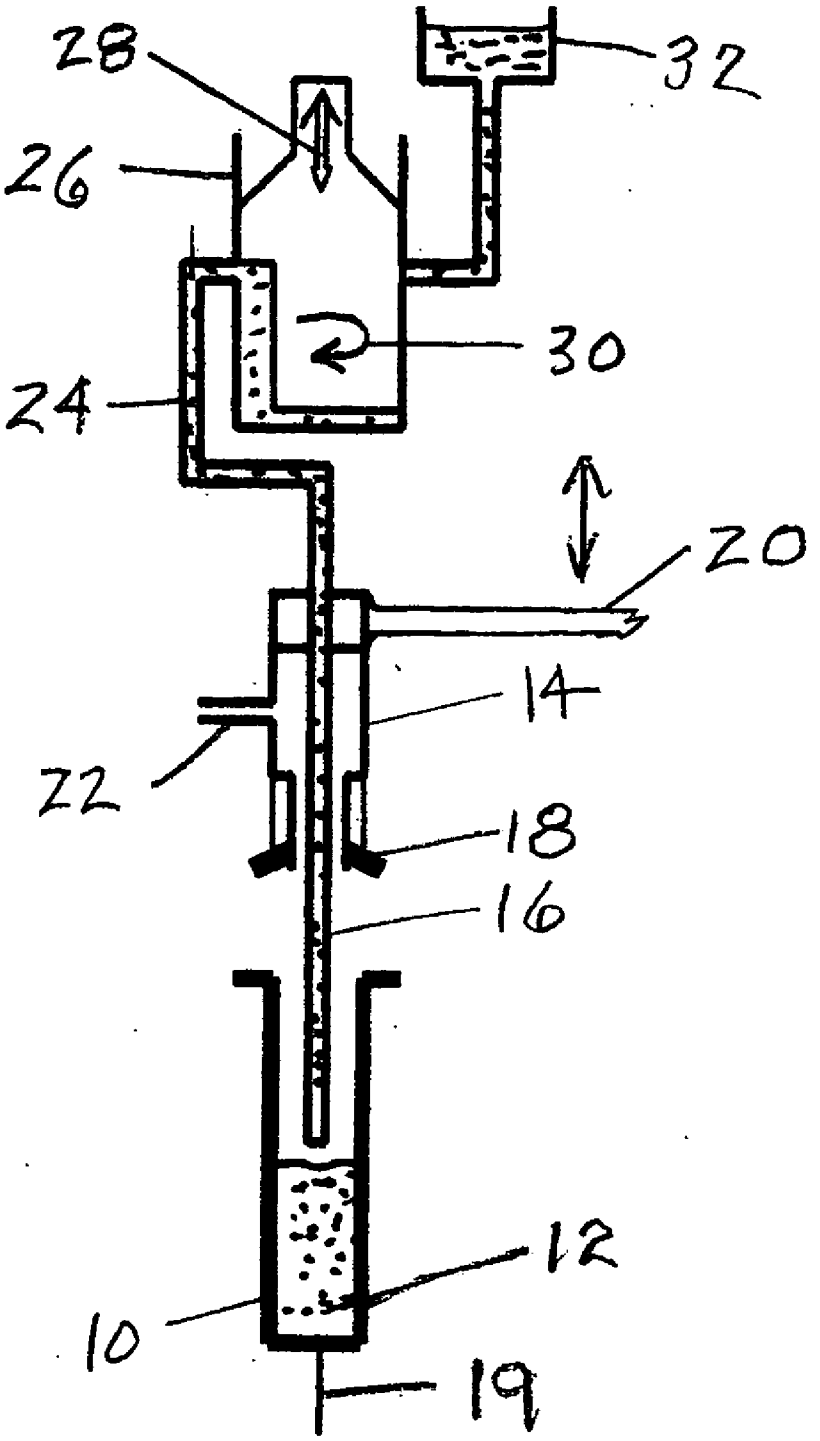


FIG 1

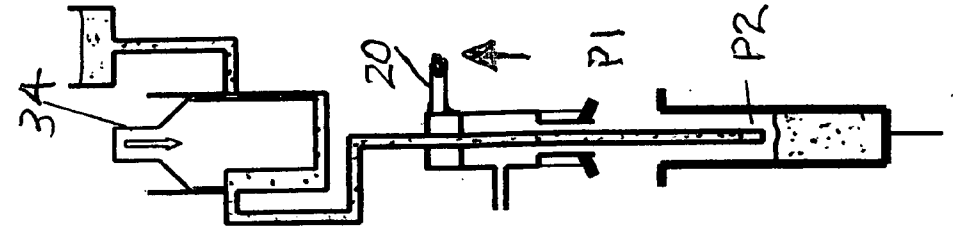


FIG 7

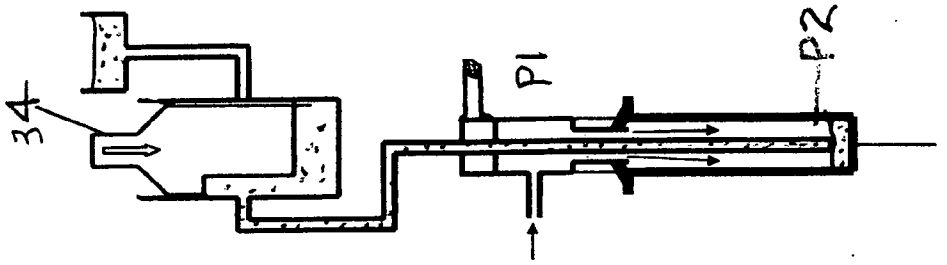


FIG 6

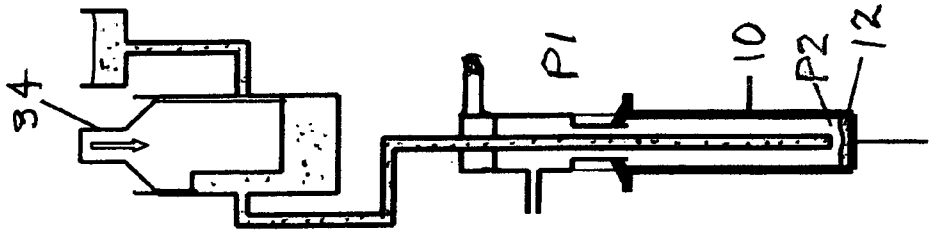


FIG 5

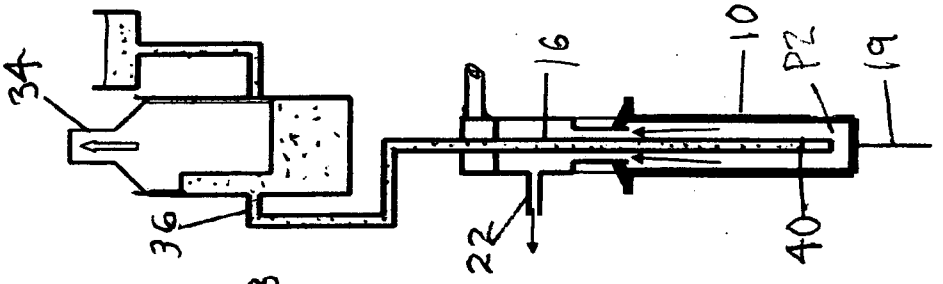


FIG 4

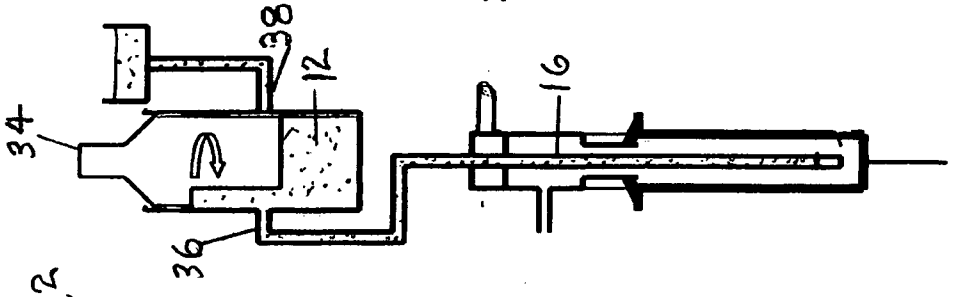


FIG 3

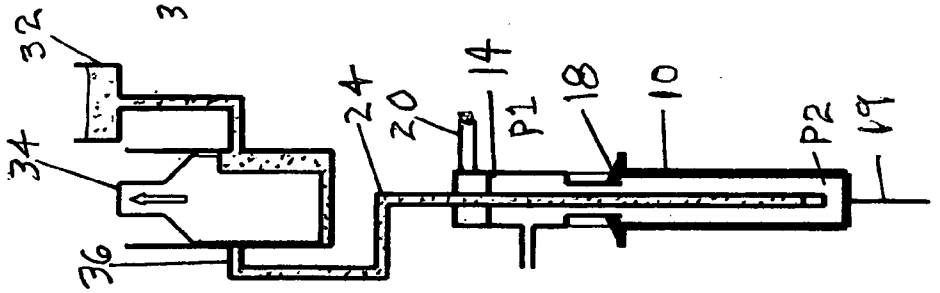


FIG 2

VACUUM FILLING OF SYRINGE LIQUIDS WITH OUTGASSING COMPENSATION STROKE

FIELD OF THE INVENTION

[0001] 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

[0002] 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 $180000 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

[0003] 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.

[0004] 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:

[0005] a) filling the pump with fluid by raising the pump piston;

[0006] b) rotating the piston to open a flow path from pump to fill needle;

[0007] 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;

[0008] d) lowering the piston and discharging fluid into the syringe and syringe needle;

[0009] e) releasing the vacuum and continuing the discharge of fluid into the syringe; and

[0010] 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

[0011] FIG. **1** is a side section schematic view of the apparatus used to fill a syringe showing the rotatable piston pump, vacuum adapter and syringe of the present invention.

[0012] FIG. **2** is a section view of the apparatus at the start of a fill cycle.

[0013] FIG. **3** is a section view showing the pump piston rotation.

[0014] FIG. **4** is a section view showing the pump compensation stroke.

[0015] FIG. **5** is a section view showing the fluid injection stroke.

[0016] FIG. **6** is a section view showing the continued injection and release of vacuum.

[0017] FIG. **7** is a section view showing the end of the filling stroke

DETAILED DESCRIPTION OF THE INVENTION

[0018] 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 P**1** and within the syringe **10** at P**2** 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**.

[0019] 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 P**2** 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 P**2** 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 P**1**. 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 P**2** is equal to atmospheric pressure P**1** so that the fluid **12** does not start to boil.

[0023] Once equal pressures are reached when P**1** equals P**2** 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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