Design and Development of Prefilled Syringe Filling & Stopping Machine

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Abstract— The current practices in the industry of Prefilled syringes employs a manual transfer of filled Syringes from filling unit to syringe and therefore is a cumbersome practice, time consuming, and due to the involvement of the human element is a unhygienic practice. These limitations have serious repercussions on the use of the medicine and in delivering the right amount of dosage of medicine to the patient. It is to be noted that right amount of the medicine to the patient is a very important aspect as it effects the patient's life. Therefore there is an important need to automate the process of the syringe filling and sealing as well transfer from filling unit to the syringe unit wherein multiple syringe can be simultaneously be filled and packaged into a clean and hygienic medical device. This Dissertation brings about the details of the Design and development of prefilled syringe filling and stoppering Machine then automate the process of filling by using a programmable logic controlled. This works also highlight the development of 3D Computer Aided Model and stress analysis of few components included in the PFS system.

Key words: Prefilled syringes, 3D Computer Aided Model, PFS system, Prefilled Syringe Filling & Stopping Machine

I. INTRODUCTION

Prefilled syringes are now used across a wide array of therapeutics sectors outside of the traditional domains of anticoagulants and vaccines. The use of prefilled syringes is expected to accelerate over the coming decades.

For the pharmaceutical company, the advantages of prefilled syringes are minimizing drug waste; increasing product life span and enhancing level of market share are some of driving market demand. For healthcare workers, prefilled syringes are recognized as an efficient, reliable and convenient method for drug administration. Furthermore, the ease at which patient can self-administer many types of injectables drugs make prefilled syringes of healthcare treatment out of hospital and into home. So, in future emerging challenge in the pharmaceutical market for prefilled syringes will be there.

This broad acceptance of prefilled syringes is not surprising because of the range of compelling benefits including simplicity, suitability for home use, reduction in wasted products, and greater dose precision. Prefilled are convenient and help ease the administration process [10].

Patient does not have to worry about the transfer of a drug from a vial to a syringe and therefore do not have to worry about leaving a small percentage of dose behind.

Prefilled provide greater patient safety by reducing the potential for inadvertent needle sticks and exposure to toxic products that can occur while drawing medication from vials Prefilled syringes, with their pre measures dosage, can reduce dosing errors and increase patient compliance.[10]

Prefilled syringes can virtually reduce the manufactures need to overfill unlike vials those are overfill by as much 20-30% to account for potential waste. This is particularly important where manufacturing and product costs are high and bulk manufacturing capacity is low.

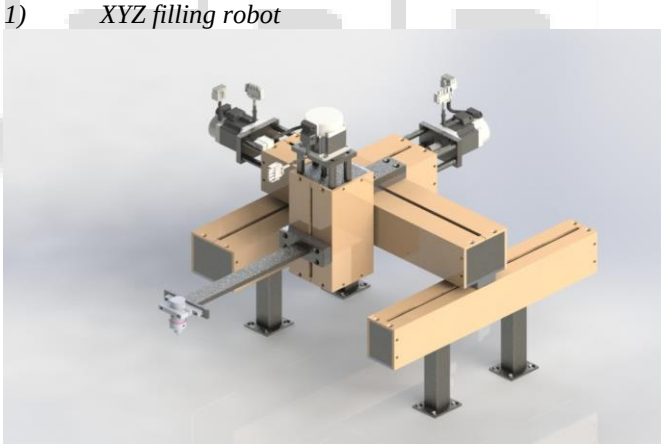
II. OBJECTIVES OF RESEARCH

(1) To design and develop a PFS having an ability to handle various filling capacity with Different Syringe Capacity like 0.2ml,05mletcon single machine
(2) Need fully automated plan
(3) Develop 5-head Automatic Machine where there is no any human Interferences to transfer filled Syringe tub from Filling Unit to Sealing Unit.
(4) Need no human interference in entire filling and sealing system
(5) Develop a machine which provide right amount of dosage.
(6) Maintain accuracy beyond 0.5%.

III. PARTS OF PFS

(1) XYZ filling robot
(2) Filling unit and vacuum chamber assembly
(3) Load out conveyor assembly
(4) Structure assembly

1) XYZ filling robot



This robot made of following key components:

A. 3 servo motor – each servo motor for each axis (motion controller & coordinated axis application) -

B. Motor Capacity – 400 Watts , 1.3 Nm output Torque ,3000 rpm

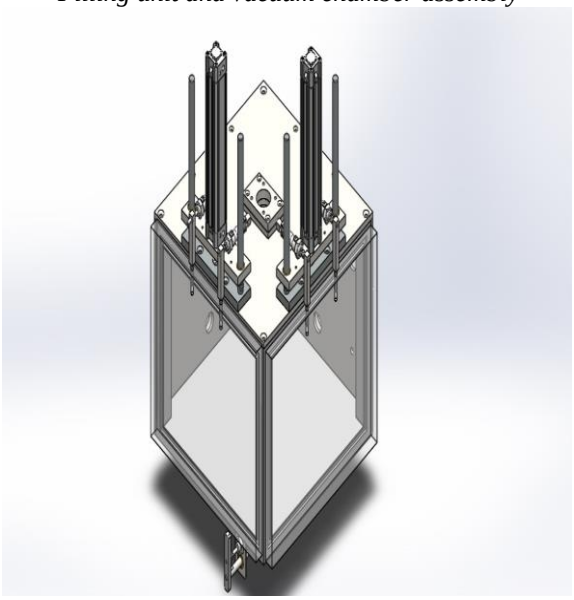
- Make - Omron

C. Lead screw mechanism

- Aseptic Dispense Valve Filler 400watt
- Aseptic dispense valve filler is a new addition in the automatic machine rather than typical nozzle for filling syringe.
- Aseptic dispense valve is readily available in the market which automatically controls the volume of liquid needs to be fill into the syringe. ADV is directly connected with the medicine hopper with

the flexible pipe and filling volume is control by the drive controller attached to the ADV.

2) Filling unit and vacuum chamber assembly



Following are the new development done in the filling unit & vacuum chamber assembly: -

- Filled syringed tub stop on the load out conveyor with the help of sensors
- At the time of operation of sensor the acrylic door will open with the help of two hydraulic piston cylinder mechanism.
- Then vacuum mechanism pulled the filled tub in the filling chamber with the help of PLC automation
- Then the sealing process will done as per the old machine mechanism and at the same time acrylic door will be close.
- Then the sealing will done, one hydraulic piston cylinder mechanism push the filled syringe tub towards the automatic load out conveyor and at the same time exit door of filling chamber will be open through the piston cylinder mechanism.

3) Load out conveyor assembly

In the load out conveyor assembly following are the key component

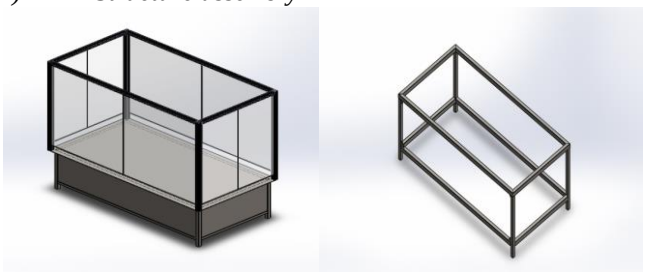
- Electrical motor (0.5 Hp)
- Chain and sprocket mechanism
- Stopper
- Material of the chain: - Delrin, Make: - Tetra plast

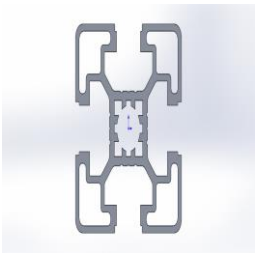
Electric motor drive the shaft of sprocket and sprocket convert the rotary motion into the linear motion of chain and provides continuous movement of syringe tub on the chain sprocket mechanism.

One stopper used to stop the empty syringe tub at a particular location to fill the medicine in the syringe. At the time of filling, stopper lift the empty syringe tub at a height from load out conveyor. It means the motion of load out conveyor is continuous and will not affect the filling process. Once the tub will filled with syringe stopper keep the tub down on the load out conveyor and tub moves towards the filling unit. Second stopper works with the sensor.

Once the filled tub reach at a particular distance of sensor which converts automatic opening of acrylic door and vacuum mechanism will pull the tub inside the filling chamber at the same time another syringe tub will proceed for filling on the load out conveyor.

4) Structure assembly



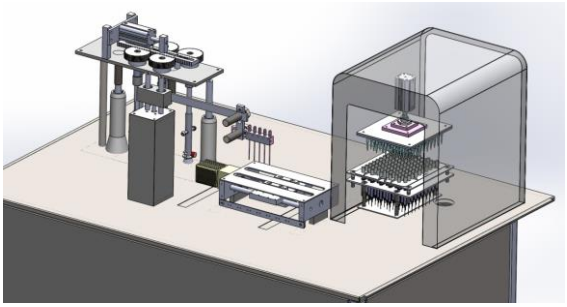


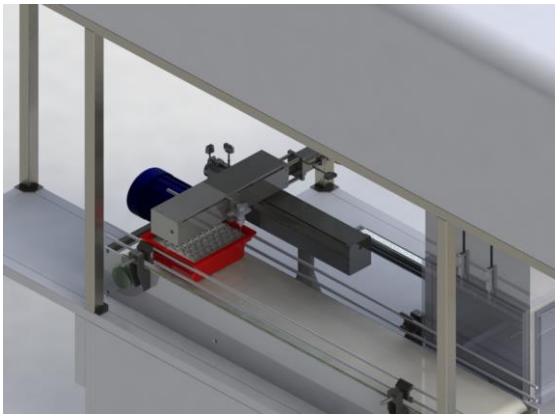
The structure assembly contains the guard plate which is made up of AISI 1035 structural steel. The thickness of the plate is 1.2mm and bend radius is 0.7366 mm and the size of the plate is 919mm x 469 mm. The no of quantity are four.

This is used to support the main base of the PFS machine and it is made out of AISI 4340 industrial grade steel with a cross section of 40 x 40 x 2. The 12 tubes are welded together with a gusset to form the frame structure.

This aluminium profile of 45 x 45 mm cross section is used to support the machine working area and seal it with an acrylic glass frame to protect is from contamination and dust.

IV. COMPARISON





Sr.	Description	Existing PFS	Proposed PFS
1	Size of the machine (mm)	1560×800×1800	2100×1100×2100
2	Mass (Kg)	650	750
3	Power Consumption (Kw)	4.5	5
4	Filling Technology	XYZ Table	XYZ Robot
5	Filling Equipment	Nozzle	Ascetic valve
6	Filling capacity (units/min)	35-45	25-35
7	No of filling heads	5 heads	1 heads
8	Filling Accuracy	≤ 0.3%	≤ 0.03%
9	Automation	Manual	PLC, Sensor based
10	Servo motors	9 Nos	3 Nos
11	Servo Capacity (Kw)	0.25 each	0.4 Each
12	Conveyor	Absent	Present
13	Hygiene	Absent	Present
14	Automatic Door	Absent	Present
15	Cost	11, 00, 000	18, 00, 000

V. CONCLUSION

A novel automated PFS machine is proposed. The design and development aspects are covered. The proposed machine has benefits over the present configuration in terms of filling accuracy and hygiene maintenance while filling the medicine. Filling capacity is nearly equal to the existing machine. the cost of the proposed machine is higher and compare to the existing machine due to the addition of automation and improvement in hygiene. However the cost can be compensated with the addition of more number of filling heads so that the filling capacity can overrule the cost of the machine.

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