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AN OUTLOOK TO FORM FILL SEAL TECHNOLOGY

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ABSTRACT

Form fill seal (FFS) technology is an automated computer operated technology, to prepare sterile products. Form-fill-seal technology is subject to constant development, a manufacturer requires modern and reliable packaging machinery in order to produce better packages more quickly and more profitably. The reason behind FFS technology is to reduce the contamination during production in a closed sterile chamber of a machine. Thus there should be no personnel intervention to reduce the chances of contamination during the manufacturing of sterile products. Mostly in pharmaceutical industry it is applicable for I.V. infusion bottles. In this process all steps such as formation of container, filling of container with content and sealing of container are performed sequentially, consistently and automatically in a closed sterile chamber of machine. This technology reduces the rate of contamination to the final product. It increases the production rate in very low operational cost with high assurance of sterility.

KEYWORDS: FFS, Sterile products, I.V infusion, Low operational costs.

INTRODUCTION

Form Fill Seal (FFS) machines are packaging machines that in a sequence it forms fills and seals a package on the same machine. Today many FFS systems are highly sophisticated featuring computer interfaces and control networks. Greater speed and versatility are the major benefits of FFS systems for user companies. The main types are vertical form fill seal (VFFS) and horizontal forms fill seal (HFFS) machines.

A vertical form fill sealing machine is a type of automated assembly-line product packaging system, commonly used in the packaging industry for food, and a wide variety of other products. Walter Zwoyer, the inventor of the technology, patented his idea for the VFFS machine in 1936 while working with the Henry Heide Candy Company.[1] The machine constructs plastic bags out of a flat roll of film, while simultaneously filling the bags with product and sealing the filled bags. Both solids and liquids can be bagged using this packaging system.[2]

The Horizontal Form Fill Seal Machine comprises of a Product Filler & the HFFS Bagging Unit. The Product Filler (Liquid / Paste – Piston, Peristaltic Filler etc, Solids - Fillers - Multihead or Linear Weighers, etc., Powders & Granules - Auger Fillers, Cup Fillers, etc.) controls the amount of product to be dispensed. In the bagging unit the heat sealable film flowing horizontally folds around a forming plough, then THREE vertical seals are imparted by vertical sealing units to form the pouch side seals and horizontal seal is imparted at the bottom of the pouch to form the bottom seal and at next station the filler dispenses the product and then the top seal is imparted to form a Standard HFFS 4 side sealed Flat Pouch or Stand-up Pouches. The HFFS packaging machine is generally used when the product is fragile and cant withstand a high drop. It is also considered where the customer requires a stand up pouch or a pouch with a zipper and or with a spout that facilitates ease of opening and comfortable consumption of products. HFFS machines can deliver shaped pouches, which result in better product aesthetics and shelf presence.[3]

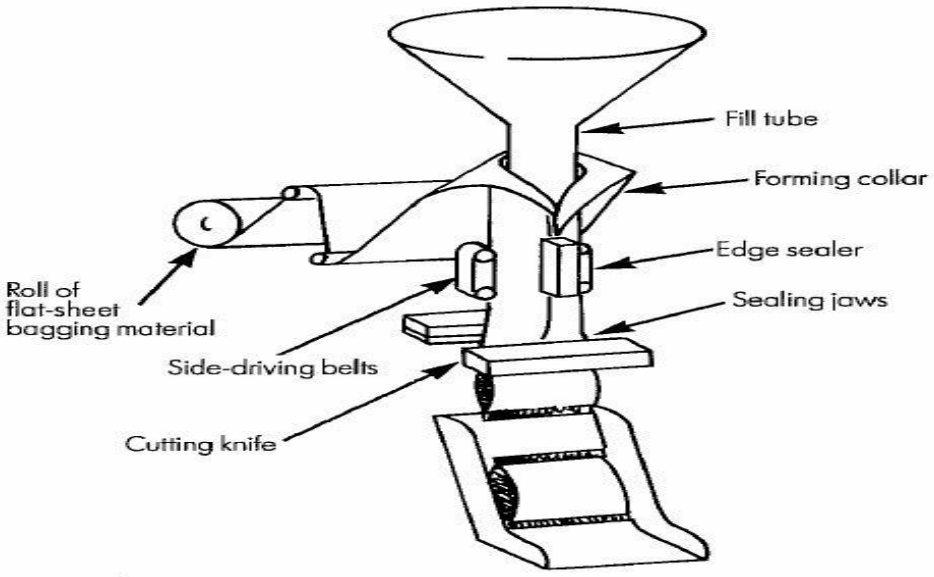

Fig: Vertical FFS.

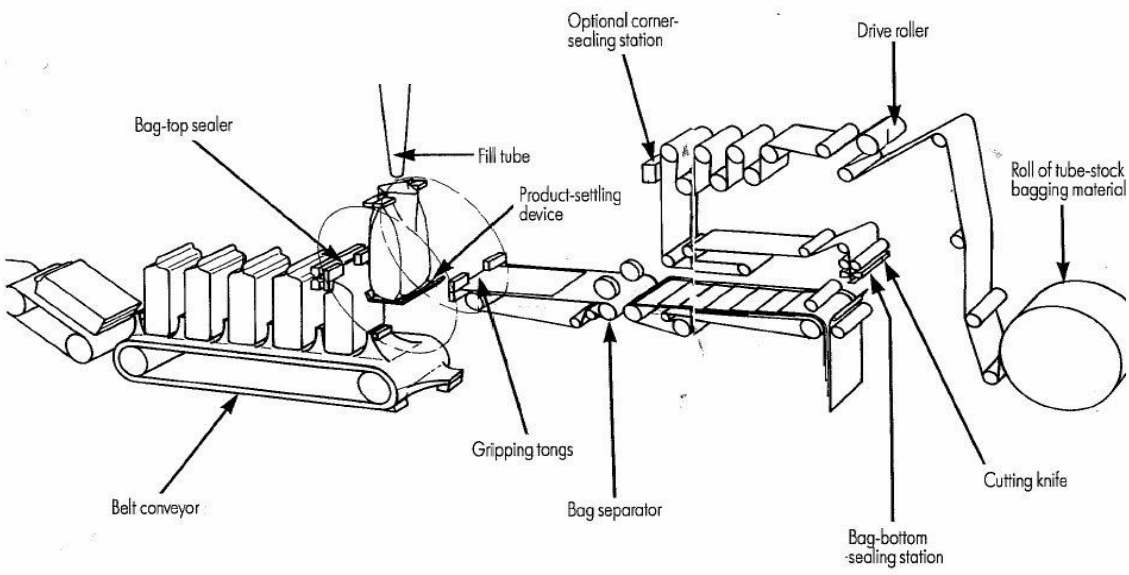

Fig: Horizontal FFS.

Advantages of FFS Technology[4]

- Bags made on FFS are less expensive than pre-made bags = "pay back"
- Lower capital cost than fully auto machine when packing rate above 500 bags/h
- Total automation - usually unattended, labour saving provides = "pay-back"
- Consistent packing rate
- Compact (especially the Vertical FFS)
- Fast - increased production rate, reduced no. of shifts = "pay back"
- Easy and quick to clean-out between production batches
- Fewer moving parts - especially Vertical FFS
- 'Online' film printing provides readable bar code and product info

Disadvantages of FFS Technology[4]

- Not economical for short production runs of one bag size - below 1000 x 25 Kg bags = 25 tons
- Cannot handle paper.
- Cannot handle multi-ply packing materials.
- Not economical for packing low density, aerated powders such as wheat flour, talcum powder, skimmed and whey powder at medium speeds.
- Cannot remove 'trapped air' very quickly or easily.
- Shape of package made by Vertical FFS or 'C' type FFS not as good as valve sack.

- Cannot self adjust for different widths of bag (but changing length is very easy on Horizontal and Vertical FFS machines).

Processing of FFS

It involves 3 actions

1. Pre-sterilization of machine[5]

Pre-sterilization of machine is carried out in 2 different phases:

Programmed in sequence

The first is steam sterilization phase consisting of a water steam sterilization cycle at a minimum temperature of 121°C, which will take less than 60 minutes for product tank, filling unit, product pipelines and filling nozzles.

H_2O_2 sterilization cycle

It takes approximately one hour and 40 minutes and it consists in spraying machine tunnel, forming plugs, bell and counter mould, sterilization baths and sterile air pipelines (blowers and diffusers) with hydrogen peroxide fog followed by a drying phase obtained through mechanical dryers and sterile hot air.

2. Production in aseptic chamber[6]

This is the heart of FFS technology, which involves 3 working steps

Formation of container

In this process polypropylene granules are heated at 200 ± 30ºC to form parison (a tube like structure). The parison reaches the mould forming the container by the pressure 350 Bar of a sterile compressed air and temperature 170 - 230ºC. Here two halves of the mould closed around the parison to seal the base. Simultaneously the top of the parison is cut free by hot knife edges.

Filling of container with content

Bulk solution prepared under aseptic condition is delivered to the machine through a bacteria retaining filter, before entering in container. Fill nozzle (mandrel) fills the liquid in to container with a metered volume of solution, displacing the sterile air. The pipe, filter housing and machine parts that are coming in contact with the product are steam sterilized.

Again system uses nylon filter media to remove colloidal silica, pyrogens, mycoplasma, viruses and other contaminants.

Sealing of container

After filling the container the filling unit is raised above and the containers are sealed automatically. Then the mould is opened. It takes 10-15 seconds to produce one container.

Post-production cleaning[7]

After completion of the process the machine is cleaned at the place, means the concept of Clean In Place (CIP). In this step machine is cleaned at the place where it is installed and should not be transferred to clean room or anywhere else. Again it includes once circulation system and recirculation system. In once circulation system the washed liquid is directly withdrawn from the machine and thrown off. While in case of recirculation system the washed liquid is again re-used to clean the machine and gets recirculateds. The machine may be steam sterilized finally.

FFS machine should be surrounded by class 1,00,000 area. Container formation, filling and sealing process is done in class 100 area within the machine. System should be validated by media fill runs before starting the commercial production.

This is a fully automated computer controlled technology which allows filling and packing of up to 40,000 I.V. bottles per day. N_2 purging is available to machine. Sterilization is achieved through an automatic microprocessor controlled circulating water shower. The pressure and temperature link controls the whole process.

Form Fill Seal Machine Based On Packaging

Bags and Pillow Packs

Flow-Wrapper; Lower Reel Flow-Wrapper; Vertical Form Fill And Seal; Mandrel Form Fill Seal.

Bottles/Vials

Blow Fill Seal.

Cartons

Vertical Carton Board Form Fill Seal.

Pots Trays and Blisters

Cold Form Fill Seal; Thermoform Fill Seal; Blister Form Fill Seal.

Sachets and Envelopes

Edge Seal Machine; Horizontal Form Fill Seal; Vertical Sachet Form Fill Seal.

Sacks and Bags

Tubular Sack Form Fill Seal And Vertical Form Fill Seal.

CONCLUSION

The present review elaborates the entire operation of form fill seal technology. It is an automated computer operated technology, to prepare sterile products. In this process all steps such as formation of container, filling of container with content and sealing of container are performed sequentially, consistently and automatically in a closed sterile chamber of machine. It increases the production rate in very low operational cost with high assurance of sterility.

CONFLICT OF INTEREST

Declared none

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