Ampoule Filling Machine
Using Allen-Bradley CompactLogix Programmable Automation Controllers and Kinetix 350 Servo Drives

This paper provides an overview of an ampoule filling machine using Rockwell Automation technology to improve machine productivity, reduce machine delivery time to market, and reduce raw and packaging material waste.
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Executive Summary

Machine builders need tools and technologies that lower their Total Cost to Design, Develop and Deliver® machines. End-users need innovative solutions that help ease integration, increase business agility, optimize productivity and achieve sustainability objectives while lowering their total cost of ownership.

Ampoule (bottle) filling in aseptic pharmaceutical applications may be the most demanding in the pharmaceutical manufacturing process. The filling application must adhere to stringent requirements such as a critical static clean room and environmental factors like temperature, humidity, output, accuracy and quality. These machines face high regulatory scrutiny and must meet the standards of good manufacturing practices (GMP).

In addition, the machines must be flexible enough to adapt to different products, bottles and production speeds, as well as quick changeovers.
Today we have entered a **new era of dynamic action with smart machines**. The next generation of ampoule filling machines demonstrates an unsurpassed level of intelligence; with automation that provides pharmaceutical companies the ability to automatically consume and generate information, adapt to new situations, and provide remote access and insight. The machines also enable manufacturers to achieve their productivity optimization and sustainable goals through real-time decision making.

At the heart of the smart ampoule filling machine is a single, convergence-ready control platform with a common control engine, networking technology, configuration environment, and communication services.

The data from the ampoule filling machine can be gathered and transferred more easily and analyzed by leveraging a single control and information platform. By replacing the multi-tier control and networking strategy with a standard architecture, machine builders can reduce their engineering time, integration risks and Total Cost to Design, Develop and Deliver machines. These give end users an edge in addressing production issues with real-time, plant wide intelligence, helping them respond quickly and cost-effectively to market demands.

Whether measured from a business, commercial or technical perspective, Rockwell Automation can help improve your ampoule filling machine’s performance, and simplify the whole system with Ethernet architecture, reduced system integration, and safer remote diagnosis to reduce your mean time between failure (MTBF) and mean time to repair (MTTR).
Introduction

An ampoule filling machine is most commonly used in the filling and sealing section of the aqueous injection wash-dry-fill line for pharmaceutical applications that require filling and sealing of unit dose ampoules under stringent sterile or aseptic conditions.

The standard ampoule filling machine consists of 5 basic functions: bottle in-feed, product filling, bottle heating, drawing and out-feed. The machine may contain subsidiary functions such as pre-nitrogen and post-nitrogen filling to protect product against product oxidizing, auto-sample and weighing for on-line filling accuracy check, and automatic filling volume adjustment.

Various speeds of this machine are available depending on the different sizes of bottles, including (8, 12, 14, 16 and 20) nozzle variants with various filling volume: 1-2 ml, 5-10 ml and 20 ml. These three configurations are designed and manufactured to cater to different sizes of ampoule bottles. While their structures are almost identical, the different sizes are not interchangeable.

Ampoule in-feed

In aseptic processes, ampoules must be delivered smoothly and consistently from the infeed screw and screw conveyor to the filling section to prevent glass breakage and the contamination that could result. Real-time synchronization ensures accurate delivery of empty bottles into the walking beam.

During the filling process, the filling switch value first changes to a suction position, then the pump servo drive changes the piston back to a pre-set position to intake the solution. Then, the filling switch value changes to a discharge position and the pump servo moves to a zero position to discharge all of the solution and reverses to prevent solution in the nozzles from dropping into the bottle.
Servo motors are equipped for driving the pump piston for filling. The positioning accuracy is critical and should not be affected even if any medical solution should spill or splash. During the filling process, the filling switch value first changes to a suction position, then the pump servo drive changes the piston back to a pre-set position to intake the solution. Then, the filling switch value changes to a discharge position and the pump servo moves to a zero position to discharge all of the solution and reverses to prevent solution in the nozzles from dropping into the bottle. Any mistake in this sequence will damage the mechanical parts.

If no bottle or ampoule is present (due to a misfeed or breakage), the filling station must detect there is no bottle. Otherwise the machine will dispense product and risk contaminating the clean room environment.

**No bottle No fill Function**
For startup of the filling section, one filling cycle is completed when the main axis reaches a certain position. When the bottle in-feed motor is transferring bottles, the situation might arise of "no bottle to fill" under a certain needle. This can occur because the mesh bag uses pressure to feed bottles by pressurizing, and the bottle in-feed has an independent start / stop function. To avoid medical solution spillage and environmental pollution, the machine must have the No Bottle No filling function.

**Implementation of No bottle no fill function**

A filling movement is completed whenever the main axis rotates by 360 degrees and a sensor is used to detect a bottle when the main axis achieves a full rotation of 360 degrees. Hypothetically speaking, a bottle is in the correct position when the sensor detects a 30 degrees rotation of the main axis. The array shift method is used as a guide to indicate which needles in a filling station have no bottles under them.
Note that the detected position is not always at expected 0 degree, (although it is randomly located between 0-30 degrees); the thickness and gap between each other also vary. As a result, it is necessary to adjust manually for the sensor on-off position.

Nozzle Control

The nozzle includes the reversal valve and piston pump. As it only offers simple positioning control without requiring any electronic cam, the Kinetix® 3 servo drive can be used to help reduce costs. The index functions of the Kinetix® 3 servo drive with DI/DO triggering the nozzle movement and the Modbus modify control position, speed and acceleration. Other nozzle control benefits include:

- Filling / valve reversal.
- Index function triggered by DO offers accurate positioning without any influence by noise.
- I/O control for index trigger that offers fast response.
- Modbus communication with easy programming and flexible parameter modification, provide the possibility for on-line filling volume changing.
- An absolute encoder offers power-loss recovery without homing.

Drawing and Sealing

When the ampoule reaches the sealing station, it must be held with zero movement by the bottle-pressing roller, followed by a rotation. A high-temperature flame melts the neck while the pneumatic drawing clamp moves along the guide rail to clamp the head. When the drawing clamp rises to the specified position, it will open and close twice again to cut off the tail end.

Bottle out-feed

The out-feed screw synchronizes with the main axis to ensure no bottle breakage.
Challenges for machine builders and end users

Globalization, pricing pressures and increasingly stringent environmental regulations are constant challenges to pharmaceutical companies. While machine builders and end users strive to find the best approaches to optimize operations and lower costs to remain competitive; ultimately the bottom line is to find a solution that provides better and faster results, delivers projects faster with better regulatory compliance and a longer sustained value.

Efficiency in the manufacturing process is a crucial factor in reducing overall time to market. Eliminating paperwork, reducing errors and maintaining high quality standards will increase the throughput of the plant. It also minimizes resources which are performing unnecessary tasks and helps reduce material waste.

In addition, machine builders specifically expect ampoule filling machines to be:

- **Modular**: Mix and match ampoule filling machine functions specific to products, customer applications and local market demands, with pre-developed Add-on Instructions (AOI) for all potential end user requirements.

- **Scalable**: Full-range products with the ability to customize features to a particular market and add functionality based on a customer’s requirements.

- **Standard**: Develop and document mechanisms common to ampoule filling machines that can be easily redeployed with minimum modification reduce machine design and development time.

- **Cost-effective**: Highly competitive solution reduces machine integration, mechanical, electrical optimization and wiring costs while shortening software development time and maintenance.

- **Global support**: Fast response and remote access to decrease end user downtime.
Solutions & Benefits

System Configuration

The implementation of synchronized motion with Kinetix® 350 servo drives on the in-feed screw, filling nozzle station driver, dragon screw and out-feed screw improve the smooth consistency of the ampoules’ movements through the machine operation line. This synchronization reduces breakage, spillage and other possible sources of contamination.

An integrated Kinetix 350 and Kinetix 3 solution is a competitive solution that can help reduce bottle breakage risk while still maintaining high filling accuracy and no-bottle-no-fill function, on-line filling volume adjustment, and filling profile design functions. Ultimately, the solution can help reduce machine cost and improves performance.

Vial filling machine Rockwell Automation architecture:
- CompactLogix™ Programmable Automation Controller (PAC), Kinetix® 350 Servo Drive, PowerFlex® 4M AC Drive, Kinetix® 3 Servo Drive.

Non-synchronized motion with Kinetix 3 Servo Drive:
- 16 Filling motors
- 1 Pump Valve
- Modbus for patch set
- Index for high accurate PTP movement.

A standard software structure can be easily replicated and expanded to reduce the time required for engineering, commissioning, testing and system validation. In this scenario, when programming the CompactLogix™ programmable controller, only the control module and equipment module level need to be programmed.

Depending on the end user’s recipe and production requirements, a machine builder can customize the machine with speed and volume by Rockwell Automation HMI standard recipe Active X control.
The machine can also include an independent start and stop of the ampoule in-feed screw, indicated position stop, no bottle no filling and liquid back flow. In addition, on-line sampling AOIs may also be pre-programmed.

When problems occur at the upstream and in-feed parts, end users can keep running the filling and auto-recovery machine after the in-feed parts problem are rectified. With the no bottle no filling function, no product can be filled without the bottle to reduce product waste and prevent environment pollution.

As the industry continues to extend regulatory requirements, OEMs and end users can save programming, commissioning and maintenance time with a solution that incorporates broadly adopted standards – ISA-88. New ideas and contributions to the ISA-88 standard are helping drive innovation and expand the concept of modular programming. PackML provides a broadly recognized machine state model and standardized data model (PackTags) to help ensure that programmers are speaking the same language and using terminology consistently. This creates a predictable, reusable model when multiple programmers are involved during machine design.

**Development Tools**

**Power Programming** is suitable for any programmable logic controller and is useful for moderately complex applications.

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Modular programming technique with ready-to-use predefined templates is reusable resulting in shorter engineering time across the machine portfolio.
Flexible production allows existing assets to be adapted to new product requirements with minimal time and capital investment. Ease of modular implementations to test software objects reduces development time, on average, by 50 percent.

Example of Power Programming on an ampoule filling machine:

- Ampoule filling machine is a package machine, so PackML is used to meet the standard.
- Modular programming shortens the machine development time for any different filling nozzles machine and mechanical structure.
Control Loop Diagram

- For the four axes, main filter station works as the master, dragon screw and out feed screw follow the master axis.
- Dragon screw is the master axis for in-feed screw axis, if in-feed part encountered problem, the in-feed screw is stopped, and other axes continue to run, after the dragon screw is recovered, in-feed screw synchronizes with dragon screw again.
Kinetix 3 control :  Kinetix 3 control mode /index control
Drive and index control by digital input (PLC output)

K3 digital output single such \ reach position \ in motion...
Convergence of control and information for plant-wide optimization and machine builder performance

Through the convergence of control and information systems, Integrated Architecture® delivers plant-wide optimization, machine builder performance, and sustainable production and serves as a foundation to help:

- Improve Productivity with better asset utilization and system performance
- Promote Globalization with easy access to actionable, plant-wide information
- Support Sustainability with extended product lifecycles and better asset utilization
- Cultivate Innovation with increased system flexibility and technical risk mitigation

Add-on Instruction (AOI) sets bring the power of the Integrated Architecture to your system quickly and easily.

- AOI_PosComp_M allows slave axis position compensation to the master axis.
- Axis_VelocityCPT_CD calculates and changes the speed dynamically to the axis.
- Axis_ObjectCD combines general control elements including command bit, status bit and parameters to Kinetix 350 servo driver.
- Axis_MI_Jog_CD provides integrated jog function to Kinetix 350 driver.
- PackMLv3_StateModel is the core of the state model and manages all machine states.
- AOI_NBNF enables integrated "no bottle no filling" function for the machine.
Summary

The CompactLogix Programmable Controllers, Kinetix 350 and Kinetix 3 servo drives offer integrated solutions for ampoule filling machines packed with performance at an exceptional value.

The Rockwell Automation solution helps a 12 filling nozzle ampoule filling machine easily achieve 600 ampoule per min. Other benefits:

- Standard, flexible machine programming with Power Programming.
- Reduce machine programming and commissioning time that leverage function blocks and pre-programmed standard functionalities: no-bottle-no-filling, nozzle control.
- Improve your machine performance and save cost with the motion index function.
- Increase machine functionality and scalability with the ability to choose expansions like on line sampling, on line weighting, automatic filling volume adjustment, and product recorder functions.

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Whether you’re around the corner or around the world, our Services & Support network can provide the skills and resources you need to optimize performance and utilization of your automation equipment, helping you meet your business objectives.

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