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Glass Bottle Filling, Capping, & Terminal Sterilization Line for LVP

Listing # 1822-01

DF Model LF-GV 800/6 Bottle Washer, 2020 YOM

- The bottle washer Mod. LF-GV 800/6 complies with good manufacturing standards (GMP) and complies with FDA directives.
- Made entirely of AISI 316 and AISI 304 stainless steel and anticorrosive aluminum. With the particular type of bottle grip on the neck with self-centering clamp, it allows high pressure washing (up to 5 bar), the elimination of the transport format change, and also for the particular design of the position of the pliers and chains, the guarantee of centering of the washing needles over time.
- The machine is particularly compact and the sets of format parts necessary for the processing of all the bottle formats requested by the user specifications are supplied.
- **Technical characteristics:**
 - Mechanical production : Up to 5,500 pcs/hr
 - Bottles types : Glass/Plastic bottles with diameter up to 80 mm
 - Bottles supply : From conveyor with adjustable speed
 - Bottles transport : Intermittent with side chains transfer
 - Washing system : no. 6 spraying needles each washing station with bottle centering/holding by pliers
 - SW control : PLC SIEMENS

MEA Pharma Linear Filling & Rubber Stoppering Machine, 2018 YOM

- Under LAF with in-out conveyor belts
- 4-up filling system running Pharmaceutical infusion solutions
- Output: 1250 - 1500 bottles/hour depending on the size
- Recommended dosage range: 100 - 500 ml
- Fill accuracy: 500 ml ± 1.5 %
- Mass flow filling system in connection with a pneumatic fill valve, in-line sterilizable (CIP/SIP) up to 125°C
- Parts in contact with solutions are in stainless steel AISI 316L, other parts are in stainless steel and/or covered with stainless steel of different qualities.
- The product must be delivered either by pump or pressure tank by the distribution piping, and must be under pressure. Required delivery pressure on the machine inlet should be between 1.0 - 5.0 +/- 0.2 kg/cm².

- Power requirements: 400 V, 50 Hz 3ph+N
- Compressed air requirements: 6.0 kg/ cm²
- Operator language: English
- Recommended personnel: 1 operator
- Bottles: Glass
- Sealing method: Rubber cap

DF Model GC/4T-R Capper, YOM 2020

- The capping machine Mod. GC/4T-R is a continuous movement model with 4 capping heads by rolls
- The incoming bottles are transported by a conveyor belt with adjustable speed and synchronized by a screw, then transferred to the main star-wheel after the collection of a cap from the chute where they pass down.
- Each capping head will lower on a bottle and follow it until the transfer back to the conveyor belt.
- The caps are supplied by a vibrating bowl with adjustable speed.
- The machine is provided of change size parts (screw, star-wheels) and can be adjusted for the different vials height and diameter (conveyor guides, capping height).
- The different caps don't require any change to the vibrating system but the capping heads have to be replaced with the corresponding set.
- Output: 1100 -1500 vials/hour depending on the size

Fedegari Model FOW6/C Autoclave, YOM 2018

- Superheated water sterilization autoclave, 2 trolleys double door interlocked
- Capacity: 5m³ or 5,190 Liters ... 100ml= 6412 bottles/cycle, 250ml= 2620 bottles/cycle, 500ml= 1976 bottles/cycle
- Cycle length: Overkill at 121C approx. 80 minutes
- FOW6/C Fedegari Autoclave is designated for the sterilization of LVPs or similar type of products and is functioning on superheated water sterilization principle.
- The sterilization chamber is a horizontal pressure vessel made of 316TiStainless Steel
- 4 flexible probes (2 product probes; 1 for autoclave and 1 for drain)
- The Autoclave is provided with two automatic sliding doors in a horizontal direction, used for loading/unloading the products in two different areas.
- The sealing system is constituted by silicone rubber gaskets.
- Tightness of the chamber when the door is closed is achieved by supplying compressed air to the gasket seat. In this manner, the gasket is pushed out and compressed against the door.
- Door opening is allowed by discharging the compressed air from inside the gasket seat.
- The autoclave is totally controlled and monitored by means of a computerized system known as THEMA4, a stand-alone microprocessor-based system, which manages cycles and controls operative parameters as temperature, time/or F0 and pressure.
- The autoclave is provided with a remote user interface which allows the central control

system connection to a Personal Computer, with the possibility to manage the process by the panel with Touch Screen display, mounted on side 1 of the autoclave, or by the dedicated Computer.

- The Autoclave is controlled and monitored by the THEMA4 controller, a stand-alone computer-based system.
- The system duties are as follows:
 - Manage communication with operator through interface devices; including password management, level access, history and audit archiving according to 21 CFR part 11.
 - Command of all the ancillary control devices (solenoid valves, motor starters, etc.)
 - Carry out logic sequences according to the programmed operation, with consideration to input from digital and analogue devices
 - Provide proportional control of both pressures and temperatures by means of interpretation of analogue inputs and outputs and programmed set-points.
- Utility requirements: compressed air, electrical power, industrial steam, purified water, cooling water

The maximum load is an amount of 6412 bottles of 100 mL	The maximum load is an amount of 2620 glass bottles of 250 mL	The maximum load is an amount of 1976 bottles of 500 ml
• 546 bottles / tray no. 1	• 270 bottles / tray no. 1	204 bottles / first tray
• 532 bottles / trays no. 2-6	• 260 bottles / trays no. 2-5	196 bottles / each other 4 trays
• 3206 bottles / trolley (546 + 532x 5)	• 1310 bottles / trolley (270 + 260 x 4)	988 bottles / trolley (204 + 196 x 4)
• 6412 bottles / autoclave (3206 x 2)	• 2620 bottles / autoclave (1310 x 2)	1976 bottles / autoclave (988 x 2)

DF Model SSA/5 ETA1000 Visual Inspection & Semi-Automatic Labeling, YOM 2020

- The Inspection/Labeling machine Mod. SSA/5 ETA1000 checks the bottles contents magnified by a video-camera, with selective manual discard, and then applies the label with the lot code.
- The incoming bottles are transported by a conveyor belt with adjustable speed and loaded on the transport chain with pliers by a pneumatic device. The advancement is at step with adjustable speed. The pliers are pneumatically commanded.
- After leaving back the bottles, the out-feed pneumatic device will move each bottle on the outfeed belt or in the discard tray according to the operator selection at the check station.
- The correct bottles are then labelled and sent to the outfeed line.
- The machine is provided of change size parts (load, unload profiles) and can be adjusted for the different vials height and diameter (conveyor guides, transport chain height, label position).
- Output: Approx 970 bottles/hour