

# Technical Specification For Vial Filling & Stoppering Machine FF0216

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### Summary

#### 1.1 Structural Composition and Application Features

The filling and stoppering machine is suitable to fill sterile liquids into containers and insert stopper into containers stably. Half or full inserting is available based on production characteristics. It is possible to install different dosing systems according to product characteristics. Class A is assured in all process areas above the openings of the containers.

The machine has been designed and manufactured conforming to cGMP standards.

#### 1.2 Equipment Performance Summary

##### 1.2.1 Machine Basic Details

Filling and Stoppering Machine	
Model	FF0216
Container Specification	Vials size:100ml, 250ml Vials diameter: 50-68mm Vials height: 88-117 mm

Filling and Stoppering Machine	
Main Parameter	Pumps quantity: 16

## 1.2.2 Output Details

The rated production capacity: 75 containers per minute based on 250 ml (Diameter: 68 mm, Height: 117 mm), and 100 ml filling volume of cool WFI

Note: The indicated performance data is the maximum machine performance. The output depends on:

- Format
- Product properties and behaviors
- Packing material
- Constant and proper product and utility supply
- Properly prepared packing material
- Proper maintenance according to maintenance manual
- As most of the containers are uncontrollable accurately, the production capacity of the line will be reconfirmed only after samples receipt and testing.

## 1.2.3 Container Details

SN	Size (ml)	Body Diameter (mm)	Height (mm)	Filling volume	Capacity (VPM)
1	100	50	88	Based on 100ml	100
2	250	68	117	Based on 250ml	75

Note: The main production container is 100 ml.  
Customer should provide the technical drawings of all containers, stoppers, caps.

## 1.2.4 Stopper Details

SN	Size (mm)	Type of Stopper	For Container No	Diameter (mm)	Height (mm)
1	20	LIQUID	100 ml, 250ml		

Note: The main production stopper is 20mm LIQUID Stopper for main production container.  
Customer should provide the technical drawings of all containers, stoppers, caps.

## 1.2.5 Test Conditions for Whole Line

### 1.2.4.1 Samples for engineering

Each size vial for the whole line: 30

Each size stopper for the whole line: 3,000

Each size capper for the whole line: 3,000

Note: The packaging materials should be received by Tofflon within 10 days after the order to avoid delays to the FAT and/or equipment delivery.

### 1.2.4.2 Packaging materials for test in factory

Each size: for running 2 hours continuously

Note: The packaging materials should be received at the Tofflon factory according to the required quantities at least 8 weeks prior to the agreed factory acceptance test date.

#### 1.2.4.3 Packaging materials for FAT (if requested)

Each size: for test 1 hour continuously

Note: The packaging materials should be received at the Tofflon factory according to the required quantities at least 8 weeks prior to the agreed factory acceptance test date.

#### 1.2.4.4 Others

The Buyer is requested to provide dimensioned drawings and samples of the packaging material on time to avoid delay.

All the relevant costs towards packaging materials will be charged to the Buyer.

Packaging materials have to be identical in shape, dimension and weight as per those listed in the URS (Unless modified prior to order placement and acceptance by Tofflon).

Equipment delivery will be delayed in case of any issues with the packaging materials (delivery, quality and so on).

### 1. Technical Specifications

The standard machine is supplied complete with:

#### 2.1 Basic Structure

The frame is set on feet that can be adjusted in height for reaching a work surface at 913(+/- 20) mm. The height is subjected to the full line design.

Primary structure of operational table is aluminum sheet, then cover one stainless steel 304 plate above the aluminum sheet. Standard integration with machine is oRABS.

Substructure with easy access to the drive system and components is completely separated from the processing section.

Glass doors of barrier system are monitored with safety switches that automatically shut down the machine when a door is opened.

#### 2.2 Infeed Station

The operator feeds vials into filling machine manually, then the vials are transported by infeed belt and turntable. At the beginning of production. Infeed starwheel will run when one sensor activated far from infeed starwheel. An alarm generates and the machine stops in case of lack of containers.

Infeed belt is driven by inverter motor with adjustable speed.

Infeed starwheel is driven by servo motor.

Special guides are designed to prevent damage from failing container.

#### 2.3 Main transport belt

The containers are transported to the filling stations by a belt with V-block driven by servo motor. Stable transport is available between main transport belt and starwheel.

There is one checking system at the belt frame with the function: "no container -no filling - no stoppering".

#### 2.4 Filling Station

Time-Pressure method of filling will be provided according to customer requirement.

- Automatic adjuster for the central dosing volume adjustment. The setting values can be entered at the operating terminal and memorized separately for each size.
- Normal liquid buffer tank and manifold are available as standard design.

- Filling system can integrate in CIP-SIP function (option).
- All media-conducting parts are made of stainless steel 316L, and polished interior surfaces of the pipes for minimal risk of corrosion.
- High-quality surface is provided for easy cleaning ( $Ra \leq 0.8 \mu m$ ).
- Filter housing with polished surface and sloped drainage is as per cGMP compliance.
- Pipe fittings are tri-clamp type.

Note: Tofflon will not be responsible for possible malfunctions caused by products due to loss previously evaluated and tested by customer.

## 2.5 Stoppering Station

This station is composed of vibrator bowl with min. accumulation monitoring sensor, chute and picking up and inserting plate.

All the above components are adjustable to match the height of the containers.

The stoppers can be inserted as full.

The material of vibrator bowl is stainless steel SS 316L, its internal hood is double welded and sterilizable.

The material of feeding chute is stainless steel SS 316L.

Stoppering heads made by stainless steel 316L are vacuum assisted.

Stoppering system for rubber stoppers is driven by servo motor.

Sensor for detection of stoppers shortage in the feed track is provided with audible signal. The function "machine stop" as well as "automatic restart" can be achieved.

Level monitor is provided for stoppers in the vibrator bowl to activate the hopper system if the quantity drops below minimum, the hopper system is activated until the stoppers have been replenished in the vibrator bowl (it is not necessary for low speed filling line).

## 2.6 Rejection Station

After stoppering station, there is one sensor for detecting stopper presence. The container without stopper will be rejected by starwheel with vacuum suction nozzle accurately.

## 2.7 Outfeed Station

Stopped containers are leaving the machine on a discharge belt with adjustable speed. There is one sensor for monitoring accumulation of containers on outfeed belt with automatic machine stop and alarm on the control panel.

## 2.8 Sampling

Filled container can be selected to check weight or other purpose by pressing sampling button on HMI. Container can be tracked for which pump filled during sampling

## 2.9 Size Change Parts

A full set of change parts for main container and stopper is provided. The set of change parts is comprised of:

- Turntable guides
- Infeed belt guides
- Infeed starwheel and guides

- Main starwheel
- Needles
- Hoše
- Stoppering starwheel and guides
- Stoppering plate
- Outfeed starwheel and guides
- Vibrator bowl and relevant parts

## 2.10 Control System

HMI: 12" color touch screen

PLC: Siemens.

4 levels password: Administrator Group, Parameter Group, Operator Group, Visitor Group.

Electric cabinet: integrated in machine.

Electric control panel: integrated with main machine, and connected with the electric cabinet standard wire. Equipped with color touch screen, emergency button and other buttons, it can display the alarm, all production and operation data. Control system is used for touch screen control panel which prevents loss of data due to voltage loss.

Interlock control: interlock is provided with the upstream tunnel and the downstream machine to show the causes of fault, position of fault and simple solution.

## 2.11 Control Items Details

SN	Item/Name	Set	Display	Stop	Alarm	Manual reset	Auto reset
1	Capacity & Recipes	√	√				
2	Containers min. accumulation at infeed station		√	√	√		√
3	Pump overload		√	√	√	√	
4	Servo motor overload		√	√	√	√	
5	Outfeed is blocked or malfunction from downstream machine		√	√	√		√
6	Liquid not enough		√	√	√		√

## 2.12 Safety Device

Emergency stop button.

Safety guards with interlocked switches.

Colored light indicators to show the operating status of the machine with acoustic signal.

## 2. Specification of Main Standard Materials

SN	Name	MSM	Remark
1	Filling needles	SS 316L	contact with liquid
2	Manifolds and pipes	SS 316L	contact with liquid
3	Filling hoses	Silicone	contact with liquid
4	Buffer tank	SS 316L	contact with liquid
5	Body of diaphragm valve	SS 316L	Contact with liquid
6	Diaphragm of diaphragm valve	EPDM	Contact with liquid
7	Bowl and chute	SS 316L	contact with stopper
8	Stoppering plate	SS 316L	contact with stopper
9	Infeed starwheel	POM	contact with the container
10	V-block	POM	contact with the container
11	Rejection starwheel	POM	contact with the container
12	Discharging starwheel	POM	contact with the container
13	Discharge belt	POM	contact with the container
14	Guide	POM /PE	contact with the container

## 3. Specification of Components

### 4.1 Main Standard Components

Include one complete set change parts for main container and stopper

SN	Name	MSM	Remark
1	Turntable motor	OTG	N/A
2	Infeed belt motor	OTG	N/A
3	Infeed starwheel servo motor	Siemens	N/A
4	Main belt servo motor	Siemens	N/A
5	Stoppering servo motor	Siemens	N/A
6	Rejection Starwheel servo motor	Siemens	N/A
7	Discharge Starwheel servo motor		
8	Filling diaphragm valve	Gemu	N/A
9	Time pressure system	Tofflon	20 filling needle
10	Diaphragm valve for CIP-SIP system	Fujiking	N/A
11	Temperature sensor	GTAM	N/A
12	Pressure sensor	GTAM	N/A
13	Pneumatic system	SMC	N/A
14	Vibrator bowl	Good bowl	N/A
15	PLC	Siemens	N/A

SN	Name	MSM	Remark
16	HMI	Siemens	N/A
17	Sensor for container accumulation before accelerative wheel	Omron	N/A
18	Sensor for detecting stopper accumulation	Omron	N/A
19	Sensor for detecting stopper presence	Omron	N/A
20	Sensor for container accumulation on discharge belt	Omron	N/A
21	Emergency button	Schneider	N/A
22	Power switcher	Schneider	N/A
23	Breaker	Schneider	N/A
24	Contactora	Schneider	N/A

#### 4.2 Other Change Parts

1. One complete set change parts for one additional container: One set for 250ml vial		
SN	Name	Remark
1	Turntable guides	N/A
2	Infeed starwheel and guides	N/A
3	Main starwheel guides	N/A
4	Stoppering starwheel and guides	N/A
5	Sampling guides	N/A
6	Rejection starwheel and guides.	N/A
7	Outfeed starwheel and guides	N/A
2. One complete set change parts for one additional stopper: N/A (If available, it will be extra quotation.)		
SN	Name	Remark
1	Vibrator bowl and relevant parts for liquid stopper	N/A
2	Stoppering plate	N/A
3. One complete set change parts for one additional filling volume: 100-250ml		
SN	Name	Remark
1	Needles	N/A
2	Hose	N/A

#### 4. Utility Requirements (Approx.)

SN	Description	Requirements
1	Total power	6 Kw @ 380V, 50Hz, 3P, 5W
2	Connected load vacuum	80 L/min @ P≤-0.85bar



SN	Description	Requirements
3	Compressed air	150 L/min @ 6-7bar

## 5. Standard Documentation

SN	Name	QTY
1	Operation Manual (OM)	1
2	Maintenance Manual (MM)	1
3	Installation Manual (IM)	1
4	Piping and Instrument Diagram (P&ID)	1
5	Layout Drawing	1
6	Wiring Drawing	1
7	Main Components Instructions	1
8	Material of Certificate	1
9	Pipes Welding Map	1
10	Factory Acceptance Test (FAT)	1
11	Site Acceptance Test (SAT)	1
12	Installation Qualification (IQ)	1
13	Operation Qualification (OQ)	1

## 6. Options Request

SN	Name	QTY	Remark
1	Additional change parts for container	1 set	Based on final contract.
2	Additional change parts for stopper	N/A	Based on final contract.
3	Vacuum pump	1 set	Based on final contract.
4	Physical isolation system(Open RABS)	1 set	Based on final contract.

## Technical Specification for Open Restrict Access Barrier System

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## 1. Summary

### 1.1 Equipment Performance Summary Table:

SN	Description	Equipment Performance
1	Total height of equipment	According to elevation drawing
2	Height of plenum	According to elevation drawing
3	Height of frame	According to elevation drawing
4	Height of glove center	1250mm
5	Weight	About 200 Kg/m <sup>2</sup>
6	Power supply	380V 50Hz 3Phase,5wires

## 2. Technical Specifications

### 2.1 Mechanical Specification

A. Design Specifications			
SN	Description	Specifications	
1	Illuminance	≥300Lux on work height	
2	Roughness (outside)	Ra≤1.6μm	
B. Technical configuration			
SN	Name	MSM	QTY
1	Main frame	SS 304	N/A
2	Viewing panel	Tempered glass or PC	N/A
3	Glove ports	Size: Oval 315*210 Material of flange: UPE	N/A
4	Gloves	Material: Hypalon Length: 800 Diameter: 10" Quantity: To be defined	N/A
5	Hinges	SS 304	N/A
6	Adjustable foot	SS 304	N/A
7	Illumination Light (LED)	Philips or equal brand	N/A
8	Door signal	Omron or equal brand	N/A
C. Feature			
1	The whole system designed as per cGMP and relative international standards.		
2	The bracket and glass form a set of physical isolation system to avoid personnel directly entering the interior of the isolation system for intervention.		
3	The glass door is equipped with sterile gloves according to the needs of the production process, which can be used for necessary intervention in the production process.		

## 2.2 Filtration System

A. Design Specifications			
SN	Description	Specifications	
1	Cleanliness inner isolator	Grade A as per cGMP	
2	Airflow pattern	Unidirectional flow	
3	Air supply style	From the background of equipment.	
4	Airflow velocity	0.45m/s±20% (150~300mm under diffuser)	
5	Port for filter integrity test	3/4" TC Included for all HEPA filters	
B. Technical configuration			
SN	Name	MSM	QTY
1	Plenum	SS 304	N/A
2	Unidirectional airflow fans	Airflow or equal	N/A
3	Unidirectional filter	Camfil H14 HEPA filter or equal	N/A
4	Air diffuser	Polyester film	N/A
5	Anemometer	Dwyer or equal	N/A
6	Differential pressure gauge for HEPA filters	Tofflon	N/A

## 2.3 Clean & Disinfection System

A. Design Specifications		
SN	Description	Specifications
1	Disinfection	Disinfection with environment
2	Clean	Manual wipe

## 2.4 Control System

A. Design Specifications			
SN	Description	Specifications	
1	Safety light	Included	
2	Control	- Fan on/off - Internal illumination	
3	Monitor	Airflow speed	
4	Alarm	- Fan failed - Abnormal opening the doors	
B. Technical configuration			
SN	Name	MSM	QTY

1	PLC	Germany Siemens S7-300(share with other equipment)	N/A
2	Touch screen	Germany Siemens(share with other equipment)	N/A
3	Air breaker	Schneider or equal	TBD
4	AC contactor	Schneider or equal	TBD

### 3. Utility Requirement (Approx.)

SN	Description	Requirements (approx..)
1	Air volume	1944m <sup>3</sup> / (h*m <sup>3</sup> )
2	Power	350W/m <sup>2</sup> , 380V 50Hz 3Phase/5lines

### 4. Documentation

SN	Name	QTY
Manuals		
1.	Operation Manual (OM)	1
2.	Maintenance Manual (MM)	1
3.	Installation Manual (IM)	1
Standard		
1.	Pipes & Instruments Drawing (P&ID)	1
2.	Instruction for the Main Parts	1
3.	Material Certificate	1

### 5. Spare Parts List

SN	Name	MSN	QTY
1	Differential pressure gauge	Tofflon	1
2	Light	Philips or equal brand	1
3	Gloves	10" Hypalon	1