Flex-Line™ Robotic Filler

ATS LIFE SCIENCES GROUP

Key Features

- Ability to handle vials, syringes, cartridges
- Small footprint, fast changeover, and short lead time
- One FAT, SAT, and validation, accelerate market entry
- Conformance to gmp guidelines. Annex 1 and 21 CFR Part 11
- Robotic handling, no-touch transfer (ntt), automated de-bagging

Filler Specifications

Dimensions (mm)	W: 2580, L: 3430, H: 3030
Vial Running Surface Height	950 mm +/- 20 mm
Vial Range	2R - 50R
Syringe Range	1 mL - 5 mL
Cartridge Range[1]	1 mL - 3 mL
Weight[1]	7,000 kg Approx.
In-feed System	Semi-automatic Debbaging
Dosing System	Piston pumps
Weight Check	Statistical weigh check (1 load cell)
Mechanical Plungering	Mechanical plungering and stoppering
Outfeed System	Machine outfeed via rolling conveyor
De-lidding & Filling Enclosure	Comecer Isolator
Debagging Enclosure	Restricted Access Barrier (RABS)
Contact Parts	Electropolished AISI-316L
Surface Bench Material	AISI-316L (fine-brushed) stainless steel
Exterior Panels	Exterior Panels AISI-304 stainless steel
Electrical Cabinet	IP 54; cabinet located remotely
HMI	HMI, Panell PC 18,5”
Main Drive and Critical Movements	Servo Motor
Utility Requirement (other options available)	400 Volt 3 Phase + Neutral + Ground 50/60 Hz 7kW approx.
Air Consumption	800 Nl/min (Max) – 6 bars (87 psi)
Regulations	CE Mark, GMP, Annex 11/ 21CFR part 11, UL 508A
Documentation Package	Package 0 - Includes layouts, FS, manual, and FAT docs

Container	Capacity (ml)	Filling Speed UPM (max)	Nest Quantity	Filling Accuracy (+/-)
VIALS				
2R	4.0	140	100	1%
4R	6.0	140	100	1%
10R	13.5	70	48	1%
20R	32.5	50	24	1%
30R	32.5	30	24	1%
50R	37.5	30	16	1%
SYRINGES				
1 mL long	1.0	200	100	1%
1 mL short	1.0	200	100	1%
3 mL	3.0	150	100	1%
5 mL	5.0	70	48	1%
CARTRIDGES				
1.5 mL	1.0	150	100	1%
1.8 mL	1.8	150	100	1%
3 mL	3.0	140	100	1%

*Mechanical speed of machine with water

Isolator Specifications

Isolator Unidirection Air Speed	0.45 m/s ± 20%
Operating Pressure	+15 Pa to +30 Pa with Respect to Installation Area
Operating Temperature	Ambient 20°C
Operating Humidity	Range 30% to 60%
EMS	Viable & Non-Viable PMS

All Grade A Chambers Will Consist of the Following:

- AISI-316Lstainless steel chambers with Mirror Bright internal surface finish Ra<0.5 µm
- Enclosure air tight class 3 ISO 10648-2
- The particle content in the air of the LAF chambers in operational conditions complies with the ISO 14644-1 and EEC-cGMP requisites
- Grade A "At rest" (EEC-cGMP)
- Class ISO 5 (ISO 14644-1) ≤ 3520 particles/m^3 for particles Ø ≤ 0.5 µm
- Access Doors made with hinged safe tempered glass panels
- Chambers tightness ensured by inflatable gasket system and electromechanical interlocks
- The chamber is designed to take air from a Class C or Class D room
- Ventilation System: Inlet/Outlet Frequency controlled fans, ON/OFF Pneumatic valves for the air interception

Included in Scope:

- Lockable base guarding made of AISI 304 Scotch Brite RA<0.8 µm
- Inlet H14 laminar filters
- Glove Ports and extenders (final quantity determined during Mock-up)
- Glove flanges and internal barriers for glove detection
- Anemometer sensor (for chamber equipped with laminar airflow only)
- Pressure transmitters for filter obstruction and chamber's pressure regulation
- AISI 316L flange for automatic machine integration
- Hinged front view panels with inflatable seals made of FDA approved Silicon rubber, each panel is supplied with handles and integrated safety switches
- All internal angles have a minimum radius of curvature of 20 mm to facilitate the cleaning and sterilization operations
- Ventilation System: Inlet/Outlet Frequency controlled fans, ON/OFF Pneumatic valves for the air interception
- All welds are ground, smoothed, and polished
- All welds are passivated and pickled
- All stainless steel is welded using TIG method (in argon atmosphere)

Additional Flex-Line™ Options

Debagging Extension Uni Directional Air Flow (UDAF)
Manual Debagging
Nitrogen Purging During Filling
Product Tank 8 L
Tank Mixer
Disposable Surge/Product Bag
Product recirculation
Peristaltic pumps
Vacuum Plungering
UDAF Module
O-RABS
NVPC-VPC supports
PMS Complete system
Exit conveyor
Outfeed UDAF extension
Siemens or Allen Bradley I/O & Communications
Additional change Parts
Stainless Steel Remote Cabinet
Documentation Package 1 - Includes documentation package 0 and HDS, SDS, SAT and IQOQ docs
Documentation Package 2 - Includes documentation package 0 and 1, RTM (requirements traceability matrix), CCL (commissioning check list), and summary report

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