Formulation Development

Pre-Filled Syringes 1mL-3mL

Vials 2mL-30mL

Lyophilization

RTP FORMULATION AND STERILE FILL-FINISH SERVICES.

Facility Overview

- State-of-the-art isolator manufacturing environment for liquid and lyophilized products
- Highest level of contamination control available for Grade A processing of biologic or small molecule products
- Capable of meeting batch completion targets in a single operating shift
- Lines 1 and 2 will be available October 2020, Lines 3 and 4 will be available in 2021
- Information about pre-qualified equipment available upon request

Line 1: Groninger FlexPro 50 (syringe)

- Groninger Flex-Pro 50 / Franz Ziel Isolator
- Nested 1mL long syringe, nested 1mL to 3mL, 160 nest (gas and vacuum), 100 nest (gas and vacuum), plungers
- 0.5mL – 1.0mL and 0.5mL – 3.0mL fill volumes
- 2 filling nozzles, rotary piston fiilling pump, vacuum stoppering
- Up to 30L (5,000 to 10,000 units, liquid filling) batch sizes
- Up to 750 cps viscosity

Line 2: Flexicon-Watson Marlow FPC 50 (liquid only)

- Flexicon-Watson Marlow FPC50W / Franz Ziel Isolator
- Nested 2R to 30R vial
- 0.5mL – 30mL fill volume
- 1 filling nozzle, peristaltic filling pump
- Up to 30L (600 - 10,000 vials, liquid filling) batch sizes
- Up to 25 vials/min (14 vials/min with 100% check weighing) filling sizes
- Up to 100 cps - optimal viscosity

Line 3: Fully-Integrated SP Filling Line (vial)

- SP Scientific / Idositechno / Esco Isolator
- Nested 2R to 30R vial, 13mm and 20mm stoppers, 13mm and 20mm flip-off seal
- 0.5mL – 30mL fill volume
- 2 filling nozzles, peristaltic filling pump
- Up to 30L (600 - 10,000 vials, liquid filling) batch sizes
- S20, 2,330 (30R) to 8,460 units (2R) lyo capability
- Up to 100 cps viscosity

Line 4: Fully-Integrated SP Filling Line (vial)

- SP Scientific / Idositechno / Esco Isolator
- 2R to 30R vial, 13mm and 20mm stoppers, 13mm and 20mm flip-off seal
- 0.5mL – 30mL fill volume
- 4 filling nozzles, peristaltic filling pump
- Up to 200L (27,000 units for 2mL; 12,600 units for 30mL; liquid filling) batch sizes
- S100, 12,213 (30R) to 44,244 units (2R) lyo capability
- Up to 100 cps viscosity

Formulation Development

- Risk assessment and mitigation
- Process optimization and formulation justification
- API tox evaluation and prototype selection
- Pre-formulation studies and technical transfer
- Formulation screening and stability
- Admixture compatibility studies and material compatibility
- Development of freeze-dried products
- Cycle time development

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CAPABILITIES	LINE 1: GRONINGER FLEXPRO 50	LINE 2: FLEXICON-WATSON MARLOW FPC 50	LINE 3: FULLY-INTEGRATED SP FILLING LINE	LINE 4: FULLY-INTEGRATED SP FILLING LINE
Vial or Syringe	Syringe	Vial	Vial	Vial
Nested	1mL long syringe 1mL to 3mL 160 nest (gas and vacuum) 100 nest (gas and vacuum)	2R to 30R vial	2R to 30R vial 13mm and 20mm stoppers 13mm and 20mm flip-off seal	2R to 30R vial 13mm and 20mm stoppers 13mm and 20mm flip-off seal
Fill Volume	0.5mL – 1.0mL 0.5mL – 3.0mL	0.5mL – 30mL	0.5mL – 30mL	0.5mL – 30mL
Filling Nozzles	2	1	2	4
Filling Pump	Rotary Piston	Peristaltic	Peristaltic	Peristaltic
Batch Size	Up to 30L (5,000 to 10,000 units)	Up to 30L (600 - 10,000 vials)	Up to 30L (600 - 10,000 vials)	Up to 200L (27,000 units for 2mL) (12,600 units for 30mL)
Viscosity	Up to 750 cps	Up to 100 cps (optimal)	Up to 100 cps	Up to 100 cps
Lyo Capability	N / A	N / A	S20 2,330 (30R) to 8,460 units (2R)	S100 12,213 (30R) to 44,244 units (2R)

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