



EQUIPMENT LIST

PARENTERAL MANUFACTURING

Supporting Equipment

- Metromatic Vial Washer
- Vial Washer
- Disposable Product Contact Parts
- Fedegari Air Over Pressure Autoclave (2)
- Disposable Pall Allergro Compounding Systems
- Gruenberg Depyrogenation Oven
- Baker Co. Isolator
- Howorth Isolator
- Glass, COC and COP Vials and Syringes
- Beta-Star Autoclave
- Tanks up to 1,000L
- FP Inspection Hoods (semi automated)
- Reverse Osmosis and DI System

Robotic Filling Line

AST GENISYS[®] R Robotic Small Batch Filling & Closing System

- Components ranges: Vials (2R to 30R vials), Syringes (1mL syringes), Cartridges (TBD)
- Fill rate: 10-20 Syringes/Cartridges/Vials per minute
- Environment: RABS
- Components utilized: ready to use vials/stoppers and overseals

Vial Filling

- M&O Perry; 3mL (2R) - 100mL vials (up to 50,000 batch size)
- Bosch Filler 4700; 2mL - 100mL vials (up to 300,000 batch size)
- M&O Perry Manual Powder Filler (R&D) (up to 3kg batch size)

Syringe Filling

- Groninger DFVN 1000 Syringe Filler:
- 0.5mL - 5mL syringes; (2,500/hr)
- Pre and post inert gas overlay

Lyophilization

- R&D: Millrock REVO[®] Pro
- GMP: Millrock CIP / SIP 60ft²
- Vials (2mL to 50mL)
- Millrock Tech Lyophilizer

LIQUID MANUFACTURING

- Liquids & Semi Solid Processing
- Homogenizers: Ross 150L, Silverson DX60 & 275LS, IKA Turrax T25, Kinematica AG PT-MR 3100

Kettles/Tanks/Fillers:

- Lee "Tri-Mix" Turbo Shear Jacketed Kettles (100 & 200Gal)
- Fryma AG Colloid Mill MZ80/A Gel
- Tank (150L, 300L, 400L, 1000L)
- Cozzoli Liquid Filler (12 bottles/min)
- Chase-Logeman Liquid Filler (20 bpm)
- Bochang Gel Melter 2,000L
- Quadro Y Tron Mixer

ENCAPSULATION

Liquid Filled Hard Gel Capsules:

- Shionogi LIQFIL SUPER 40 (up to 40,000/hr)
- Capsugel CFS-1200 (up to 1,200/hr)
- Shionogi Capsule Bander S100 (up to 100,000/hr)
- Quali Seal Capsule Banding, size 3 to 00 (10 capsules/plate)
- Anritsu Capsule Check Weighers

Soft Gel:

- Bochang Soft Gel Encapsulator (4" & 10")
- Gwalo & Key Capsule Polishers (36" & 48")
- Ackley Printing Machine
- Bochang Capsule Sorter
- Roller inspectors
- Drying Tunnels

PACKAGING

- Fully automated, custom-built solid dosage packaging line (up to 60 bottles/min)
- Blister Packaging—Thermo & Cold forming
- Ima TR100 (140 blisters/min)
- Zed Ind. Z-Med Card Sealer
- SEPHA Deblistering Machine
- Hoonga Blister - Ministar
- Hartland Comet Labeling Machine
- Vibrac Automatic Application/Removal Torque Tester
- Abbess Vaccum Chambers
- Video Jet Printers for Vial Coding
- FP Inspection Booth
- Blister Cartoner
- Bottle Cartoner
- OMAG Stick Pack Filler

Supporting Equipment Includes: Bar code readers & verifiers, bin feeders, printers, conveyors, check weighting systems, cappers, counters, induction sealers, torque testers, metal detectors and NeoFox Oxygen Sensor.

SOLID MANUFACTURING

Blending:

- V-shell (1qt to 75 cu. ft. with intensifier bar), V-Shell Processors (2 cu. ft. \$ 20 cu. ft. with intensifier bar & spray), Bin (Bohle 1 to 40L)

Granulation:

- Key High Shear KG-5 (4L), Fuji Vertical (100L)
- Weston Sifters, Vac-U-Max Powder conveying system
- AMF Glen 340 (150kg, heat jacketed bowl), Hobart (30qt & 140qt)
- TK Fielder (25L, 65L & 150L)
- Fluid Air (600L) with heating and cooling system can do 250kg granulation

Roller Compactor:

- Freund TF156 (20kg to 30kg/hour)

Fluid Bed Processing:

- Niro MP1 (5kg)
- Fluid Air (120L & 300L); with solvent recovery & Wurster column with top spray with thermal oxidizer

SPRAY DRYING:

- Niro MOBILE MINOR (aqueous and solvent systems)
Supporting Equipment Includes: mills and drying ovens

COMPRESSION

Small Scale:

- Globe Manual Tablet Press
- Fette & Key Tablet Press

Rotary:

- Key DC16 - 16 station, B tooling (up to 36,000/hr)
- Kikusui Libra (7) - 36 station, B tooling (up to 150,000/hr)
- Sejong MRC-30N - 30 station, D tooling (up to 216,000/hr)
- Manesty Tablet Press

Instrumented Presses:

- Kikusui Aquarius LD-A - 9 station, B tooling (up to 8,100/hr)

Tablet in Tablet:

- Kikusui Aquarius 2 2L 36 station, B tooling; 30 station

Supporting Equipment Includes: Weight checking, deduster, counters, friability & hardness testing, and metal detection

EXTRUSION/SPHERONIZATION

- CALEVA Extruder/Spheronization

COATING/PRINTING

- Tablet Printing: Hartnett Delta model (250,000 tablets/hr)
- Driam Driacoater - 8" & 24" pans (5kg to 25kg)
- O'Hara Coating Pan-48" (120kg)
- Wurster Coating Columns for Fluid Air, Niro MP1
- Mendal Tablet Coater
- R&D Labcoat 1
- Gruenberg Drying Oven

ENCAPSULATION

Powders, Pellets & Granules:

- Minicap 50 & 100 (up to 1500 & 3000/hr)
- Zanasi IMA 40F (up to 40,000/hr)
- MG America MG2 Futurea (up to 48,000/hr)
- MG America Suprema (up to 48,000/hr)
- IMA Adapta

Supporting Equipment:

- Ackley Ramp Printers
- Hartnet Roller Printer

MILLING

- Quadro Comils (194 & 197)
- Fitzmill Comminutor
- Erweka AR400
- Shifters: Weston Vibrating Sifter (24")
- Fryma Colloid Mill MZ80/A
- US Stoneware Roller Mills (non-product contact)

ANALYTICAL R&D & QC

- HPLC / UPLC testing with a wide variety of detection capabilities (UV, DAD, RI, FLD, ELSD, ECD)
- Dissolution Testing (USP Apparatus I, II, III, IV)
- Particle Size Determination by Laser Diffraction
- GC / Headspace analysis
- UV/VIS spectrophotometry
- FTIR spectroscopy
- Color spectrophotometry
- CCIT by Vacuum Decay (Veripac 355)
- ICP-MS for elemental impurities
- Malvern Zetasizer for nano particle analysis
- Jeol Scanning electron microscopy (SEM)
- DSC
- Break Through/Glide Force (Syringe)

ANALYTICAL MICRO

- Autoclave for sterilization of accessories/media
- Laminar Flow Biological Safety Cabinets for microbiological testing
- Isolator for sterility test
- SteriText Pump for sterility test
- Hydrogen Peroxide Vapor Generator for decontamination of isolators
- Liquid Particle Counter for particle count in injectable products
- CCIT by Vacuum Decay (Veripac 355) for container enclosure integrity test.
- MAS/SAS Air Samplers for environment monitoring
- Incubators for incubation of media from microbiological tests
- Refrigerators for storage of media and microorganisms



Challenges Frame Opportunities

12/16/2021