



PHARMACEUTICS KNOW-HOW™

EQUIPMENT LIST

PARENTERAL MANUFACTURING

Supporting Equipment:

- Disposable product contact parts
- Fedegari Air Over Pressure Autoclave (2)
- Disposable Pall Allegro Compounding Systems
- Grunenburg Oven
- Baker Co. Isolator
- Howorth Isolator
- COC and COP vials and syringes
- Beta-Star Autoclave

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: 25 syringes/cartridges/vials per minute: ~1,500/hr
 - Environment: RABS
 - Components utilized: ready to use vials/stoppers and overseals

Vial Filling:

- M&O Perry; 2mL - 100mL vials (up to 20,000 batch size)
- Bosch (TL Systems) Filler 4700 (up to 150,000 batch size)

Syringe Filling:

- Groninger DFVN 1000 Syringe Filler:
- 0.5mL - 5mL syringes; (2,000/hr)
- Pre and post inert gas overlay

Lyophilization:

- R&D: Millrock REVO® Pro
- GMP: Millrock CIP / SIP 60ft
- Vials (3mL 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:

- Lee "Tri-Mix" Turbo Shear Jacketed Kettles (100 & 200Gal)
- Hamilton Jacketed Kettle (50Gal)
- Fryma AG Colloid Mill MZ80/A Gel
- Tank (300L, 400L, 1000L and 1750L)

- Cozzoli Liquid Filler (12 bottles/min)
- CO.MA.DI.S C-945 (45 tube/min)
- Chase-Logeman Liquid Filler (20 bpm)
- DynoMill 0.5L & 1.4L (Size reduction from 500 µm to 0.30 µm)
- Bochang Gel Melter 2,000L
- Quadro Y Tron Mixer
- Ross Turbo Emulsifier

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:

- Vanguard Mini Encapsulator – 2" die, R&D 1-2,000 capsules
- Gwalo Capsule Polishers (36" & 48")
- Ackley Printing Machine
- Bochang Capsule Sorter
- Roller Inspectors

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
- Allfill Powder Line
- Perfill Powder Filler
- Vibrac Automatic Application/Removal Torque Tester
- Abbess Vacuum Chambers
- Klockner CP1200 with a Cartoner P3000 fully automated blister line
- Video Jet Printers for Vial Coding
- FP Inspection Booth
- Bottle Cartoner – SERPA
- Blister 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 (4qt 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)
- Weston Sifters, Vac-U-Max Powder conveying system, PIAB Powder conveying system
- AMF Glen 340 (150kg, heat jacketed bowl), Hobart (30qt & 140qt), T.K.
- Fielder (25L, 65L & 150L), KeumSung KM450 (200L/150kg)
- 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

Rotary:

- Cadmach DB16 - 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)

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

Bi-Layer:

- Supporting Equipment Includes: Weight checking, de-dusting friability & hardness testing, and metal detection



PHARMACEUTICS KNOW-HOW™

COATING/PRINTING

- Tablet Printing: Hartnett Delta model (50,000 tablets/hr)
- Driam Driacoater – 8" & 24" pans (5kg to 25kg)
- O'Hara Coating Pan – 48' (120 kg)
- Wurster Coating Columns for Fluid Air, Niro MP1

ENCAPSULATION

Powders, Pellets & Granules:

- Minicap 50 & 100 (up to 1500 & 3000/hr)
- Zanasi IMA 40F (up to 40,000/hr)
- MG America MG2 Futura (up to 48,000/hr)
- MG America Suprema (up to 48,000/hr)
- MG America MG2 G140, size 5 to 00 (up to 140,000/hr)
- IMA Adapta

OVER ENCAPSULATION

- 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 with Empower Software with a wide variety of detection capabilities (UV, DAD, RI, FLD, ELSD, ECD)
- Dissolution Testing (USP Apparatus I and II)
- Particle Size Determination by Laser Diffraction
- GC / Headspace Analysis
- UV/VIS Spectrophotometry
- FTIR Spectroscopy
- Color Spectrophotometry
- ICP-MS for Elemental Impurities
- Malvern Zetasizer for Nano Particle Analysis
- Jeol Scanning Electron Microscopy (SEM)
- DSC

ANALYTICAL MICRO

- Autoclave for sterilization of accessories / media
- Laminar Flow Biological Safety Cabinets for microbiological testing
- Isolator for sterility test
- SteriTest 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 closure integrity test
- MAS/SAS Air Samplers for environment monitoring
- Incubators for incubation of media from microbiological tests
- Refrigerators for storage of media and microorganism

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