



Xcelience®

Formulation Development

2009 Equipment List

Formulation Development

Processing

Mixing

- 4 qt. and 16 qt. Patterson-Kelly (P-K) V-Blenders
- Turbula T10B Mixer
- KitchenAid Planetary Mixer
- Omni Mixer Homogenizer Model 17105
- Fisher and Lightnin Mixers
- Misonix Sonicator 3000 UltraSonic Mixer
- Microfluidics Model 110 Microfluidizer

Granulation/Drying

- Diosna Minilab Fluid Bed Granulator/Dryer with Top Spray Insert and Wurster Column
- 1L and 6L Diosna P1/6 Vertical High Shear Granulator with Jacketed Vessels

Particle Sizing

- Quadro Comil Model 197
- Fitzpatrick Model J Mill
- US Stoneware Ball Mill

Encapsulation

- Schaefer/Dott Bonapace IN-CAP Automatic Capsule Filler (Dosing Disc)
- Feton Manual Fill Encapsulators Sizes AA and 0-4
- PAM Model MF-30 Encapsulator (Manual Fill)
- Schaefer Laboratory Model Capsule Bander

Tableting and Coating

- Stokes Rotary Tablet Presses, 16 Station, Type B-2 Tooling with Bb dies
- Vector Laboratory Development Coating System with 9.25" (1.3 liter) and 14.5" pan sizes (3.75 liters)
- Carver Single Station Press



In Process/Physical Testing

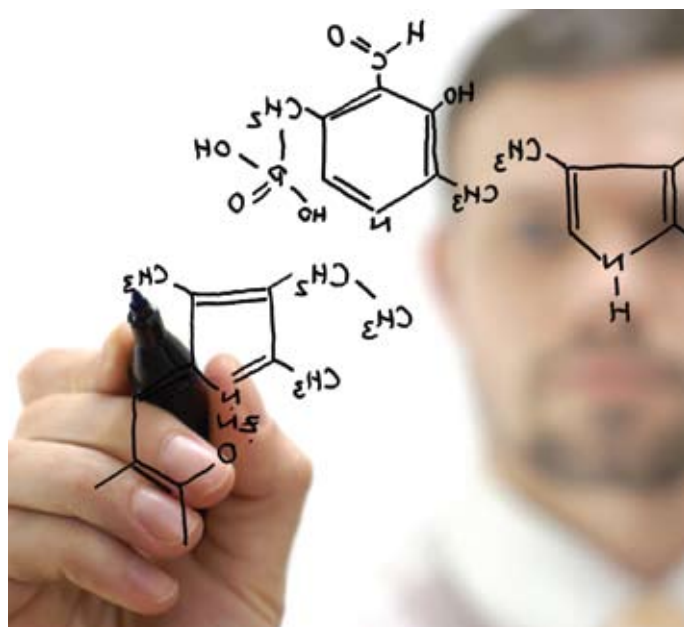
- ATM Sonic Sifter
- Brookfield RV-DVIII+ Rheometer (with Small Sample Adapter)
- Flodex Flow Meter Flowability Index Tester
- Mettler Toledo Moisture Analyzer
- Mitutoyo Thickness Gauges
- Advanced Instruments Osmometer Model 3320
- Ro-Tap Sieve Shaker
- Optimal Hardness Testers
- VanKel Disintegration Tester
- VanKel Friabilator
- VanKel Tap Density Tester

Transfer/Packaging

- Baxa Repeater Pumps
- Fuji Impulse FA-300 Auto Sealer
- Lepel Lepak Jr. Induction Sealer
- MasterFlex Peristaltic Pumps
- Spring Torque Tester

Miscellaneous

- Consolidated Automatic Steam Sterilizer
- Nuair Laminar Flow Hood



cGMP Manufacturing

Solids Processing

Mixing

- 4 qt., 8 qt. and 16 qt. Patterson-Kelly V-Blenders
- 1 cu.ft., 3 cu.ft. and 5 cu.ft. Patterson-Kelly Cross-Flow V-Blenders

Granulation/Drying

- Fluid Bed Processor, Glatt GPCG-3 (with top spray and rotor granulator inserts)
- Hobart Models H-600DT & A-200DT
- KitchenAid Planetary Mixer
- Littleford MGT-125 High Shear Granulator
- Powrex VG High Shear Granulator
- Vector TFC-Lab Micro Roller Compactor
- Diosna P1/6 High Shear Granulator (Multiple Processing Bowl Sizes)

Particle Size Reduction

- Micron-Master Jet Pulverizer Air Jet Mill
- Fitzmill Model D6A
- Quadro Comil Model 194

Encapsulation

- Capsugel Ultra 8 II
- PAM Model MF-30/AL-90
- Capsugel Xcelodose® 600 Precision Micro-Filling System/Automated Encapsulator
- Capsugel Xcelodose® 600S Precision Micro-Filling System/Automated Encapsulator
- Capsugel CFS1200 Liquid Encapsulator
- IN-CAP Automatic Capsule Filler (Dosing Disc)

Tableting and Coating

- Fette P1200 I Tablet Press, Type B Tooling with Tablet Deduster
- Manesty Beta Press, 16 Station, Type B Tooling with Tablet Deduster
- Schleuniger Hardness Tester
- Vector Model HCT-60 Tablet Coating System (24" Pan)
- Vector LDCS Tablet Coating System (Multiple Pan Sizes)

Liquid/Semi-Solids Processing

Mixing

- Agimixer (Countersweep, Jacketed Kettle with Homogenizer)
- Gifford Wood Colloid Mill
- Stainless Steel Jacketed Tank (60 gallon)
- Kinetics Refrigerated Chiller Unit
- Lightnin NS 1 Mixer
- Lightnin EV 1 Mixer
- Omni Macro Homogenizer

Transfer

- Single Piston Bottle Filler
- MasterFlex Peristaltic Pumps
- Baxa Repeater Pumps

Lyophilization

- Virtis Lyophilizer Genesis 25 EL

Finishing/Packaging

- Cap Torque Testers
- Capsule Polishers
- Kalish Bicaptight Bottle Capper
- King Tablet/Capsule Counter
- Lepel CS Plus Junior H2C Conveyor Cap Induction Sealing System
- Lepel Lepak Junior Induction Sealer
- Loma Metal Detector
- SADE P2 Tablet/Capsule Check Weighers
- Tablet/Capsule Inspection Belt
- Micron Pharma Works TF1 Blister Packaging Machine

Xcelodose® 600S



Analytical and Preformulation

Liquid Chromatography

- Waters Acquity UPLC
- Agilent 1100s and 1200s with UV/Vis, PDA, Fluorescence, ELS and Electrochemical Detectors
- Waters Alliance 2695

Gas Chromatography

- HP 6890 GC with 7694 Headspace Sampler and 7683 Injector

Data Management

- Waters Empower 2 Chromatography Data System

Dissolution

USP Apparatus I & II

- Distek 2100 Series Water-Bath Based Dissolution Systems
- Distek Premier 5100 Bathless Dissolution Systems
- Distek Evolution 6100 Bathless Dissolution Systems
- Distek Evolution 6300 Water-Bath Based Dissolution System
- Distek Evolution 4300 Autosamplers
- Distek EZ-Fill 4500 Media Preparation Station
- VanKel VK7000 Water-Bath Based Dissolution Systems
- VanKel VK8000 Autosamplers
- VanKel VK650A and VK750D Heaters/Circulators

Particle Size Analysis

- Beckman Coulter LS 13 320 Laser Diffraction Particle Size Analyzer with Powder and Liquid Modules
- ATM Sonic Sifter

Additional Analytical Tools

- Advanced Instruments Model 3320 Osmometer
- Agilent 8453 UV/Vis Spectrophotometer
- AquaStar AQC34 Coulometric Karl Fischer Titrator with DO307 Oven
- AquaStar C3000 Volumetric Karl Fischer Titrator
- Beckman GS-15R and Beckton Dickinson Dynac Centrifuges
- Brookfield RV-DVIII+ Rheometer (with Small Sample Adapter)
- Metrohm Titrando Titrator Model 836, Potentiometer and Karl Fischer Titrator
- Mettler Analytical Balances, Models MT5, AT201, and AT400
- Muffle Furnace for ROI
- Parker Balston Nitrogen Generator

Additional Analytical Tools Continued From Previous Column

- Pierce Reacti-Vap III and Reacti-Therm III
- PolyScience SR6 Polarimeter
- Vacuum pumps
- VWR Drying Ovens, with and without vacuum
- Various water baths with shaking, sonication, and heating abilities
- Wrist action and other shakers
- Accumet Model 15 pH Meters
- Accumet Model AB15 pH Meters

Preformulation

- Rigaku MiniFlex II Desktop and Portable X-ray Diffraction System
- Heraeus SunTest CPS+ and SunCool Temperature Controller
- Mettler Toledo FP82HT Hot Stage and FP90 Central Processor
- Olympus BX51 Polarizing Microscope (Several Varying strength objectives) with Digital Camera
- Perkin Elmer Spectrum One FTIR
- Sirius GLpKa
- TA Instruments Q100 Modulated DSC
- TA Instruments Q500 TGA with Hi-Res and Modulated Modes
- VTI SGA-100 Vapor Sorption Analyzer

Stability Chambers

cGMP Stability Chambers (ICH Conditions)

Walk-In Chamber

- 25°C/60% RH

Reach-In Chambers

- 25°C/40% RH
- 30°C/40% RH
- 30°C/65% RH (2)
- 40°C/15% RH
- 40°C/75% RH (2)
- 5°C

cGMP Storage Refrigerators

- Puffer Hubbard 2-8°C (3)
- Revco Ultima II -20°C
- Warehouse Refrigerator for QA retains; Storage 2-8°C

Data Handling

- Stability Laboratory Information Management Software (SLIM™)
- Dedicated Server for SLIM™

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