Pii

Pharmaceutics International, Inc

Hunt Valley, Maryland USA

Summary of Capabilities

Development and Clinical/Commercial Drug Product Manufacturing Facility Facts

Pharmaceutics International, Inc. (Pii) is a science-driven contract development and manufacturing organization (CDMO) located in Hunt Valley, MD, USA, offering unparalleled scientific insight and depth of product knowledge to supply high-quality dosage forms that enhance the lives of patients worldwide.

Founded in 1994, Pii has grown from 12 employees to more than 270 scientists and support staff and over 360,000 square feet of operating space. Pii's cGMP and DEA-registered facilities are state-of-the-art and contain over 70 manufacturing suites, including containment areas for handling high potency compounds and hormones, dedicated manufacturing suites for oral products (e.g., soft gels) and injectables (e.g., vials, syringes, cartridges), a formulation development center, and state-of-the-art analytical and micro laboratories.

Business Longevity: 28+ years
Employees: 270
Regulatory Approval: FDA, EMA

Two approved commercial production facilities:
FEI# 1000513101
FEI# 3006503102

Potency Capability: Up to Band 5
(Note: each compound is individually evaluated through a rigorous EH&S program)

DEA Controlled Drug Manufacturer/Analytical Lab

Schedule Registrations: Schedules 1-5, L1

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pharm-int.com

Specialized Capabilities

OSD/oral liquids
- Formulation and bioavailability enhancement
- Handling capability for non-potent, potent, hormone, cytotoxics and DEA-Controlled Substances (Schedule I-V, L1)
- Soft gel capsules
- Liquid filled hard capsules (gelatin/HPMC)
- Tablets:
  - Tab-in-tab and bi-layer tableting
  - Mini, chewable, orally disintegrating, sublingual
- Immediate, modified, zero-order and pulsed release
- Top spray granulation
- Granulations (wet/dry; low and high shear)
- Hot melt granulation
- Coating, functional and film-coat (aqueous and solvent)
- Roller compaction
- Spray drying (R&D and clinical scale)
- Multi-particulates (fluid bed)
- API – polymer bead layering
- Oven drying and fluid bed drying
- Wet milling/nano milling
- Encapsulation:
  - Multi-pellets
  - Powder
  - Granulation
- Printing soft gel and tablets
- Stick-pack powder filling
- Clinical packaging and labeling (blisters, bottles)
- Oral liquids and suspensions into bottles
- Full analytical and microbiology support

Sterile Injectables
- Small molecule, biologic, potent, hormone drug products and DEA-Controlled Substances (Schedule I-V, L1)
- Highly viscous and difficult-to-formulate products
- Aseptic, fill/finish and terminal sterilization
- Lyophilization (R&D and GMP)
- Prefilled syringes (single chamber), vials, cartridges
- Labeling and packaging

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Lifecycle by Dosage Form

Dosage Forms	Early Development				Late Dev	Commercial Supply		
	Formulation Development	Analytical and Micro Development Validation	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Commercial Supply
Liquid vials	•	•	•	•	•	•	•	•
Lyophilized vials	•	•	•	•	•	•	•	•
Prefilled syringes	•	•	•	•	•	•	•	•
Cartridges	•	•	•	•	•	•	•	•
Tablets/Capsules/Soft gels/ Liquid filled hard capsules	•	•	•	•	•	•	•	•
Powders/Granules/Multi-particulates	•	•	•	•	•	•	•	•
Oral liquids/suspensions	•	•	•	•	•	•	•	•

Key Equipment List – Analytical and Micro Support

Equipment	
Analytical Method Development/Verification/ Validation and Testing	HPLC/UPLC testing with wide range of detection capabilities: UV, DAD, RI, ELSD, ECD, CAD, (Agilent and Waters)
	UV VIS Spectrophotometry (Agilent and Thermo Scientific)
	Dissolution Testing USP I, II (Vankel/Agilent), USP IV (Sotax)
	GC/Headspace (Agilent with Tekmar T3, Sample 80, G1888)
	Elemental Impurities (ICP-MS, Agilent 7700)
	Particle Size Determination by Laser Diffraction (Malvern Hydro 2000, Malvern 3000, Zetasizer Nano)
	FTIR Spectroscopy (Perkin-Elmer Spectrum 100)
	Color Instrumental Measurement (Hunter Lab UltraScan VIS)
	Break Loose/Glide Force Prefilled syringes (Instron Model 3342)
	Scanning Electron Microscopy (SEM-for non-GMP activities)
	Differential Scanning Calorimetry DSC (TA Instruments)
	TOC Analysis (Shimadzu)
	Specific Optical Rotation by Polarimeter (Rudolph Research Analytical)
	Melting Point (OptiMelt)
	Wet Chemistry Analysis
Micro Method Verification and Testing	**USP Testing**
	Microbial Enumeration <61>
	Test for Specified Organisms <62>
	Antimicrobial Effectiveness Testing <51>
	Sterility Testing <71>
	Bacterial Endotoxin <85>
	Particulate Matter in Injections <788>
	Container Closure Integrity Testing (CCIT) by Vacuum Decay <1207>

Key Equipment List – Solid Dose/Oral Liquid Dose

Equipment (Features / Scale)		Capsules	Powders, Granules & Beads	Tablets	Soft Gel/Liquids
Blending	V-Blenders of various sizes: 8 qt, 16 qt, 1 cu ft, 2 cu ft, 5 cu ft, 10 cu ft, 20 cu ft,	●	●	●	
	75 cu ft.; (~ 1KG- 700KG depending on bulk density)	●	●	●	
	V-shell processors (2 cu ft & 20 cu ft with intensifier bar and spray	●	●	●	
Kettles, Tanks	Lee “Tri-Mix” Turbo Shear Jacketed Kettle (200 gallon)				●
	Various tanks: 150L, 300L; OLSA 150L (jacketed)				●
	Bochang Gel Melter 400L, 1,000L and 2,000L				●
	Quadro Y Tron Mixer				●
	Rotor Stator				●
Granulation	Roller Compaction: Fruend TF156 with auger (20kg-30kg/hr) (Dry granulation)	●	●	●	
	Low Shear: Hobart 340 qt High Shear: TK Fielder 25L, 65L, 150L; AMF Glen-600L connected to 300L Fluid Air Granulator/Dryer (Fluid Air with heating and cooling system for drying and granulation up to 250KG)	●	●	●	
	Wurster Column coating for beads		●		
Milling and Sifting	Milling: Quadro Comil (194 & 197); Fitzmill Comminutor; Fryma Colloid Mill MZ80/A; Dyno-Mill (0.6L, 1.4L and 16.5L)	●	●	●	●
	Various size sieves, Weston Vibrating Sifter (24”)	●	●	●	●
Bead Manufacturing	Fluid Air 120L (Wurster column and top spray, solvent capable with oxidizer) Fluid Air 300L	●	●		
Extrusion/ Spheronization	Caleva Extruder (Model 25) and Caleva Spheronizer (Model 250)-small batch only	●	●	●	
Spray Drying	Niro Mobile Minor (aqueous and solvent capabilities (spray-rate 2kg/hr-7kg/hr) small scale and phase 1/2 support	●	●	●	
Drying	Fluid Air 120L, Fluid Air 300L	●	●	●	
	Oven drying (Electric + Steam)		●		●
	Temperature and RH controlled drying tunnels				●
Compression Tablets & Mini-Tabs	Kikusui Aquarius LD-A (Tab-in-Tab Tooling)			●	
	Aquarius G (B + D Tooling)			●	
	Kikusui Libra 2-2L (Bilayer) Sejong MRC-30N (D tooling 30 station) up to 216,000/hr Kikusui Libra (#6) (B tooling capable) Small-scale Fette and Key Tablet Press for R&D			●	
Coating	Driam Driacoater 8” and 24” pans (5kg to 25kg)			●	
	O’Hara Coating Pan 48” (80kg to120kg)			●	
	R&D O’Hara Labcoat LCMX (small scale with 12” and 17” pans) Gruenberg Drying Oven			●	
Liquid fill, Soft gel	Capsugel CFS-1200 for liquid fill- small scale programs (up to 1,200 caps/hr)				●
	Shionogi LIQFILL SUPER 40 (up to 40,000/hr into hard gelatin capsules) with bander Shionogi S100				●
	Bochang Encapsulator, 10-inch rolls, 3 oblong to 22 oblong, also ovals				●
Encapsulation Including Powder fill, Granulation fill, Multi-bead fill	Minicap semi-automated 50 & 100 (up to 1500 and 3000/hr) Zanasi IMA 40E and 40F (up to 40,000/hr) MG America MG2 Futura (up to 48,000/hr) MG America Suprema (up to 48,000/hr) IMA Adapta	●	●	●	
Oral Liquid Filler	Chase Logman Liquid Filler (20 bottles per min) Cozzoli Liquid Filler (12 bottles per min; semi-automated)				●
Printing (tabs/soft gels)	Hartnett Delta model (250,000 tablets /hr) Ackley Soft gel/tablet printer and Hartnett roller printer			●	●
Packaging	Blistering	●		●	●
	Bottles	●		●	●
	Bulk	●	●	●	●
	Equipment for packaging serialization (Trace-Link/Metler-Toledo)	●		●	●

Key Equipment List – Sterile Injectable Dose

Equipment (Features / Scale)		Liquid Vials	Lyophilized Vials	Syringes/Cartridges
Compounding	Stainless steel tanks, Disposable Pall Allegro Bag System (up to 1,000L), Glass Carboys Dedicated customer tanks	●	●	●
	Jacketed Tanks up to 1,000L	●	●	
Washing	Metromatic vial washer, pre-sterilized components; Pentech Rotary Vial Washer	●	●	
Depyrogenation	In line depyrogenation tunnel (Bosch commercial line); Gruenberg Depyrogenation Oven	●	●	
Component Sterilization and Drying	Fedegari Autoclave and Beta-Star Autoclave			
Vial Filling/Stoppering	M&O Perry Line— 3mL up to 100mL vials; Speed: 3mL-10mL up to 40 vials/min.; 20mL-50mL up to 30 vials/min; 100mL up to 12 vials/min; Batch size 1L to 500L or 50,000 units depending on size Two filling heads with stainless steel or single use disposable needles; third needle to support inert gas/nitrogen overlay prior to stoppering Rotary piston or peristaltic pump Can support viscous product filling and also lyo	●	●	
Lyophilization	Millrock CIP/SIP 60 sq ft Lyophilizer-3mL up to 50mL; Capacity from 3,000 units to 21,000 units, depending on vial size Supported by R&D Millrock REVO-PRO 8 sq ft unit for cycle development and seamless transition to GMP scale up SEM and modulated DSC capabilities for evaluation/testing		●	
Clinical/Commercial Scale Vial Filling/Stoppering	BOSCH Line-3mL up to 100mL vials; Speed: up to 120 vials/min depending on size; Batch size up to 1,000L or 300,000 vials depending on vial size; Eight filling heads with stainless steel or single use disposable needles; in-line nitrogen overlay post filling; Rolling diaphragm pump Ready-to-use or Ready-to-sterilize components using Pentech Rotary Vial washer and Steriline Depyrogenation tunnel integrated to filler Can support viscous product	●		
Syringe Filling	Groninger DFVN 1000 Line-0.5mL up to 5mL syringes; 100 nest pre-sterilized syringes; 0.5mL up to 41 syringes/min; 1mL up to 32 syringes/min; 5 mL up to 20 syringes/min; up to 42,000 syringes per batch depending on syringe size Single head needle with pre and post inert gas overlay Rotary piston or peristaltic pump (Stainless or disposable) Can support breakthrough/glide-force testing in house Can support highly viscous product filling			●
Robotic Filling/ Closing Line AST GENiSYS® R20	Supports ready-to-fill vials, syringes and cartridges in nested configurations; currently qualified to support 2R, 6R, 20R vials, 1mL syringe and 3mL cartridges; other size components can be considered, depending on timing for change parts Fully robotic automation with Adaptable Class 100 RABS-Grade A; Speed: 10-20 units/min.; Batch sizes up to 5,000 units/day Peristaltic and Rotary Piston pumps Continuous 100% in-process weight check system (non-destructive) Electronic balance eliminates loss of drug product and waste to maximize product yield Integrated Electronic Batch Report System	●		● includes cartridges
Terminal Sterilization	Fedegari Air Over Pressure Autoclave (2); Beta-Star Autoclave	●	●	
Capping	M&O Perry capper for both vial lines (M&O Perry and BOSCH)	●	●	
Inspection	Semi-Automated Inspection Units-Dabrico (2)	●	●	●
	Manual Inspection	●	●	●
Packaging	Vial Labeling and Cartoning - Serpa	●	●	
	Manual Packaging Processes for Syringes and Cartridges	●	●	●
	Packaging serialization for vials	●	●	

* For detailed equipment information, please contact your PII representative.
* BATCH sizes are not necessarily related to scale, batch size requirements are dependent on the project details and current media fill qualifications