



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 300 scientists and support staff and over 300,000 square feet of operating space across Pii's campus and 4 Centers of Excellence.

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, oral liquids & suspensions) and injectables (e.g., vials, syringes, cartridges), a formulation development center, and analytical and micro laboratories.

Business Longevity: 30+ years

Employees: 300

Regulatory Approval: FDA, EMA

Two approved commercial production facilities:

- FEI# 1000513101
- FEI# 3006503102

Potency Capability: Up to Band 4

(Note: Each compound is individually evaluated through a rigorous EH&S program)

DEA Controlled Drug Manufacturer/Analytical Lab

Schedule Registrations: Schedules I-V, L1

Contact Info: 10819 Gilroy Road
Hunt Valley, MD 21031
USA
Tel: +1 410-584-0001
pharm-int.com

Specialized Capabilities

Oral Dosage Forms

- Formulation and bioavailability enhancement
- Handling capability for non-potent, potent, hormone, cytotoxics and DEA-Controlled Substances (Schedule I-V, L1)
- Soft gel capsules
- Hard capsules (gelatin/HPMC)
 - Powder
 - Pellets
 - Liquid
- Tablets
 - Tab-in-tab and bi-layer tableting
 - Mini-tab, chewable, orally disintegrating, sublingual
- Coating, functional and film-coat (aqueous and solvent)
- Printing soft gel and tablets
- Immediate, modified, zero-order and pulsed release
- Fluid Bed (Solvent Capable)
 - Top spray granulation
 - Wurster coating (pellet/API/powder)
- Granulations (low and high shear)
 - Wet/Dry
 - Hot melt
- Roller compaction
- Spray drying (clinical scale)
- Drying (Oven & Fluid Bed)
- Milling
 - Wet / Nano
 - Powder
- Stick-pack filling
- Packaging and Labeling (bottles, blisters)
- Oral Liquids and Suspensions into bottles
- Full Analytical and Microbiology support

Sterile Injectables

- Small and Large molecules
- Non-potent and potent drugs including cytotoxics and hormones
- DEA-Controlled Substances (Schedule I-V)
- Complex processes and formulations, including viscous products
- Aseptic fill/finish and terminal sterilization
- Lyophilization (R&D and GMP)
- Pre-filled syringes (single chamber), vials, cartridges
- Labeling and Packaging

Lifecycle by Dosage Form

Dosage Forms	Early Development			Late Dev			Commercial Supply		
	Formulation Development	Analytical & Micro Development Validation	Phase I	Phase II	Phase III	Commercial Scale-Up	Tech Transfer	Commercial Supply	
Liquid Vials	●	●	●	●	●	●	●	●	
Lyophilized Vials	●	●	●	●	●	●	●	●	
Pre-Filled Syringes	●	●	●	●	●	●	●	●	
Cartridges	●	●	●	●	●	●	●	●	
Tablets / Capsules / Soft Gels Liquid Filled Hard Capsules	●	●	●	●	●	●	●	●	
Powders/Granules/ Multi-particulates	●	●	●	●	●	●	●	●	
Oral Liquids / Suspensions	●	●	●	●	●	●	●	●	

Key Equipment List - Analytical & Micro Support

Equipment	
Analytical Method Development/Verification/Validation and Testing	HPLC/UPLC testing with wide range of detection capabilities: UV, DAD, RI, ELSD
	UV VIS Spectrophotometry (Thermo Scientific)
	Dissolution Testing USP I, II (Vankel/Agilent), USP IV (Sotax)
	GC/Headspace (Agilent with Tekmar T3, Sample 80, G1888)
	Ion Chromatography (Dionex with Conductivity Detector)
	ICP-MS for Elemental Impurities (Agilent 7700)
	Particle Size Determination by Laser Diffraction (Malvern 3000, Zetasizer Nano)
	FTIR Spectroscopy (Perkin-Elmer Spectrum 100)
	Color Instrumental Measurement (Hunter Lab UltraScan VIS)
	Break Loose / Glide Force Pre-Filled 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 & 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	Oral Liquids & Suspensions
Blending	V-Blenders of various sizes: 4 qt, 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: Freund 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; Dyno-Mill (0.6L [R&D]; 1.4L and 16.5L)	●	●	●	●	
	Various size sieves, Weston Vibrating Sifter (24")	●	●	●	●	
Bead Manufacturing	Fluid Air 120L & Fluid Air 300L (Wurster column and top spray, solvent capable with oxidizer)	●	●			
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 I & II support)	●	●	●		
Drying	Fluid Air 120L, Fluid Air 300L	●	●	●		
	Gruenberg 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 Key Tablet Press for R&D (B3B Manesty, DC-16)			●		
Coating	O'Hara Coating Pan 48" (80kg to 120kg)			●		
	R&D O'Hara Labcoat LCMX (small scale with 12" and 17" pans)			●		
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/hr and 3000/hr)	●	●	●		
	Zanasi IMA 40E and 40F (up to 40,000/hr)	●	●	●		
	Zanasi IMA 48F (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 Logeman Liquid Filler (20 bottles/min) Cozzoli Liquid Filler (12 bottles/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 (~40 blisters/min) – for small scale / clinical programs	●		●	●	
	Swift Pack Counter / Slat Counter Bottle Filler (18 bottles/min) for potent product With Cotton, Capper, Sealer, Torque, Labeler, Re-Torque	●		●	●	
	Cremer Tablet/Capsule Counter Bottle Filler (10 bottles/min) for non-potent product With Cotton, Capper, Sealer, Torque, TopSert, Labeler, Re-Torque	●	●	●	●	
	Serpa Cartoner for Bottles and Vials (20 cartons/min) With Insert and Labeler	●	●	●	●	●
	Cam Cartoner for Blister Cards (50 cartons/min) ; With Inserts	●		●	●	
	Equipment for Packaging Serialization (Trace-Link/Mettler-Toledo)	●		●	●	
	Bulk (manual)	●	●	●	●	●

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	●		●
	Penntech Rotary Vial Washer	●		
Depyrogeneration	Steriline In-line Depyrogeneration Tunnel (Bosch Commercial Line)	●		
	Gruenberg Depyrogeneration Oven	●	●	●
Component Sterilization and Drying	Fedegari Autoclave	●		●
	Beta-Star Autoclave	●	●	●
M&O Perry® Vial Filling Line	<ul style="list-style-type: none"> M&O Perry Line - 3mL up to 50mL vials; Speed: 3mL-10mL up to 40 vials/min; 20mL-50mL up to 30 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 Supports Viscous Product Filling 	●	●	
Millrock Technology® Lyophilization	<ul style="list-style-type: none"> Millrock CIP/SIP 60 sq ft Lyophilizer - 3mL up to 50mL; Integrates with M&O Perry® Vial Filling Line Capacity from 3,000 units to 20,000 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 Lyophilization of products from 3mL to 50mL 		●	
BOSCH High Speed Vial Filling	<ul style="list-style-type: none"> BOSCH Line - 3mL up to 50mL vials; Speed: up to 100 vials/min depending on size; Batch size up to 1,000L Eight filling heads with stainless steel or single-use disposable needles In-line Nitrogen Overlay Post Filling Rolling diaphragm pump Ready-to-Sterilize components using Penntech Rotary Vial Washer and Steriline Depyrogeneration tunnel integrated to filler Supports Viscous Product Filling and supports Oxygen Sensitive Products 	●		
Groninger Pre-filled Syringe (PFS) Line	<ul style="list-style-type: none"> Groninger DFVN 1000 Line - 1mL up to 5mL syringes; 100 nest pre-sterilized syringes 1mL up to 32 syringes/min; 5 mL up to 20 syringes/min Up to 50,000 syringes per batch depending on syringe size Single head needle with pre- and post-inert gas overlay Rotary piston pump Breakthrough / glide-force testing in-house Supports Highly Viscous Product Filling and Low Fill Volumes 			●
AST GENISYS® R20 Robotic Filling Line (Vials, Pre-filled Syringes, & Cartridges)	<ul style="list-style-type: none"> Supports ready-to-fill vials, syringes and cartridges in nested configurations Capabilities include 2R, 6R, 10R, 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 Capable of (non-destructive) in-process weight checks 	●		● includes cartridges
Terminal Sterilization	Fedegari Air Over Pressure Autoclave; 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 (Development programs only)			●
	Packaging Serialization & Aggregation 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.