



Summary of Capabilities

Whitby, ON Canada

Facility Facts:

PDS Workforce: ~70

Commercial Workforce: ~500

Regulatory Approval: US FDA, US DEA, Health Canada,

ANVISA, Turkish MOH, Taiwan Health Authority, Gulf Central Committee, Korea, Russian Authority, EMEA

Mutual Recognition

Potency Capability: Cat 1 & 2

Controlled Drug

Schedule Registrations: Manufacturer / Analytical Lab CI – CV

Distribution / Import/ Export CIII – CV

Contact Info: 111 Consumers Drive

Whitby, Ontario L1N 5Z5

Canada

Tel: 905-668-3368 Fax: 905-666-4984

Unique Offering:

Explosion-Proof Manufacturing, Controlled Substance Manufacturing, Small Scale Commercial, all packaging lines serialization-ready

Specialized Capabilities:

- Multi-layer tablets
- Non-Sterile Solutions / Suspensions
- Roller Compaction
- Sachet Products
- Solvent Granulation
- Large Scale Manufacturing

Lifecycle by Dosage Form

Dosage Forms		Early Development			ate Dev	Commercial Supply		
		Analytical Development	Phase I	Phase II	Phase III	Commercial Scale Up	Tech Transfer	Regulatory
Tablet/Capsule	•	•	•	•	•	•	•	•
Solutions/Suspensions	•	•	•	•	•	•	•	•
Powders/Granules	•	•	•	•	•	•	•	•

Whitby Key Equipment List - Development Scale

	Equipment (Features / Scale)	GMP
Blending	V-Blender (1 – 60 L)	•
Granulation	Gerteis Macropactor (with side feed port for small scale)	•
	High Shear Granulator (Key KG-5 / 1 – 5 L bowls – PMA 65)	•
	Mill	•
Drying	Fluid Bed Dryer/Granulator (Aeromatic Fielder STREA-1, Aeromatic S2)	•
Compression	Korsch XL100 10 Station Tablet Press	•
Coating	Tablet Coater (12" – 30")	•
Encapsulation	Encapsulators (2- Manual) Size 00-4	•
Packaging	Blistering	•
	Bottles	•
	Bulk	•
	Sachet	•
	Non-sterile liquid filling	•
Non-sterile compounding	Mixing / Holding tanks	•
	Homogenizer	•

Whitby Key Equipment List - Commercial Scale

	Equipment (Features / Scale)	Capsules	Powders & Granules	Solutions & Suspensions	Tablets
Blending	Ribbon Blender (425 – 1800 L)	•	•		•
	V-Blender (60 – 850 L)	•	•		•
	Tumble Blender (283 – 4000 L)	•	•		•
Granulation	Roller Compactor (Alexanderwerk, Gerteis)		•		•
	High Shear Granulator (PMA600, PMA1200)	•	•		•
	Mill	•	•		•
Drying	FBD/Granulator (Aeromatic T8A, Niro S6, Vector, Glatt)	•	•		•
	Drying Ovens	•	•		•
Compression	Tablet Presses (Korsch, Hata, Fette)				•
Coating	Tablet Coater's (48" Accela-cota, 60" Accela-cota, O'hara)				•
Non-sterile Compounding	Mill			•	
	Jacketed Tanks (100 - 8,000 L)			•	
	Mixing/Holding Tanks (500 – 8,000 L)			•	
	Homogenizer			•	
Filling	Liquid Filling Line (Cozzoli)			•	
Encapsulation	Encapsulators (H&K1200, H&K1500, Anritsu checkweigher)	•			
Packaging	Blistering	•			•
	Bottles	•		•	•
	Bulk	•	•		•
	Sachet		•		

 $^{^{\}star}$ For detailed equipment information please contact your Thermo Fisher Scientific representative.



^{*} Minimum and maximum batch sizes are not necessarily related to scale, batch size requirements are dependent on the project details.