



Summary of Capabilities

# Toronto, ON Canada

**Facility Facts:** 

PDS Workforce: ~160

Commercial Workforce: ~730

Development Area: 43,960 ft<sup>2</sup>

Commercial Area: 263,000 ft<sup>2</sup>

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

ANVISA, COFEPRIS, KFDA, EMEA,

MoH (Turkey)

Potency Capability: Up to Cat 3b

Controlled Drug Canadian OCS

Schedule Registrations: Controlled Drugs License

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## **Unique Offering:**

High Potency and Fixed Dose Combinations

#### **Specialized Capabilities:**

- Oral Disintegrating Tablet (ODT)
- Low Solubility
- Roller Compaction
- Bilayer/Microtabletting
- Spray Granulation
- Low Humidity Processing
- High Potency Manufacturing

#### Lifecycle by Dosage Form

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

### **Toronto Key Equipment List - Development Scale**

	Equipment (Features / Scale)	Capsules	Powders & Granules	Tablets
Blending	V-Blender s (142L/5 cu. Ft., with intensifier bar)	•	•	•
	Galley Tote Bins (113 – 1500)	•	•	•
Compounding	Jacketed Kettles (15 – 300L)			
	Mixers / Homogenizers			
Granulation	Roller Compactor (Gerteis, Vector TFC-220, mini-pactor/macropactor)	•	•	•
	High Shear Granulator (PMA, 1 – 300 L)	•	•	•
	Milling (Quadro), Screening (Russell, Kason)	•	•	•
Drying	Fluid Bed Dryers / Granulators (Aeromatic S1, S2, S4)	•	•	•
Compression	Tablet Presses (Manesty monolayer Belopress – 16 stations, Korsch XH12 D tooling – B layer/Single layer – 18 stations, 10 station, 12 station D, 16 station B, Courtoy Modul S, microtableting) Picoola monolayer – 10 stations (B tooling)			•
	Bi-layer (11 station, 18 station D)			•
Coating	Tablet Coaters (12" - 36")			•
Encapsulation	Encapsulators (4)	•		
	Tamping, Dosing	•		
Packaging	Blistering	•		•
	Bottles	•	•	•
	Bulk	•		•

## **Toronto Key Equipment List - Commercial Scale**

	Equipment (Features / Scale)	Capsules	Powders & Granules	Tablets
Blending	V-Blender (1 – 142 L, V-5) maximum with intensifier bar	•	•	•
	Galley Tote Bin (113 – 1500 L)	•	•	•
Granulation	Roller Compactor (Gerteis Macropactor C) Gerteis Minipactor/ Macropactor	•		•
	High Shear Granulator (PMA: 65, 300, 400, 800, 1200)	•	•	•
	Top Spray Granulation (S4, S6, MP7)	•	•	•
	Milling (Quadro, Fitzpatrick), Screening (Russell, Kason, Flex sift)	•	•	•
Drying	Fluid Bed Dryer/Granulator (Aeromatic S2, S4, S6, MP6, MP7)	•	•	•
Compression	Tablet Press (Korsch x2, 29D-35B, Courtoy x2)			•
Coating	Tablet Coater (24" - 60")			•
Encapsulation	Encapsulators (3) Gerteis Minipactor/Macropactor	•		
	Tamping	•		
Packaging + Serialization Certon and bottle label serialization	Blistering (thermo form and cold form)	•		•
	Bottles	•	•	•
	Bulk	•	•	•

<sup>\*</sup> For detailed equipment information please contact your Thermo Fisher Scientific representative.



<sup>\*</sup> Minimum and maximum batch sizes are not necessarily related to scale, batch size requirements are dependent on the project details.