



## Italy Isso, Bergamo

## **Facility Facts**

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Workforce: ~110 Capacity: 130 m³

Potency Capability: OEL > 1 μg/m<sup>3</sup>

## **Offerings**

- Production scales ranging from kilos to MTs
- Process optimization, non-cGMP demo batches
- Analytical method development and validation
- · Process safety studies
- cGMP scale-up and commercial manufacturing
- Design of Experiment and Quality by Design studies
- Regulatory Submission
- AIFA inspected

## **Summary**

Flamma's Isso facility was acquired in 2012 to help provide more capacity close to our Chignolo headquarters. Significant upgrades have continued since this time including the installation of new R&D labs, containment labs, press filter dryers, upgraded reactors, and much more. As we look towards the future, a recent land purchase will allow for future expansion.

The Isso site has similar capacity to Chignolo but it also has some unique capabilities for customers. The ability to handle thionyl chloride can be accomplished at Isso in a dedicated workshop (BTC Box). There is also technology to handle anhydrous and liquid ammonia as well as cryogenic capabilities to -90°C.

Initial & Early Development					Late stage	Commercial Supply			
Analytical Development	Process Development	Pre-clinical	Phase I	Phase II	Phase III	Tech Transfer	Commercial Scale-up	Regulatory	
•	•	•	•	•	•	•	•	•	

		ISSO EQUIPA	Initial & Early Development			Late stage		
Location on-site	Detailed location	Activity or Equipment Overview	Further Detail	Process Development	Analytical Development	Pre-clinical to Phase I/II	Phase III	Commercial
cess and Ana			Glass reactors (up to 7 L), -90°C to +150°C	•		•		
		Organic Synthesis Development	High Pressure Capabilities (up to 5 L) @10 bar	•		•		
	ent		Mettler Toledo OptiMax (up to 1L)	•		•		
	Process Development	Reaction Calorimetry/Safety	PE double-furnace, power compensation DSC 8000, Mettler Toledo OptiMax HFCal Reaction Calorimeter, Mettler Toledo RC1e Process Safety Workstation			•		
		Solid State	Mettler Toledo Particle Track FBRM G600, Mettler Toledo Particle View V19, Horiba Laser Scattering Particle Size Distribution Analyzer, Rigaku Miniflex XRPD	•		•		
		Monitoring	HPLC, LCMS, KF, GC, UPLC, NMR, XRPD, Mettler Toledo ReactIR 15			•		
	HP Suite	Bench top hood with Process Development Isolator	1 x Wet Chemistry up to 2-3 L (balances and vacuum oven built into isolator; containment performance up to OEL 0.1ug/m³)	•		•		
	Analytical	Analytical Development	HPLC/UPLC (UV, MS, DAD), GC (FID, MS), NMR, LOD, KF, FT-IR, DSC, titration, melting point, Chromosword software	•	•	•		
		Glass Lined Reactors	10 (from 3,000 L to 9,000 L, -20°C to +150°C			•	•	•
		Stainless steel 316 Reactors	8 (from 5,000 L to 8,000 L , -20°C to +150°C)*			•	•	•
		Stainless steel 316 Reactor	1 6,000 L , -90°C to +150°C)			•	•	•
Production Plant		Centrifuges	5 total- Stainless steel (SS) 1,250 mm (3); Halar coated (2) 1,250 mm			•	•	•
		Press Filter Dryer	2 total- SS (with active glovebox) 2,000 mm (3,000 L); 1,900 mm (2,800 L)	•		•	•	•
	Plant	Other dryers	3 total- SS double cone dryer (4,000 L); Hastelloy double cone (2,000 L); SS static tray dryer (50 kg max)			•	•	•
	tion	Milling/Blending	Manual Screening, Delumper	•		•	•	•
	roduc	Containment Equipment	Drum loader with isolator, Powder Transfer System, Continuous liner			•	•	•
	В	Cryogenic capabilities	Reactor (stainless steel 316) 5,000 L, -90 °C via direct liquid nitrogen in the jacket	•		•	•	•
		Special technology	Thionyl chloride handling technology (BTC Box); Liquid and gas anhydrous ammonia handling; Hydrogen (low pressure); Organometallics in solution distribution line, Cryogenic system for methylene chloride off-gas abatement, Storage capability: 15-25°C, 2-8°C, -20°C			•	•	•
		Temperature range & vacuum	From -90°C to 150°C, full-vacuum to 6 barg			•	•	•
QC	Analytical	Analytical Equipment	HPLCs (UV, DAD), GCs (FID), FTIR, KF Volumetric, Polarimeter, UV-VIS, Melting Point, Thermobalance, TOC	•	•	•	•	•

<sup>\*</sup> Hydrogenation 6,000L SS (to 5 bar)