ITALY
Chignolo d'Isola | Bergamo

FACILITY FACTS

Contact info: Via Bedeschi 22
24040 Chignolo d'Isola
(BG) Italy
Phone: +39 035 4991811
Workforce: ~240
Capacity: 140 m^3
Potency
Capability: OEL > 1 µg/m^3

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
- FDA and AIFA inspected

SUMMARY

The Headquarters of Flamma, the Chignolo site is a modern pharmaceutical manufacturing facility located outside of Milan, Italy. The site contains a cGMP Pilot Plant to deal with projects needing smaller volumes or to assess the process prior to moving into the large scale Production Plant that is monitored and directed by a computer assisted system. Coupled with the solid state group that helps to develop robust and reproducible crystallization procedures as well as a risk assessment group, the R&D team helps to move projects along quickly and safely. Flamma continues to invest in itself to provide customers with not only what they expect but what they deserve. The Chignolo site has significantly expanded its R&D capabilities, with the new R&D building opened in 2023 providing additional space and capacity to support process and analytical development. Flamma has also invested in containment with the addition of multiple Filter Dryers along with an Inverted Basket Centrifuge for difficult to filter materials. The addition of Powder Transfer System (PTS), continuous liners, glove boxes, and more helps protect personnel and provides high quality APIs for clinical supply under cGMP conditions.

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
■	■	■	■	■	■	■	■	■

CHIGNOLO EQUIPMENT OVERVIEW				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
Process and Anal. R&D Labs	Process Development	Organic Synthesis Development	Glass jacketed reactors with overhead stirrer (up to 3 L), -90°C to +150°C	■		■		
			Pressure Reactor (10 bar, up to 250 ml)	■		■		
			OptiMax (up to 1 L) Hitech Zhang Lab. Automated Dosing Unit	■		■		
		Reaction Calorimetry/Safety	OptiMax HFCal, DSC, TSU	■		■		
		Flow chemistry	MicroInnova Plug Flow + CSTR (MTP) Chemtrix Microreactor (KiloFlow) Zaiput Membrane Separator, Multistage Extraction	■		■		
		Monitoring	HPLC/UPLC (UV, MS, DAD, CAD CORONA), GC (FID, MS), NMR, LOD, KF, DSC, Titration	■		■		
	Highly Potent	Bench top hood with Process Development Isolator	1 x Wet Chemistry up to 1 L (containment performance up to OEL 0.1ug/m^3)	■		■		
	Analytical	Analytical Development	HPLC/UPLC (UV, MS, DAD, CAD CORONA), GC (FID, MS), Prep HPLC, NMR, LOD, KF, Titration, Chromsword and Fusion aQbD softwares, DSC	■	■	■		
Production	Kilo Lab	Glass Reactors	2 (from 40 L to 80 L, -20°C to +150°C)	■		■		
		Glass Filter Dryer	1 (60 L)	■		■		
	Pilot Plant	Glass Lined Reactors	3 (from 600 L to 2000 L, -15°C to +140°C)	■		■	■	■
		Stainless Steel 316 Reactors	1 (1,500 L, -40° to +140°C)	■		■	■	■
		Hastelloy Reactors	1 (600L, -40°+140°C)	■		■	■	■
		Hastelloy Filter Dryers	1 (230 L, 650 mm diameter) with glove box	■		■	■	■
		Stainless Steel Centrifuges	1 (handling up to 60 kg)	■		■	■	■
		Stainless Steel Tray Dryers	1 (1 m^3)	■		■	■	
		Fractional distillation equipment	SS 316, boiler of 1700 liters, 2 columns, suitable for production scale	■		■	■	■
		Continuous Flow	pyrolysis equipment	■		■	■	■
		Containment Equipment	1 Isolator, 2 Powder Transfer System, 1 Continuous Liner for packaging	■		■	■	■
	Production Plant	Glass Lined Reactors	13 (from 1,200 L to 7,000 L; volume 62,500 L)	■		■	■	■
		Stainless Steel 316 Reactors	12 (from 1,000 L to 7,000 L; volume 67,200 L)	■		■	■	■
		Stainless Steel 304 reactor	1 (3,000 L)	■		■	■	■
		Hastelloy Reactors	1 (7,700 L)	■		■	■	■
		Centrifuges	2 x 1500 mm diam. SS 316 bag-lifting, 2 x 1500 mm diam. Hastelloy bag-lifting, 1 x 1250 mm diam. Hastelloy bottom discharge, 1 x 700 mm diam. SS 316 horizontal inverting bag; 1 x 1300 mm diam. SS 316 horizontal peeler, 1 x 1300 mm diam. Hastelloy horizontal peeler	■		■	■	■
		Nutsche Agitated Filter Dryers	1 x Hastelloy 1400 mm diameter with glove box, 1 x Hastelloy 1600 mm diameter with glove box 1 x SS 316 1600 mm diameter 1 x SS 316 1800 mm diameter with glove box	■		■	■	■
		Other dryers	1 conical SS 316 2500 L, 1 conical Hastalloy 2500 L, 1 SS 316 horizontal paddle 1600 L, 1 SS 316 horizontal paddle 2500 L	■		■	■	■
		Milling/Blending	Pin mill, Mill, Cone mill, F10 Quadro grind mill system	■		■	■	■
		Containment Equipment	2 Isolators with drum loader, 4 Powder Transfer Systems, 5 Continuous Liners for packaging	■		■	■	■
		Cryogenic capabilities	4 Reactors 6000 L (Diathermic oil to -45°C)	■		■	■	■
		Special Technology	1 Hydrogen loading station, 1 Organometallic loading station, 1 Falling thin film evaporator, 6 Automated Dosing Tanks (3 SS 316, 3 Glass-lined - from 1600 L to 2000 L)	■		■	■	■
		Temperature range & vacuum	From -40°C to 120°C, full-vacuum to 6 barg	■		■	■	■
QC	Analytical	Analytical Equipment	HPLCs (UV, DAD, ELSD, MS), GCs (HS-FID, MS), ICP-MS, IC, FTIR, Potentiometric titrators, KF Volumetric, KF Coulometric, Polarimeter, UV-VIS, Melting Point, PS Determination	■		■	■	■

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