



China Flamma Honkai, Dalian

Facility Facts

Contact info: Jing 11 Road

Songmudao Chemical Industry Park

Puwan New Area, Dalian, China

Phone: +86 411 62395598

Workforce: ~250 Capacity: 200 m³

Potency Capability: OEL > 1 μ g/m³

Offerings

- Production scale ranging from grams to kgs to 10s of MTs
- Process optimization, non-cGMP demo batches
- RSMs, NCEs, key starting materials
- Analytical method development and validation
- 100% owned and managed by Flamma
- Strong material sourcing department
- Chinese FDA (NMPA) inspected, cGMP certified
- Drug manufacturing license

Summary

Flamma Honkai (Dalian) Pharmaceutical Co., Ltd. is a respected and well established Flamma facility within China. Located within the Songmudao Chemical Park outside of Dalian, this area, known as the Jinpu New District, was awarded the prestigious Special Development Status from the Central Government. Having the advantage of being located on the coast of China, Flamma Honkai is easy to visit via air as it is close to Seoul (1 h 15 min.), Beijing (1.5 h), Shanghai (2 h), and Tokyo (3 h).

Flamma has continues to heavily invest in its Honkai site. It added a cGMP workshop in 2017 and is currently completing the construction of Honkai 2 which will add eventually an additional 600 m³ of capacity. Investments of over \$75M into the site shows Flamma's commitment to a first-class overseas operation that is 100% owned and managed. While many fear working in China, Flamma offers security in knowing who you are working with.

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	
•	•	•	•	•	•	•	•	•	

HONKAI EQUIPMENT OVERVIEW						Initial & Early Development		
Location on-site	Detailed location	Activity or Equipment Overview	Further Detail	Process Development	Analytical Development	Pre-clinical to Phase I/II	Phase III	Commercial
abs.	Process Development	Organic Synthesis	Glass reactors (up to 30 L), -90°C to +150°C	•		•		
%D1	dolə	Development	High Pressure Capabilities (up to 1 L) @10 bar	•		•		
E E	Dev	Safety Study	Optimax, DSC	•		•	•	•
ytica	sess	Containment Equipment	Glove box	•		•	•	•
Anal		Monitoring	HPLC, LCMS, KF, GC, GC-HD, UPLC, NMR	•	•	•		
Process/Analytical R&D Labs	Analytical	Analytical Development	HPLC/UPLC (UV, MS, DAD), GC (FID, HD), NMR, LOD, KF, Titration, melting point	•	•	•		
		Glass Lined Reactors	20 (from 200 L to 5,000 L, -20°C to +150°C	•		•	•	•
Production Production Plant		Stainless steel 316 Reactors	9 (from 500 L to 5,000 L , -20°C to +200°C)			•	•	•
	ır L	Centrifuges	7 total: SS, 600 mm; Halar coated, 1,050 mm + 1,250 mm; HC22Alloy, 1,050 mm (2); Titanium, 1,250 mm (2)	•		•	•	•
	ction Pla	Press Filter Dryer	3 X Filter Dryers: SS, 3,400 L (1,800mm), Hastelloy, 3,400 L (1800mm); Hastelloy, 200 L (600mm)	•		•	•	•
rodi	npo	Other dryers	3 X Double cone dryers: SS, 2,000 L	•		•	•	•
	2 Pr	Milling/Blending	Cone miller	•		•	•	•
	M2	Containment Equipment	Glove box, Powder Transfer System, Continuous liner			•	•	•
		Cryogenic capabilities	-80°C direct liquid nitrogen in jacket; -30 °C direct refrigeration	•		•	•	•
		Temperature range & vacuum	From -80°C to 240°C, full-vacuum to 40 bar	•		•	•	•
ا Plant		Glass Lined Reactors	12 (from 3,000 L to 10,000 L, -19°C to +200°C)	•		•	•	•
		Stainless steel 316 Reactors	7 (from 3,000 L to10,000 L , -19°C to +200°C)	•		•	•	•
		Hydrogenation	SS 2,000 L (20°C to +200°C, 0 to 40 bar) Hastelloy 670 L (20°C to +200°C, 0 to 40 bar)	•		•	•	•
	M3 Production Plant	Centrifuges	4 total: SS (3) 1,250 mm (2) + 1,050 mm; Halar coated, 1,050 mm			•	•	•
Production	luction	Press Filter Dryer	3 total: SS, 3,400 L (1,800 mm) + 2,100 L (1,400 mm); Hastelloy, 3,400 L (1,800 mm)	•		•	•	•
Pro	3 Prod	Other dryers	Single cone (2): SS, 3,000 L + Hastelloy 3,000 L; Paddle: SS, 2,000 L; Box: SS, 1,400 L			•	•	•
	×	Milling/Blending	Screening, hammer miller with temp. control			•	•	•
		Containment Equipment	Glove box, DCS, Continuous liner -80°C direct liquid nitrogen in jacket;			•	•	•
		Cryogenic capabilities	-15 °C direct refrigeration			•	•	•
	_	Temperature range & vacuum	From -80°C to 150°C, full-vacuum to 40 bar			•	•	•
QC	Analytical	Analytical Equipment	HPLCs (UV, DAD),UPLC, GC (FID), GC- HS,FTIR, Titrator, KF, Polarimeter, UV-VIS, Melting Point, Thermobalance, IC	•	•	•	•	•