



# Florence (East), SC, USA

## Facility Facts:

Workforce:	~250
Regulatory Approval:	FDA, EMA, PMDA, Health Canada
Potency Capability:	Up to SafeBridge Cat. 3B
Contact Info:	6173 E Old Marion Hwy, Florence, SC 29506, USA Tel: +1-843-629-4300

## Unique Offering:

Flexible drug substance manufacturing site offering highly potent compound handling, process development and scale-up. Large-scale and mid-scale API production. Capabilities in solid state chemistry and micronization. The facility is fully compliant with all applicable regulations and meets the most stringent production, quality, cGMP (current Good Manufacturing Practices), safety and environmental standards.

## Offerings:

- Reactors ranging from 50–11,400 liters.
- Wide range of temperature (-100 to 165°C) and pressure (0–50 bar) control, which allows for the processing of different kinds of materials (e.g. strong base and acid) and special operations.
- Specialty technologies such as falling thin film distillation, continuous extractions, special solid charging techniques, and PAT.
- Four flexible Multipurpose Production Units (MPU) and a total reactor capacity of 34,000 gallons (130,000 L).
- Commercial Spray Drying
- Each MPU includes: Six reactors, two centrifuges and a dryer, associated vacuum pumps, vent condensers, scrubbers, portable filters.
- 2 milling suites and 1 additional drying suite.
- Pilot Plant Production
- Lab Space and Glassware

## Pilot Plant Facility

- Building (800) is a GMP multipurpose pilot plant facility intended for the manufacture of toxicology (pre-clinical) and clinical API and commercial.
- There are three (3) flexible Multipurpose Production Units (MPU) which allow for both single batch and isolation batch processing as well as “train” batch processing to mimic the commercial building. A 4th vacant MPU unit exists for future expansion of the facility.
- The pilot plant contains the Highly Active Substance (HAS) mini-plant and laboratory areas for potent compound processing and handling.
- The Alloy Bay allows for both cryogenic and/or high pressure reactions.
- Milling Suites within the pilot plant facility are available for solid state work (see list of milling capabilities above).
- The physical separation of MPUs allows for simultaneous production of different products with no risk of cross-contamination.

## Building 800 Major Equipment List

	30/50 MPU	100 MPU	100/300 MPU	HAS Mini-Plant*	Alloy Bay
Reactor Configurations	1 x 30 gal 2 x 50 gal 2x 100 gal	1 x 50 gal 2 x 100 gal	1 x 50 gal 1 x 100 gal 3 x 300 gal	2 x 60 L 1 x 100 L	1 x 30 gal 1 x 50 gal
Temperature	-30 °C to 180 °C	-30 °C to 180 °C	-30 °C to 180 °C	-30 °C to 180 °C	-100 °C to 250 °C
Pressure	Up to 4.0 bar	Up to 4.0 bar	Up to 4.0 bar	Up to 0.5 bar	Up to 41 bar
Solid Isolation	Unit	Unit	Unit	Agitated Filter Dryer	Mobile Unit

\*Containment capabilities sufficient to meet HHC 3B

## Small Scale Manufacturing

- There are two small scale manufacturing suites.
- Each dedicated manufacturing suite is equipped with 50–200 L glass reactors, chromatography columns, a centrifuge, and dryer.

### Small Scale Manufacturing Major Equipment List

Plant (MPU)	Capacity	Material of Construction	3A Containment (1 µg/m³)	Other
5th floor suite	1 – 30L Reactor	Stainless Steel	N/A	Most equipment rated for 7psi / Chromatography columns / Centrifuges are equipped with flexible containment technology
	3 – 45L Reactor / Distillers	Glass		
	1 – 5L Reactor	Glass		
	1 – 15L Reactor	Glass		
	2 – 20L Reactor	Glass		
	1 – 60L Reactor	Glass		
	1 – 30L Extractor	Glass		
	2 – 60L Extractors	Glass		
	1 – 200L Extractor	Glass		
	7 – 20L Storage Tanks	Glass		
	2 – 200L Mix Tanks	LDPE Mix Bags		
	2 – 20L Rotavap	Glass		
	1 – Centrifuge	Halar Lined		
	1 – Tray Dryers	Halar Lined		
	1 – Isolator	Stainless Steel		
6th floor suite	1 – 200L Reactor	Glass	N/A	Most equipment rated for 0.5 bar / Chromatography columns / Centrifuges are equipped with flexible containment technology
	1 – 70L Reactor	Glass		
	1 – 200L Mix Tank	Glass		
	1 – 20L Rotavap	Glass		
	2 – 1000L Mix Tanks	LDPE Mix Bags		
	1 – Centrifugal Extractor	Kynar		
	2 – Centrifuge	Stainless Steel		
	3 – Tray Dryers	Halar Lined		
	1 – Isolator	Stainless Steel		

## Large Scale Manufacturing

	300 MPU	750 MPU	2000 MPU	3000 MPU
Number of Tanks	27	29	33	20
Equipment Size (Capacity)	6 x Reactors (1140 L) 2 x Centrifuges (1000 mm) 1 x Dryer (1m³) 1 x Dryer (2m³)	6 x Reactors (2850 L) 2 x Centrifuges (1000 mm) 1 x Dryer (2m³)	6 x Reactors (7600 L) 4 x Centrifuges (1250 mm) 1 x Dryer (2m³)	2 x Reactors (7600 L) 4 x Reactors (11400 L) 2 x Centrifuges (1250 mm) 1 x Dryer (3m³)
Material of Construction	6 x Glass Lined Reactors 2 x Halar Lined Centrifuges 2 x Stainless Steel Dryers	6 x Glass Lined Reactors 2 x Halar Lined Centrifuges 1 x Hastelloy Dryer	5 x Glass Lined Reactors 1 x Hastelloy Reactor 2 x Halar Lined Centrifuges 2 x Stainless Steel Centrifuges 1 x Stainless Steel Dryer	3 x Stainless Steel Reactors (1 @ 7600 L; 2 @ 11400 L) 3 x Glass Lined Reactors (1 @ 7600 L ; 2 @ 11400 L) 1 x Stainless Steel Centrifuge 1 x Hastelloy Centrifuge 1 x Stainless Steel Dryer
(HHC 1 – 3B)	Cat 3A	Cat 3A	Cat 3A	Cat 3A
Temperature	-70 °C to 165°C	-70 °C to 165°C	-100 °C to 165°C	-25 °C to 165°C
Pressure	Up to 2.0 bar	Up to 5.0 bar	Up to 2.0 bar	Up to 5.0 bar
Liquid / Separation	Distillation, Extraction, Falling Film Evaporator	Distillation, Extraction, Centrifugal Extraction	Distillation, Extraction	Distillation, Extraction, Falling Film Evaporator
Solid / Separation	Vertical Centrifugation Filtration (Ferrum)	Vertical Centrifugation Filtration (Ferrum)	Vertical and Horizontal Centrifugation Filtration (Ferrum / Kraus Maffei)	Horizontal Centrifugation Filtration (Ferrum)
Drying Type	(Conical Screw)	(Conical Screw)	(Conical Screw)	(Conical Screw)

## Milling Capabilities

- Two (2) large scale mills (one spiral jet mill and one fluidized jet mill) capable of milling large volume of APIs with potential of 3A containment (1 µg/m³).
- Four (4) different types of mid-sized mills (spiral jet mill, air classifying mill, Fitz mill, and Quadro Comill) capable of milling smaller volumes of APIs with 3A containment (1 µg/m³) and each can be updated to 3B containment (50 ng/m³) with reasonable investment.
- Lab portable scale milling equipment is available.
- Fully equipped, GMP compliant Solid State Laboratory run by highly experienced SMEs is capable of providing full support for all the necessary solid state related tests and investigations.
- The infrastructure of the milling suites in Building 800 (Pilot Plant) and the Solid State Lab was established as Solid State Center of Excellence of Roche small molecule network.

### Milling Equipment List

Bldg. 800	Capacity	Material of Construction	3A Containment (1 µg/m³)	Other
The Jet Pulverizer Co.	8" Spiral Jet Up to ~50 kgs/hr*	316L SS	100%	Mobile
HOSOKAWA	2 Air Classifying Pin Mill Up to ~ 50 kgs/hr*	316L SS		Mobile
QUADRO ENGINEERING	5" Comill Up to ~ 360 kgs/hr*	316L SS		Mobile
Fitzpatrick	D6A Fitz (Hammer) Mill Up to ~ 200 kgs/hr*	316L SS		Mobile
Bldg. 810	Type/Capacity	Material of Construction	3A Containment (1 µg/m³)	Other
HOSOKAWA	400 AFG Fluidized Bed Opposed Jet Mill Up to ~ 200 kg/hr*	316L SS		
Micromacinazone (Micmac)	Up to ~ 500 kg/hr*	lined		

\*Product dependent

## Isolation and Drying Equipment

Dryers	Filter Dryers
300 L, SS, Agitated Conical Dryer (Bolz-Summix)	0.6 m², 415 L, Hastelloy, Agitated Filter Dryer (Rosenmund)
50 L, Hastelloy Agitated Cone Dryer (Bolz Summix)	0.25 m², 200 L, Hastelloy, Agitated Filter Dryer (Comber)
300 L, Hast C, Agitated Conical Dryer (Bolz-Summix)	0.12 m², 100 L, Hastelloy, Agitated Filter Dryer (Comber) (HAS Mini-Plant)
100 L, Hastelloy Spherical Dryer (Rosenmund)	
Wall-mounted Tray Dryer	

## Commercial Spray Drying

Mid-scale Equipment	Large-scale Equipment
Anhydro MS-400 (10's kg – 0.5 Metric Tonnes)	Anhydro MS-1250 (100's kg – Multi Metric Tonnes)