

ANALYTICAL EQUIPMENT

1. HPLC Total 79 Units

	Total	Osaka		Yonezawa		Chitose	
		QC	R&D	QC	R&D	QC	Food
PDA or UV	79	8	26	27	10	7	1
UHPLC	21	2	7	7	1	4	

2. GC Total 25 Units

		Total	Osaka		Yonezawa	Chitose	
			QC	R&D	QC	QC	Food
Capillary Type	FID	16	4	1	12	3	1
	TCD	3	1		2	1	
	Head Space Sampler	6	2		4	2	

3. Stability Test Chambers

Storage Conditions	Osaka	Yonezawa	Chitose
25°C/60%RH	Yes	Yes	Yes
40°C/75%RH	Yes	Yes	No

4. Other Equipment

※Chitose Food : non-GMP

Equipment	Total	Site				Equipment Management
		Osaka	Yonezawa	Chitose API	Chitose Food	
Atomic Absorption Spectrophotometer	2	1	1			GMP
LC/MS	1	1				GMP
Laser Diffraction Particle Size Analyzer	1	1	1			GMP
Electrometric Titrator	5	1	2	1	1	GMP
FT/IR	4	1	2	1		GMP
Karl Fischer Titrator	7	2	3	2		GMP
NMR 400MHz	3	3				GMP
Polarimeter	2	1	1			GMP
UV Spectrophotometer	4	1	1	1	1	GMP
TOC	3	1	1	1		GMP
GC/MS	1		1			GMP
Conductivity meter	2		1	1		GMP
Fluorescence Spectrophotometer	1		1			GMP
Differential scanning calorimetry	1		1			GMP
TG-DTA (Thermogravimetric analysis)	1		1			GMP
Melting point apparatus	3	2		1		GMP
XRD	1	1				GMP
Spectrophotometer	2	1		1		GMP
Viscometer	1				1	GMP



EQUIPMENT LIST COMMERCIAL SITE / CHITOSE

API MANUFACTURE AREA

Controlled room	1	VESSEL : Glass-lined 1000L	1	CENTRIFUGE : Teflon-lined (36 inch)	
			1	DRYER : Vibrating Dryer (Stainless Steel / 662L)	
Controlled room	1	VESSEL : Glass-lined 1000L	1	DRYER : Filter Dryer (Stainless Steel / 1020L)	
			1	DRYER : Filter Dryer (Hastelloy Steel / 270L)	
Controlled room	1	FILTER : Teflon-lined Nutsche			
	1	DRYER : Tray Dryer (Hastelloy)			
High potency and Peptide API	1	HPLC			2 Vacuum Dryer
	1	UHPLC	4	Rotary Evaporator	2 Freeze Dryer
Manufacturing area	2	Preparative Chromatography φ150×500mm	1	Filter Integrity Tester (Palltronic / Flowster IV)	2 Square Drying Chamber for Freeze Dryer

*Product area: ISO Class 7

1. VESSEL (m ³)		(Liter)										
Reactor Capacity	Total	2000	1500	1400	1000	750	500	300	250	200	100	Total
Glass-lined	17.4	2	2	1	6	1	2	1	1	3	1	20
Stainless Steel	4.5		1		3							4
Hastelloy	0.5						1					1

2. FILTER

- 2 Stainless Steel Nutsche
- 1 Teflon-lined Nutsche
- 3 Glass-lined Nutsche

4. DRYER

- 1 Double Cone Dryer (Glass-lined / 880L)
- 2 Tray Dryer (Stainless Steel)
- 1 Filter Dryer (Hastelloy / 1050L)

6. OTHER EQUIPMENT

- 1 Nitrogen Gas Humidity Controller

3. CENTRIFUGE

- 4 Stainless Steel (30 inch)
- 1 Hastelloy (42 inch)

5. TANK

- 4 Stainless Steel

7. UTILITIES

Brine cooling: to - 20°C

Vacuum: Up to 20mm Hg absolute

Water: Purified Water System (1)

Scrubber: Gas Scrubbers for acid gases (1)

Gas Scrubbers for solvent gases (1)

Steam heating: to 130°C

Nitrogen: Bulk tankers

EQUIPMENT LIST COMMERCIAL SITE / CHITOSE

PLANT EXTRACT MANUFACTURE AREA

MANUFACTURE BUILDING

1	VESSEL: SUS316 2000L	1	TANK: 1500L	1	MILL: SUS Crusher	2	CONCENTRATOR: Thin-film rotary evaporator
4	VESSEL: SUS 2000L	1	TANK: 1000L	1	MILL: Stone SUS Mascolloider	1	CENTRIFUGE: Clarifier
1	VESSEL: SUS 1500L					1	CENTRIFUGE(Settler): Decanter
1	VESSEL: SUS 800L					1	STERILIZER: Plate-type Sterilization

EXTRACTION BUILDING

Explosion-proof area	1	VESSEL: SUS 2000L	1	TANK: SUS316 1500L
(Chili pepper extract)	3	VESSEL: SUS 1000L		

EQUIPMENTLIST PILOT SITE / OSAKA

Controlled area	1	VESSEL : Glass-lined 1000L	1	VESSEL : Glass-lined 100L	1	DRYER: Blow Dryer	1	DRYER : DBL Cone	1	Cutter Mill
	1	VESSEL : Stainless Steel 1000L	1	CENTRIFUGE : Stainless Steel (36 i	1	DRYER : Tray Dryer			1	Pin Mill

Controlled area	1	VESSEL : Glass-lined 200L	1	CENTRIFUGE : Stainless Steel (26 i	1	DRYER: Blow Dryer	
	1	VESSEL : Stainless Steel 200L			1	DRYER : Tray Dryer	

1. VESSEL (m ³)		(Liter)										
Reactor Capacity	Total	2000	1500	1200	1000	500	200	100	75	50	10	Total
Glass-lined	12.8	1		3	5	3	2	2		1		17
Stainless Steel	8.41	1	2		2	2	2				1	10
Hastelloy	0.5					1						1
Teflon-lined	0.08								1			1

2. AUTOCLAVE		
500L	Hastelloy Steel	0.98 MPa
500L	Stainless Steel	0.49 MPa

- 3. FILTER**
- 1 Glass-lined Nutsche
 - 3 Stainless Steel Nutsche
 - 1 Glass-lined Vacuum
 - 4 Stainless Steel Vacuum
 - 1 Teflon-lined
 - 1 Hastelloy Steel

- 4. CENTRIFUGE**
- 1 Stainless Steel (26 inch)
 - 4 Stainless Steel (36 inch)

- 5. DRYER**
- 1 Double Cone Dryer
 - 3 Tray Dryer
 - 4 Vacuum Tray Dryer
 - 1 Lyophilizer

6. TANK				
Stainless Steel	Steel	GL	PE	Others
22	10	10	11	12

7. RESIN COLUMN		
300L	100L	Total
1	1	2

- 8. OTHER EQUIPMENT**
- 2 Humidity Control Device

- 9. MILLING AND PACKING ROOM**
- 2 Milling and Packing Room
 - 2 Cutter Mill
 - 1 Pin Mill
 - 1 Electric Sieve

- 10. UTILITIES**
- Vacuum: Up to 20mm Hg absolute.
 - Water: De-ionized Water system
 - Waste Treatment Unit: 54m³/day
 - Scrubber: Gas Scrubbers for acid and solvent gases (2)
 - Gas Scrubbers for solvent gases (2)
 - Gas Scrubbers for alkaline gases (2)

- Nitrogen: Bulk tankers
- Liquid Nitrogen cooling: to - 75°C
- Steam heating: to 150°C
- Brine cooling: to - 20°C
- Water cooling Cooling Towers (2)

EQUIPMENT LIST COMMERCIAL SITE / YONEZAWA

PLANT 1

Controlled room	2	DRYER : DBL Cone
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1. VESSEL		(m ³)																		(Liter)	
Reactor Capacity	Total	5000	4000	3000	2500	2300	2000	1800	1700	1500	1200	1000	800	600	500	300	200	100	50	Total	
Glass-lined	92.7	1	2	10	1	1	9		2	9	3	2	1	1	5		2		1	50	
Stainless Steel	67.7			2	3	1	8	3	0	11		8	4	1	3	2		1		47	

2. AUTOCLAVE

1700L Stainless Steel	0.8 MPa
1500L Stainless Steel	0.8 MPa
1000L Stainless Steel	0.2 MPa
500L Stainless Steel	6. 0MPa
300L Stainless Steel	0.8 MPa

3. DISTILLATION UNIT

1	Centrifugal-flow Thin-film Vacuum Evaporator
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4. FILTER

2	Glass-lined Nutsche
6	Stainless Steel Nutsche
1	Glass-lined Vacuum
6	Stainless Steel Vacuum
4	Plate and Frame Presses

5. CENTRIFUGE

13	Stainless Steel (36 inch)
1	Stainless Steel (40 inch)
1	Stainless Steel (42 inch)
1	Teflon-lined (36 inch)

6. DRYER

1	Double Cone Dryer
1	Spray Dryer
4	Tray Dryer
4	Vacuum Tray Dryer

7. TANK

Stainless Steel	Steel	GL	Teflon	Others	Total
132	37	11	2	10	192

8. COLUMN

	4000L	2500L	1000L	700L	500L	200L	Total
Resin	2	2	1			1	6
Silica Gel		1		2	1	1	5

9. MILLING AND PACKING ROOM

6	Milling and Packing Room
4	Cutter Mill
2	Hammer Mill
4	Electric Shifter Sieve
1	Supersonic wave Sieve

10. STORAGE

Tank farm consisting of 240m³ capacity
for solvents and 80m³ capacity tanks
for storing acids and alkaline materials.

11. UTILITIES

Brine cooling: from -20 to 40°C
Liquid nitrogen cooling: to -90°C
Water: De-ionized Water system (2)
Purified Water System (1)
Scrubber: Gas Scrubbers for acid and solvent gases (1)
Gas Scrubbers for solvent gases (1)
Gas Scrubbers for alkaline gases (1)

EQUIPMENT LIST COMMERCIAL SITE / YONEZAWA

PLANT 2

Controlled area	1	VESSEL : Glass-lined 2000L	1	VESSEL : Glass-lined 800L	1	VESSEL : Glass-lined 200L
	1	CENTRIFUGE : Stainless Steel (36 inch)	2	DRYER : Vacuum Tray Dryer		

Controlled room	1	VESSEL : Glass-lined 3000L	2	VESSEL : Glass-lined 2000L		
	3	CENTRIFUGE : Stainless Steel ,Teflon-lined (36 in	2	DRYER : Vertical Dryer	5	DRYER : DBL Cone

1. VESSEL (m ³)		(Liter)							
Reactor Capacity	Total	4000	3000	2000	1500	1000	800	200	Total
Glass-lined	38.5	2	3	9	1	1	1	1	18
Stainless Steel	28.2		2	8		6			16

2. DISTILLATION UNIT

- 1 Rotary Evaporator (50L Glass)

4. CENTRIFUGE

- 5 Stainless Steel (36 inch)
- 1 Stainless Steel (42 inch)
- 1 Stainless Steel (48 inch)
- 2 Rubber-lined (36 inch)
- 1 Teflon-lined (36 inch)

6. TANK

Stainless Steel	Steel	GL	PE	PP	Others	Total
87	25	8	26	4	6	156

8. MILLING AND PACKING ROOM

- 1 Milling and Packing Room

3. FILTER

- 1 Teflon-lined Nutsche
- 5 Stainless Steel Nutsche
- 3 Stainless Steel Vacuum

5. DRYER

- 6 Double Cone Dryer
- 3 Vertical Dryer
- 2 Vacuum Tray Dryer

7. COLUMN

	6000L	Total
Resin	2	2

9. UTILITIES

- Brine cooling: to - 20°C
- Water: De-ionized Water system (1)
- Purified Water System (1)
- Scrubber: Gas Scrubbers for acid and solvent gases (1)
- Gas Scrubbers for solvent gases (1)
- Gas Scrubbers for alkaline gases (1)

EQUIPMENT LIST COMMERCIAL SITE / YONEZAWA

PLANT 3 & PRODUCT PROCESSING AREA

Controlled area	2	DRYER : Nauta Dryer	1	VESSEL : Stainless Steel 3000L	1	VESSEL : Glass-lined 3000L
	2	CENTRIFUGE : Stainless Steel (36 inch)	1	Milling and Packing Room		

1. VESSEL	(m ³)											(Liter)
Reactor Capacity	Total	8000	6000	5000	4500	4000	3000	2500	2000	1600	500	Total
Glass-lined	42.0	2		2		1	4					9
Stainless Steel	26.2		1		1		1	1	3	2	2	11

2. AUTOCLAVE

- 1 2500L Stainless Steel 0.98 MPa

4. FILTER

- 1 Stainless Steel Nutsche (F900 / 200L)

7. TANK

Stainless Steel	Steel	GL	PE	PP	Others	Total
38	7	2	4			51

10. UTILITIES

Vacuum: Up to 20mm Hg absolute

Brine cooling: to - 20°C

Water: De-ionized Water System (1)

Purified Water System (1)

Scrubber: Gas Scrubbers for acid and solvent gases (1)

Gas Scrubbers for alkaline gases (1)

Steam heating: to 120°C

5. CENTRIFUGE

- 3 Stainless Steel (36 inch)
1 PFA Lining (48 inch)

8. MILLING AND PACKING ROOM

- 1 Milling and Packing Room
1 Pulverizer
1 Pin Mill

3. DISTILLATION UNIT

- 1 Distillation column (10 stages)

6. DRYER

- 1 Filter Dryer (Stainless Steel / 2400L)

9. STORAGE

Tank farm consisting of 160m³ capacity for solvents and 20m³ capacity tanks for storing acids and alkaline materials.

PRODUCT PROCESSING AREA

1. DRYER

Double Cone Dryer

2. MILLING AND PACKING ROOM

- 1 Vertical Mixer
1 Jet Mill

EQUIPMENT LIST COMMERCIAL SITE / USA

KILO LAB

1. VESSEL (Liter)

Reactor Capacity	50	20	12	10	5	Total
Jacketed reactor	1	1		1	2	5
Non-jacketed reactor		1			2	3
Round bottom flask			2			2

2. AUTOCLAVE

- 0.5 L Parr shaker
- 0.5 L Stainless steel bomb
- 2.0 L Parr shaker

3. DRYER

- 2 Vacuum oven

4. OTHER EQUIPMENT

- 1 Lyophilizer (18L)
- 1 ISCO Combi-Flash
- 1 Agilent 1100 LC/MDS VL
- 1 Agilent 1100 with DAD and ELSD detector
- 1 Agilent 1200 for chiral analysis
- 1 Metrohm 784 Karl Fisher titrator
- 1 Melting point apparatus
- 1 400 MHz NMR Magnet, associated electronics, air handling compressor
- 1 GeneVac EZ-2 personal evaporator
- 1 Perkin-Elmer Model 341 Polarimeter
- 1 HP 6890 GC with HP 5973 Mass Selective Detector
- 1 Uvikon XS UV-Vis Spectrophotometer
- 1 Tekmarr Dohrmann Headspace Autosampler
- 1 Barnstead NANOpure Diamond Water Purifier
- 1 Huber Unistat 905 heater/chiller
- 1 Huber Unistat 385 heater/chiller
- 1 Buchi R-220 Rotovapor
- 1 Biotage Alstra Peptide Synthesizer
- 1 Mettler-Toledo ME203E Analytical Balance

5. ACCESS TO . . .

- 1 NMR (500 MHz, 400 MHz, 300 MHz)
- 1 DSC
- 1 TGA
- 1 XRD
- 1 FTIR