Cambridge Major Laboratories - US

Equipment List - Large Scale API Plant

Solvent Tank Farm:

5 x 8000 Gallon Bulk Solvent Tanks
2 x 6000 Gallon Organic Waste Storage Tanks
2 x 6000 Gallon Aqueous Waste Storage Tanks

Reactor Bay 1 – Cryogenic Reactions:

1 x 500 Gallon 316L SS reaction vessel
1 x 1000 Gallon 316L SS work-up vessel

Reactor Bay 2 – Hydrogenation:

1 x 300 Gallon 316L hydrogenation vessel
Enclosed catalyst removal filter

Reactor Bay 3:

2 x 2000 Gallon GLS Reactor (DeDietrich Optimix)
1 x 1000 Gallon GLS Reactor (DeDietrich Optimix)
800 mm Horizontal Peeler Centrifuge (Kraus-Maffei)
800 liter Helix Conical Dryers (Kraus-Maffei)

Reactor Bay 4:

2 x 2000 Gallon GLS Reactor (DeDietrich Optimix)
1 x 1000 Gallon GLS Reactor (DeDietrich Optimix)
800 mm Horizontal Peeler Centrifuge (Kraus-Maffei)
900 liter Helix Conical Dryers (Kraus-Maffei)

Reactor Bay 5:

1 x 1000 Gallon GLS Reactor (DeDietrich Optimix)
1 x 1000 Gallon 316L SS Reactor
1 x 500 Gallon 316L SS Reactor
Plate Filters
Tray dryers

Reactor Bay 6:

1 x 1000 Gallon GLS Reactor (DeDietrich Optimix)
1 x 1000 Gallon 316L SS Reactor
1 x 500 Gallon GLS Reactor (DeDietrich Optimix)
Plate Filters

CML's Grant Drive facility is located adjacent to the existing Washington Drive development facility which provides a seamless technical transfer during scale-up of large scale manufacturing processes. The facility incorporates the latest in cGMP manufacturing design, adhering to the Q7A guidelines.

The facility is a multi-story structure which features multiple reactor bays with separate HVAC and product isolation suites to minimize the possibility of cross-contamination. Each bay provides a different mix of vessel sizes and/or metallurgies in order to address the variety of process requirements for multi-purpose facility. The facility also houses separate bays for hydrogenation and cryogenics.

Process control is accomplished through the combination of a single fluid system (Therminol) and a PLC-based automated control system. The system not only provides control of both process and safety limits, but is also the primary means for process data acquisition. The reactors are capable of being controlled between -20ºC to 160ºC.The cryogenic system is capable of controlling to temperatures as low as -100ºC. The vessels have high vacuum capability via Busch dry seal pumps or utility vacuum via liquid ring pumps. Process gases are vented through local scrubbers before going to the on site Thermal Oxidizer to ensure complete destruction of any hazardous or flammable vapors.

Product isolation and drying is a critical design consideration in CML's large scale API manufacturing facility. Separation trains feature identical pharmaceutical grade horizontal peeler centrifuges with a direct connection to agitated Helix conical dryers, capable of extremely low vacuum and precise temperature control. The centrifuges and dryers are pharmaceutical-grade units manufactured by Kraus-Maffei, a respected name in the business. All incoming air into the areas where final product is exposed and packaged are provided by HEPA filtered air from separate air handling systems. Product containers are then transferred to the appropriate storage rooms located nearby.

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