Attachment No. F.1  Treatment, Abatement and Control Systems

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Attachment No. F.2  Emissions Monitoring and Sampling Points

F.2.1 Site Layout with Emission Monitoring and Sampling Points
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F.1.3.1 Description of Heat Inactivation System
Attachment F.1.3.1 Description of the Heat Inactivation System

A.F.1.3.1 Process Summary

A.F.1.3.1.1 Overview
Though not expressly required by Irish regulations concerning the release of Genetically Modified Micro organisms (GMMs), a heat inactivation system is being installed to handle process waste and cleaning solution wash from GMM containing areas of the process. As per EU Council Directive 2004/54/EC, the cell lines used to produce CNTO 148 and CNTO 1275 are classified as Group 1 biological agents ‘unlikely to cause human disease.’ The inactivation system is a semi-continuous-kill thermal system utilising direct steam injection with an insulated retention coil designed to provide sufficient exposure time to render GMM cells non-viable before discharge to the on-site wastewater treatment plant.

The heat inactivation system will include a relatively small sump tank at the perimeter of the Process Building and a larger collection tank (circa 15,000 L capacity) and heat inactivation skid in the Central Utilities Plant (CUP). The collection tank in the CUP and the heat inactivation skid are designed to process in excess of the maximum daily biowaste load generated from manufacturing. Heat inactivated Biowaste is directed to the site wastewater treatment plant (WWTP). The collection tank will also serve to dampen the impact of high chemical oxygen demand (COD) waste on the WWTP by processing waste semi-continuously. The heat inactivation design parameters require the waste to be held at 90°C for 2 minutes before being released to the WWTP.

A procedure for the inspection and maintenance of the heat inactivation system will be implemented to ensure the system operates effectively at all times during production.

With the exception of the plastic tanks, the system will have the capability to be steam inactivated for maintenance access. The tanks are designed with the ability to chemically inactivate. As per EU Council Directive 98/81/EC, the cell lines used in the facility are in the Class 1 operator risk category, which does not specifically require such inactivation.

A.F.1.3.1.2 Operational Summary

Process Waste Segregation
The process wastes arising from the Manufacturing Building may be categorised as either WWTP (wastewater treatment plant) and heat inactivation streams. The WWTP streams will flow directly to the equalisation and neutralisation area located in the WWTP on site. The heat inactivation streams will be routed first through the heat inactivation system before being sent on to neutralisation/equalisation in the WWTP.

All drains from Cell Culture Rooms, Media/Harvest Hold, DPC Recovery area, the Level 1 Clean-In-Place (CIP) skids, and Level 1 glass washers will be routed to the heat inactivation system. In addition, automation on the two first floor glass washers and two first floor CIP skids will allow the initial rinse step and caustic washes for cell culture and Direct Product Capture (DPC) area activities to be diverted to heat inactivation.

Process waste streams which are not routed to the heat inactivation vessel or the WWTP are detailed in Table H.1(ii).

A block flow diagram of the heat inactivation system is shown in Figure A.F.1.3.1.
Figure A.F.1.3.1: Heat Inactivation System Block Flow Diagram

Manufacturing Building
Process GMM streams from:
- Cell Culture Rooms
- Media/Harvest Hold Rooms
- Recovery
- Level 1 CIP skids
- Level 1 Cell Culture

Heat Inactivation
Sump Tank

Heat Inactivation
Collection Vessel

GMM Stream

Manufacturing Building:
Process Non GMM Streams

Equalisation/
Neutralisation

Downstream WWTP processing:
- Biological Treatment
- Clarification
- Dewatering
- Monitoring
- Discharge to sewer (SE1)

Laboratories/
Administration
GMM Waste Inactivated

Warehouse

C.U.P.
Manufacturing Building Sump Tanks and Pumps

The Manufacturing Building heat inactivation streams will be routed underground via gravity flow to the heat inactivation sump tank located below grade at the perimeter of the building. The containment sump is designed to hold 110% of the total cell culture tank volume, at a minimum.

Redundant self-priming heat inactivation transfer pumps on grade will respond to the level in the tank below to periodically pump waste out into the larger heat inactivation collection vessel located in the Central Utilities Plant (CUP). All instrumentation associated with the sump area will be controlled by the Non-Qualified Building Automation System (NQBAS).

Heat Inactivation Collection Vessel and Heat Inactivation Skid

Pumped waste from the heat inactivation sump tank will be received into the heat inactivation collection tank in the CUP. The collection tank and the heat inactivation skid will be located within a trenched area designed to hold 110% of the collection vessel contents. Level sensors in the tank will communicate with the inactivation skid via the NQBAS to process GMM streams as required (See Section D.1.8 for discussion on NQBAS).

When the heat inactivation collection tank reaches a specified level, the pumps below the tank will turn on, circulating waste through the heat exchanger to the steam injector where 3 barg steam will be introduced to the waste stream, raising the temperature as it enters the retention pipe. The steam flow rate will be controlled by a temperature element at the inlet of the retention pipe. At the design flow rate, the stream will travel through the retention tube for two minutes. Upon leaving the retention tube, a second temperature element will confirm the waste temperature before it travels back through the heat exchanger, pre-heating the waste leaving the collection tank. Before either being diverted back to the collection tank or on to neutralisation/equalisation, the stream will pass through a flow meter and a back-pressure regulator.

The flow rate through the retention tube will be controlled to ensure that the minimum design retention time of 2 minutes is met. The steam injection control will be calibrated to respond to the inlet temperature of the retention tube, injecting sufficient steam so that the waste stream will remain above 90°C (as confirmed by the second temperature element at the outlet of the retention pipe) throughout the retention pipe.

A.F.1.3.1.3 SIP

The heat inactivation tank vent filters, pumps, and processing lines will be capable of inactivation with plant steam prior to maintenance. Chemical inactivation will be possible for the heat inactivation sump tank and collection tank.

A.F.1.3.1.4 CIP

No CIP of the heat inactivation system will be required.
F.1.3.2 Layout of WWTP

Drawing No. ENV-S0100018 Rev A
F.1.3.4 Process Flow Diagram of Odour Control System

Figure F.1.3.4

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Attachment F.2

F.2.1 Site Layout with Emission Monitoring and Sampling Points

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F.2.7 Groundwater Monitoring Wells

Drawing No. ENV-S0100001 Rev A