Sterilization In Place –Vessel Execution Record

(Ref. SOP VAL-225)

1. OBJECTIVE

Using an appropriate sterilization cycle, demonstrate that the tested cycle will sterilize the vessel with a high degree of assurance. Each cycle should consider the location(s) within a vessel considered to demonstrate worst-case conditions.

2. PROCEDURE

2.1. Standard Procedures and Operator Instructions

Before commencement of the qualification, ensure a pre-sterilization documentation review has been conducted as per VAL-270 “Critical Documentation Verification during a Validation Study” and documented in attachment Form-910.

Initial / Date

NOTE: THIS DOCUMENT MUST BE REPRODUCED FOR EACH CYCLE

Cycle Type *EMPTY / FULL*	Load Description (include volume if full vessel cycle)

2.2. Test Instrumentation

Instrument Number	Instrument Name or Description	Date of Calibration	Calibration Due Date

2.3 Calibration and Verification of Test Devices

Initial / Date

Confirm that the data logger has a minimum sample rate of 5 seconds and that all test equipment has been calibrated and verified as per written instructions.

Project Number	Vessel number	Run Number	Number of Runs

2.4. Biological Indicators

Indicator Type (strikethrough non-relevant indicator(s))	EZ-Test Crushable Ampoule (DRY)	Glass Ampoule (WET)	Spore Strip (DRY)
Lot Number			
Organisms	*G.Stearothermophilus*	*G.Stearothermophilus*	*G.Stearothermophilus*
Population			
Manufacturer			
Manufacture Date			
Expiration Date			

Confirm that the BIs have not expired the manufacturers and expiration date.

Initial / Date

2.5. Thermocouples and Biological Indicator Placement

Record and confirm the distribution of thermocouples and BIs throughout the vessel in attachment Form-885.

Initial / Date

2.6 Filter Inlet Sterilisation (External Temperature Monitoring)

Start the data logger and commence the inlet filter sterilization when the internal temperature reads above the minimum sterilization temperature and/or the SOP conditions are met for the commencement of filter Sterilization.

For initial sterilization validation only, record the surface temperatures at five-minute intervals for the duration of the sterilization cycle time.

Record the external temperatures at the start, middle, and end of the SIP procedure for routine re-validation. Use Form-890 to record the external temperature monitoring data.

Sterilization Start Time	Sterilization Finish Time	Sterilization Duration (min)	Minimum External Temp. Achieved (°C)

Initial / Date: _____

2.7 Vessel Sterilisation External Temperature and Pressure Monitoring

Start the data logger and commence the heating until the minimum SIP temperature is reached at all monitoring locations and/or the SOP conditions are met for the commencement of vessel sterilization.

Record the external surface temperature and vessel gauge pressure at five-minute intervals for the duration of the sterilization cycle time for initial sterilization validation.

For routine re-validation external temperature monitoring is not required during the vessel SIP procedure evaluation.

SIP Stage	Start Time	Finish Time	Duration (min)	Minimum External Temp. Achieved (ºC)	Pressure Range during SIP (kPa)
Heating					
Sterilization					

Initial / Date: _____

Note: Cool the vessel on completion of the sterilization cycle to a minimum of 60°C.

3. Post Cycle

	Circle Applicable	Deviation No.
Biological Indicators were retrieved from each location and submitted along with both the exposed and control BI. During submission, the indicator-dependent Test Results Sheets shall have been submitted to Quality Control for sterility testing.	YES / NO	
Post-calibration verification results of thermocouples have been recorded.	YES / NO	
Thermocouples are within reference checkpoint verification temperature ranges as stipulated in VAL-275 “Preparation and Calibration of Thermocouples for use in Thermal Validation Studies”.	YES / NO	

Initial / Date: _____