Sterilization In Place – Transfer Lines Execution

(Ref. SOP VAL-225)

Project Number	Run Number	Number of Runs

1. OBJECTIVE

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

THIS DOCUMENT MUST BE REPRODUCED FOR EACH CYCLE

Line Description and Direction of Steam

Line Start ------→ **Key-Station** ------→ **Key-Station** ------→ **Key-Station** ------→ Line Terminus
(Steam Source) **KS - ____ - ____** **KS - ____ - ____** **KS - ____ - ____**

2. PROCEDURE

1.1. Standard Procedures and Operator Instructions

Before commencement the qualification ensures a pre-sterilization documentation review has been conducted and documented as per "VAL-270 Critical Documentation Verification during a Validation Study".

Initial/Date

1.2. Test Instrumentation

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

1.3. Calibration and Verification of Test Devices

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

Initial/Date

1.4. Biological Indicators (BIs)

Sign/Date

Verify that the BIs have not expired and record the population, organism, lot number, manufacturer and expiration date of each lot.

Indicator Type (cross out non relevant indicators)	**EZ-Test Crushable Ampoule (DRY)**	**Spore Strip (DRY)**
Lot Number		
Organisms	*G.Stearothermophilus*	*G.Stearothermophilus*
Population		
Manufacturer	Mesalabs	Mesalabs
Manufacture Date		
Expiration Date		

1.5. Thermocouples and Biological Indicator placement

Sign/Date

Distribute the calibrated thermocouples and biological indicators at the depicted locations in 'Form-900 Sterilisation In Place Validation – Transfer Line Diagram'.

1.6. Conduct Sterilization of the Transfer Line(s)

1.6.1. Start the data logger with a minimum data sample rate of 5 seconds and perform the cycle to be validated.

Sign/Date

1.6.2. **Temperature Stabilisation:** Record the time it takes for the internal temperature to stabilise at the required value (≥ 121.0°C).

Start Time	**Finish Time**	**Total Stabilisation Time (min)**	**Stabilised Temperature (°C)**

1.6.3. **Transfer Line Sterilization**

Commence the heating until the minimum SIP temperature is reached at all monitoring locations and/or the SOP conditions are met for commencement for pipe-work sterilization.

For new equipment validation, record surface temperature and line pressure at five-minute intervals using 'Form-895 Sterilisation In Place Validation – Transfer Lines' for the duration of the sterilization cycle time.

For routine re-validation, record the external temperature of the pipe-work at the start, middle and end of the SIP process and line pressure at the locations nominated on form Form-895.

Start Sterilization Time	Finish Sterilization Time	Sterilization Time (Mins)	Minimum Temperature Achieved (°C)	Pressure Range During SIP Achieved (kPa)

Sign _____ **Date** _____

1.6.4. **Line Cooling –** At the completion of the sterilization cycle cool the transfer line.

Start Cooling Time	Finish Cooling Time	Total Cooling Time	Temperature achieved at the end of Cooling

Sign _____ **Date** _____

1.7. Post Cycle

	Circle Applicable
Biological Indicators 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 check point verification temperature ranges as stipulated by 'VAL-275 Preparation and Calibration of Thermocouples for use in Thermal Validation Studies'.	YES / NO

Sign _____ **Date** _____

Upon completion of the test use this form with validation report.