Standard Operating Procedure

Title: Heat Penetration/Heat Distribution Study

Department	Validation/Technical Services		Document no	VAL-180	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

Project Number	Autoclave Number

1. OBJECTIVE

Using a *Heat Penetration Study*, demonstrate that each of the proposed cycles will, with a high degree of assurance, sterilise a defined load configuration for the worst-case load. Similarly, conduct a *Heat Distribution Study* simultaneously to determine the cold spots and uniformity of heating in the loaded autoclave chamber.

THIS DOCUMENT MUST BE REPRODUCED FOR EACH CYCLE

Cycle Number		Number of Runs	
Load Description			

2. PROCEDURE

2.1 Pre-requisite to the Heat Penetration Study

2.1.1 Synchronise the time of the Graphic Recorder (Eurotherm Chessell 6000 Multichannel Graphic Recorder) to within 1 minute of the autoclave.

Sign/Date

2.1.2 Ensure pre-cycle checks have been successfully performed. Record in Table 1.

Table 1. Pre-Cycle Check

Acceptance Criteria	Acceptance Criteria Achieved (Yes/No)	Sign/Date
Vacuum Leak Test is successfully performed.		
Steam Penetration/Air Removal Test is successfully performed.		

2.2 Run Execution

2.2.1 Record BI details in Table 2.

Note: Eurotherm Chessell 6000 Multichannel Graphic Recorder can be used to produce consistent and accurate results at all times in setting up configurations, calibrating, recording, saving, and monitoring of the real time data during validations of temperature and pressure environments.

2.3 Post Cycle

2.3.1 Verify that the recorded cycle parameters are consistent with the programmed cycle parameters. Attach the completed form(s) to this document. **Sign/Date**

2.3.2 Retrieve each exposed BI from the load. Submit the exposed and control BIs with Biological Indicator Test Results Sheet (Form-850) to Quality Control for sterility testing. **Sign/Date**

2.3.3 Attach all autoclave printouts and graphs to this document. **Sign/Date**

2.3.4 Record whether the test has met the acceptance criteria using either Form-835 Autoclave Cycle Acceptance Criteria. Attach the completed form to this document. **Sign/Date**

2.3.5 Record post-calibration verification results in Table 4.

Table 4. Thermocouple Post-Calibration Verification Results

Test Description	Acceptance Criteria	Acceptance Criteria Achieved (Yes/No)	Sign/Date
Check Point Verification (121°C)	All T/C's are within ±0.80°C of reference		

3. COMPLETION

Upon completion of test, attach this document to Form-780 Autoclave Validation Protocol.

4. REFERENCED DOCUMENTS

VAL-175	Validation of Autoclaves, Autoclave Cycles and Loads