



# AUTOCLAVE VALIDATION PROTOCOL

(Ref. SOP VAL-175)

## 1. Procedure

Conduct all tests indicated. Attach all documents to this protocol. Any deviations raised during validation must be recorded using Form-745 (Protocol Deviations/Deficiencies Report).

Before commencement of the operational verification, Documentation Verification and Cycle Review Form-765) must be completed and attached.

Sign/Date

### 1.1 Cycle and Load Selection

1.1.1 List the cycles and loads selected for validation, in Table 1.

**Table 1. Cycle and Load Description**

Cycle Number	Number of Runs	Load Description

### 1.2 Review Panel

The signatories in Table 2 have reviewed the selected cycles and found them to be acceptable for validation.

**Table 2. Signatories**

Department	Title	Name	Signature	Date
Validation	Validation Supervisor			
System Owner				
Engineering	Engineering and Maintenance Manager			
Quality Operations	Manager-Quality			

**1.3 Operational Verification for all Autoclaves.  
Complete Sections 1.3 and 2 only. Strikethrough Section 1.4**

1.3.1 Conduct an equipment calibration verification using Form-810 (Equipment Calibration Verification).

Sign/Date

1.3.2 Conduct a Vacuum Leak Test using Form-805 (Vacuum Leak Test). Record all test instances conducted in Table 3.

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**Table 3. Vacuum Leak Test Summary**

	Date	Deviation Number (if applicable)	Sign/Date
<b>a</b>			
<b>b</b>			
<b>c</b>			
<b>d</b>			

1.3.3 Perform an initial Steam Penetration/Air Removal (Bowie Dick) Test using Form-790 (Steam Penetration/Air Removal (Bowie Dick) Test).

Sign/Date

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1.3.4 Conduct a Heat Penetration and Heat Distribution Study for EACH cycle using VAL-180 (Heat Penetration and Heat Distribution Study) as listed in Table 1.

Sign/Date

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## 2. Completion

Upon completion of this protocol all executed test sheets must be attached and a report must be written (Ref VAL-175).

## 3. Signature Verification

Designated personnel assigned the responsibility of executing or reviewing execution of this document will sign, initial and date the corresponding sections in Table 3.

**Table 3. Signature Verification**

Print Name	Signature	Initials	Dept/Company Title	Date