

Installation Qualification Utilities

(Reference SOP: _____)

Project:		Project No:	
Description:			
Manufacturer:		Equipment No.:	
Location:		Protocol:	

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1. OBJECTIVE

To provide documented verification that all key aspects of the selection, application, construction and installation of (*description name of the process, equipment and system*) adheres to appropriate codes, cGMP s and approved design intentions and that the manufacturers recommendations are suitably considered.

2. ACCEPTANCE CRITERIA

A successful completion of the Installation Qualification process are based on the following:

- All activities listed in Installation Qualification have been executed.
- All entries of data have been signed and dated by the person or persons performing the activity or verification.
- All data has been adequately reviewed and reported.
- Any discrepancies that have occurred have been satisfactorily resolved and are correctly signed and dated as resolved.

3. QUALIFICATION PROCEDURES

The protocol consists of tables containing information that needs verification. The Qualification inspection and verification process are largely depended on visual inspection, comparison to As Built drawings and equipment specification as quoted in the protocol.

Any tables or sections not relating to process or equipment should not be deleted and the word N/A should be used, additional tables or sections can be included.

Other documents that support the Qualification process can be referenced or included as attachments.

All people involved in the Qualification inspection and verification process are required to fill out this protocol.

4. EQUIPMENT DESIGN DOCUMENTATION

4.1. Drawings

Drawing Identification: _____

Electronic copy supplied: Yes/No

Drawings submitted in "As Installed" format? Yes/No

Filter locations included? Yes/No

Signed _____

5. STRUCTURAL INSTALLATION

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7.6. Handover of Specifications

Specifications	File Name(s) in G:\D_Spec\	Completed
User Requirement Specification(s)		
Functional Specification(s)		
<i>Software Design Specification(s)</i>		
<i>Software Module Design Specification(s)</i>		
<i>Hardware Design Specification(s)</i>		
<i>Operator's Control Panel Specification(s)</i>		
<i>Mechanical Specification(s)</i>		

8. INSTRUMENTATION

Include list of all items requiring calibration.

8.1. Critical Instrumentation

Description	Manufacturer	Model No.	Serial No.	Preventative Maintenance No.

8.2. Non Critical Instrumentation

Description	Manufacturer	Model No.	Serial No.	Preventative Maintenance No.

8.3. Calibration SOP's

Prepared By: _____

Date Prepared: _____

Revision No: _____