

 THE SCIENCE OF WHAT'S POSSIBLE.™		(Type of verification/qualification/validation performed), i.e. Installation Qualification Report	
Report No: TE00XXXXX-XX-IQR or VALXXXXXX	Iteration No: 00	SAP No: TE00XXXXXQX or VALXXXXXX	

Instructions for the Author:

This document is intended to serve as a template for the report deliverables defined in 730001835 – Process Validation Procedure for Milford Site. Text in red is for guidance and should be deleted and replaced with applicable information based on the executed protocol or procedure.

The Report title shall be based on the type of protocol or procedure that was executed and the nomenclature of the Process, Test Method, or Equipment.

The Report Number shall be based on the Process, Test Method, or Equipment Designator; with the suffix based on the type of Protocol or Procedure being executed. The following shows the different Suffix examples:

- EDVR: For an Equipment Design Verification Report
- IQR: For an Installation Qualification Report
- TMVR: For a Test Method Validation Report
- OQR: For an Operational Qualification Report
- PQR: For a Performance Qualification Report

Examples of a Process, Equipment or Test Method Report are shown below:

- VAL000649-EDVR
- VAL000649-TMVR
- TE0084000-1-IQR

TYPE OF PROTOCOL EXECUTED (I.E. EQUIPMENT DESIGN VERIFICATION) REPORT

For the name of the Process, Test Method, or Equipment

PREPARED BY

Name	Role	Signature	Date

REVIEWED BY (minimum of one reviewer, additional reviewers may be added as applicable)

Name	Role	Signature	Date
	System Owner (If not Prepared By)		
	Test Validation Engineer		

APPROVED BY

Name	Role	Signature	Date
	Quality Engineer		

The “Prepared By” signature denotes that this document accurately describes the (verification, qualification, or validation) activities.

The “Reviewed By” signature[s] denotes agreement with the description of the (verification qualification, or validation) activities.

The “Approved By” signature denotes that this document has been reviewed and approved for overall quality and completeness.

REVISION HISTORY

Version	Author	Summary of change
XX	A.N. Other	First document for approval

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1.0 Purpose

The (name of Process, Test Method, or Equipment/station) is located in (provide the location of where the process, test method, or equipment/station is used). The (name of Process, Test Method, or Equipment/station) is used to perform (the purpose of the process, test method, or equipment/station) of the following part numbers: (List the part numbers, the process, test method, or equipment/station tests).

2.0 Scope of Report

This (type of protocol executed) Report details the (Verification, Qualification, or Validation) activities undertaken for the (name of Process, Test Method, or Equipment/station) based on the requirements of the executed protocol, (name the protocol document number, revision, and title).

This (type of protocol executed) Report defines the documents used to (verify, qualify, or validate) the (name of Process, Test Method, or Equipment/station). List all applicable documents.

3.0 Summary of Results - Statement of Fitness for Intended Use

This section should be a clear statement on the status of the Test Equipment and/or system and whether it is fit for intended use, bearing in mind any outstanding deviations or corrective actions.

The (name of Process, Test Method, or Equipment/station) was tested in accordance with (number/name or the protocol or procedure, including revision). All (reference the test requirements – such as Test Scripts) were performed and (statement of: all objective evidence requirements have been met (and all deviations have been resolved)).

Waters now has the necessary documentation in place to ensure that the (name of Process, Test Method, or Equipment/station) complies with Waters' requirements, the latest relevant quality system regulations, and cGMP practices.

Following the approval of this (Verification, Qualification, or Validation) Report, the (name of Process, Test Method, or Equipment/station) can be considered fully (verified, qualified, or validated) and fit for intended use.

4.0 Glossary

The following definitions are used in this document:

Term	Explanation
cGMP	Current Good Manufacturing Practice
TMV	Test Method Validation
EDV	Equipment Design Verification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
SOP	Standard Operating Procedure
TSP	Test Specification and Procedure
ASP	Assembly Procedure
MPR	Manufacturing Procedure
Cal/PM	Calibration/Preventive Maintenance
VAF	Validation Assessment Form
XXX	(insert/delete definitions as required)

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5.0 Training

This section should provide details of assurance that personnel involved in the verification, qualification, or validation have been trained and that this training is documented.

For any test results in which a Production Operator performed the testing a training statement to the operating procedure (TSP, MPR, etc.) shall be included. The Training Record Attachment shall be referenced.

A training statement to the Verification, Qualification, or Validation Protocol or Procedure, for any Performer(s), shall be included. The Training Record Attachment shall be referenced.

6.0 Verification, Qualification or Validation Results

This section should summarize the test activities and results specified in the Verification, Qualification, or Validation Protocol or Procedure. Photos or other objective evidence used to complete the Protocol or Procedure test scripts may be included within this section.

Script or Section	Pass/Fail	Objective Evidence	Deviations
IQ-01	Pass	Attachments 02, 03, and 04	None
IQ-02	Fail	Attachments 05 and 06	Section 8, Deviation #1

7.0 Attachments

This section is used to list all attachments used as objective evidence related to the performed Verification, Qualification, or Validation. All attachment documents, including the filled out EDV, IQ, TMV, OQ, or PQ test script documents that were performed, will be labelled and attached to this report.

Attachment examples: EDV, IQ, TMV, OQ, or PQ Data Sheets, Calibration Certificates, Preventive Maintenance Certificates, Final Test Records (including Event Logs), Training Records, etc.

All Attachments should be in logical order in reference to the report and shall be marked with the Report Document Number, the report iteration, Attachment Number, and will be paginated. Below is an example of this marking:

Iteration: 00
 Document No.: TE0084010-1-IQR
 Attachment: 7.2 Page: 1 of 1

8.0 Deviation from Test Equipment Verification, Qualification, or Validation

This section should provide an overview and resolution of any deviation occurrences during the performance of the associated Verification, Qualification, or Validation Protocol or Procedure.

All deviations must be resolved and documented within this report. If there are NO deviations during the performance of the Protocol or Procedure, simply write the following for this section:

There were no deviations generated during the execution of (name the EDV, IQ, TMV, OQ, or PQ Protocol or Procedure document, including revision).

For each deviation provide the description, resolution and/or proposed corrective action, as applicable.

9.0 References

The current approved versions of the following documents are referenced within this document:

Reference	Document Number	Document title
[x]	XXXXXXXXX	(insert/delete references as required)