

ConnectionsAQT for Empower 3

This protocol document describes the process for performing the installation qualification (IQ) and operational qualification (OQ) for Waters® Connections®AQT for the Empower™ 3, with or without Method Validation Manager (MVM) software.

Requirements before qualification begins

The owner's management must review this protocol, the ConnectionsAQT for Empower 3 release notes, Empower 3 software release notes, and the *Waters Qualification Overview* (part number: 715511111).

In the Qualification Overview document, ensure that these forms are completed:

- Qualification Approval
- Identification of Performers and Reviewers

AQT overview

The ConnectionsAQT for Empower 3 is specific to the Empower 3 release. The AQT uses a wizard to run the IQ and OQ and prints out the maintenance procedures (MP) and required logs.

The data set used for internal standard calculations is the same as the data set used in Empower 2154, Empower 1154, or Millennium^{®32} v3.2, v3.05.01, or v3.05.

The data set used for external standard calculations is the same as the data set used in Empower 2154, Empower 1154, or Millennium³² v4.0 or v3.2.

The data set used for the method validation manager is the same as the data set used in Empower 2154 FR 3.

You do not need to enable ApexTrack processing if your company uses traditional integration.

Installation qualification (IQ)

The IQ represents the installation qualification process for a Waters Empower 3 Personal, Workgroup, Enterprise, or LAC/E^{™32} module software system consisting of software and associated hardware components.

The purpose of the IQ portion of the qualification is to confirm these conditions:

- Personal, Workgroup, Enterprise, and/or LAC/E³² module software components are properly installed
- Empower 3 software is properly installed
- Empower 3 files you installed on the system are not corrupted and remain identical to the files shipped from Waters
- Any Empower 3 software options are properly installed
- The name of the operating system, build number, and all service packs applied

- The total number of Empower 3 named user licenses and system licenses for Workgroup and Enterprise
- Any Empower 3 service packs are properly installed and verified

IQ forms

Forms printed during the IQ serve to enable these tasks:

- Identify the computer component(s) associated with this software IQ. When you complete the Computer Component Identification form, compare the information entered on the form with the purchase order for the Empower 3 software system. When you install software as part of a reload or software support plan upgrade, the purchase order is sometimes unavailable. In this case, write "RELOAD" or "UPGRADE" on the Purchase Order Number line of the Computer Component Identification form for that client.
- Identify the hardcopy documents required for qualification. When you complete the Document Information Form, identify each document as follows:
 - If the document was received, initial the corresponding Received line.
 - If the document is missing, write "Missing" on the corresponding Received line.
 - If the document does not apply to the installation, write "N/A" on the corresponding Received line.

Tip: Some system configurations do not require all of the documents in the documentation list.

- Identify the computer and peripherals of the Empower 3 system associated with this software IQ. When you complete the Configuring the Computer and Peripherals form, enter your initials on the line corresponding to each device you install. Enter N/A for devices already installed.

Tip: If the Empower 3 system was purchased from Waters, you need not verify the configuration. Instead, in the Configuring the Computer and Peripherals form, certify that the computer was configured.

Software file verification

During installation of the Empower 3 software, the software automatically runs a file verification utility, which verifies that the disk files shipped from Waters were not corrupted during installation. The file used for the comparison is in \Empower\SCRIPT\DIR.CKS.

The file verification focuses on these file attributes:

- Cyclic redundancy checksum (CRC)
- File size
- File date and time stamp

If the file verification utility detects a change in any file, the installation is aborted. You can rerun the utility any time, to requalify the installation.

Rule: The software does not overwrite the original CHECKSUM.TXT file each time you run the utility. Instead, each subsequent CHECKSUM.TXT file name is annotated with the date and time: for example, \Empower\SCRIPT\Checksum_11.01.2010_12.23.41.txt.

To certify that the software installation was performed, run the IQ portion of the ConnectionsAQT for Empower 3, and then review the last page of the printed summary. If the installation was successful, the following summary statement appears.

```

*****
Waters Installation Qualification - Summary

No Installation errors were detected.
This qualifies your Empower software installation on this node.

                PASS _____ FAIL _____

The undersigned performer attests that all of the information contained in this document is correct
and complete.

    Performer: _____ Date: _____

The undersigned reviewer accepts that all of the information contained in this document is correct
and complete.

    Reviewer: _____ Date: _____
*****

```

If no installation errors were detected, initial the Pass line, and complete the form. File the form in your Waters binder under the Installation Qualification tab.

If the installation was not successful, the following summary statement appears.

```

*****
Waters Installation Qualification - Summary

The following changes were detected:

    19: MillServices.dll      NOT FOUND ! Size:      0, CRC:      0

Waters recommends that you determine the effects of these changes and verify that they will not cause
improper operation.

If your standard operating procedures have determined that non-critical
file changes (such as text files) are acceptable, then the software need not be reinstalled if the
operational qualification testing is successful.

Otherwise reinstallation of the software is recommended.

                PASS _____ FAIL _____

The undersigned performer attests that all of the information contained
in this document is correct and complete.

    Performer: _____ Date: _____

The undersigned reviewer accepts that all of the information contained
in this document is correct and complete.

    Reviewer: _____ Date: _____
*****

```

Initial the Fail line, and complete the rest of the form. File the form in your Waters binder, under the Installation Qualification tab.

When installation errors are found, and the operational qualification also fails, you must reload the Empower 3 software. Ensure that you deactivate the options prior to reloading Empower 3.

File both the signed failed report and the passed report in your Waters binder, under the Installation Qualification tab.

Operational qualification (OQ) for ConnectionsAQT for Empower 3 software only

If you use traditional integration, the OQ uses the Valid_OQ1 project. If you use ApexTrack integration, the OQ uses the Valid_OQApex project and Valid_OQ1 project.

Requirement: You must manually restore the projects according to the integration technique specified in System Policies:

- When ApexTrack integration is the data processing technique, you must manually restore both projects, and then generate a full set of OQ results for each
- When traditional integration is selected as the data processing technique, you must manually restore only the Valid_OQ1 project, and then generate only one set of OQ results and reports.

The Valid_OQ1 and Valid_OQApex projects are provided by Waters and are limited to verifying and documenting the ability of Empower 3 software to perform these tasks:

- Restore projects.
- Process standards.
- Process unknowns.
- Perform peak integration.
- Perform quantification.
- Perform calibration.
- Generate a printed report.

When the OQ runs, these summary reports are sent to the printer:

- Internal and external standard LC calibration reports
- OQ sample summary reports
- Project and database log form
- Maintenance log form
- Maintenance procedure

The reports contain an "Integration Algorithm" field that indicates whether traditional or ApexTrack integration was used.

Verifying the results of the OQ: the Internal Standard OQ Sample Summary Report

On the first seven pages of the Internal Standard OQ Sample Summary Report, ensure that "Pass" appears on each line of these two columns:

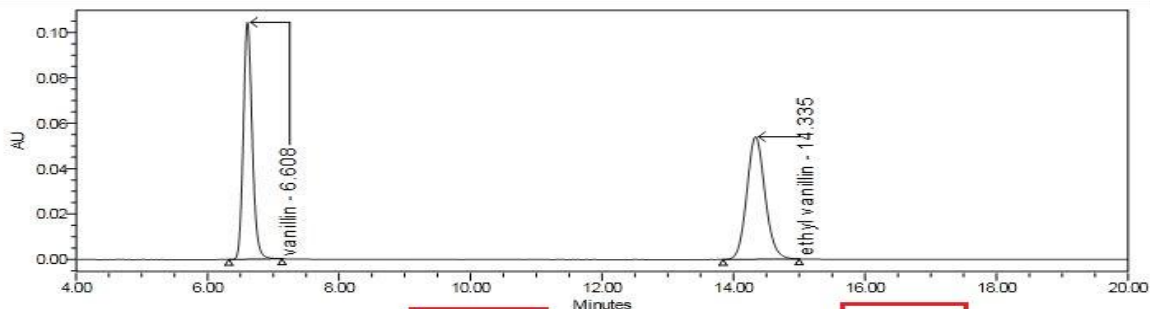
- Pass_Fail_RT
- Pass_FailAmt

of Results: 7

ACQUISITION INFORMATION

User Name: Romuald McSweeney (Romuald)
 Acquired By:
 Sample Set Name: Internal Std Sample Set
 Acq Method Set: Internal Std Method Set
 Processing Method: Internal Std Processing Method
 Channel Name: 486
 Report Method Name: Summary Report for Instd OQ
 Processing Node: Romuald-pc-w500
 Date Acquired: 9/5/1993 1:42:05 PM EST
 Date Processed: 11/1/2010 1:59:33 PM EDT

System Name: 486_sys
 SampleName: Internal Std. 1
 Sample Type: Standard
 Vial: 30
 Injection: 1
 Injection Volume: 25.00 ul
 Run Time: 20.0 Minutes
 Software: Empower 3 Software Build 3465
 Integration Algorithm: Traditional



Peak Name	ExpRT/Van	RT	ExpRT_Et/Van	Pass_Fail_RT	Amount	ExpAmt/Van	ExpAmt_Et/Van	Pass_Fail_Amt	Calibration Id
1 vanillin	6.608	6.608	0.000	Pass	100.000	100.000	0.000	Pass	2974
2 ethyl vanillin	0.000	14.335	14.335	Pass	100.000	0.000	100.000	Pass	2974

When "Pass" appears on each line, no failures were found; all retention times (RT) equal the expected retention times (ExpRT), and all amounts equal the expected amounts (ExpAmt) indicated on each report page. Thus, this portion of the OQ has passed the test.

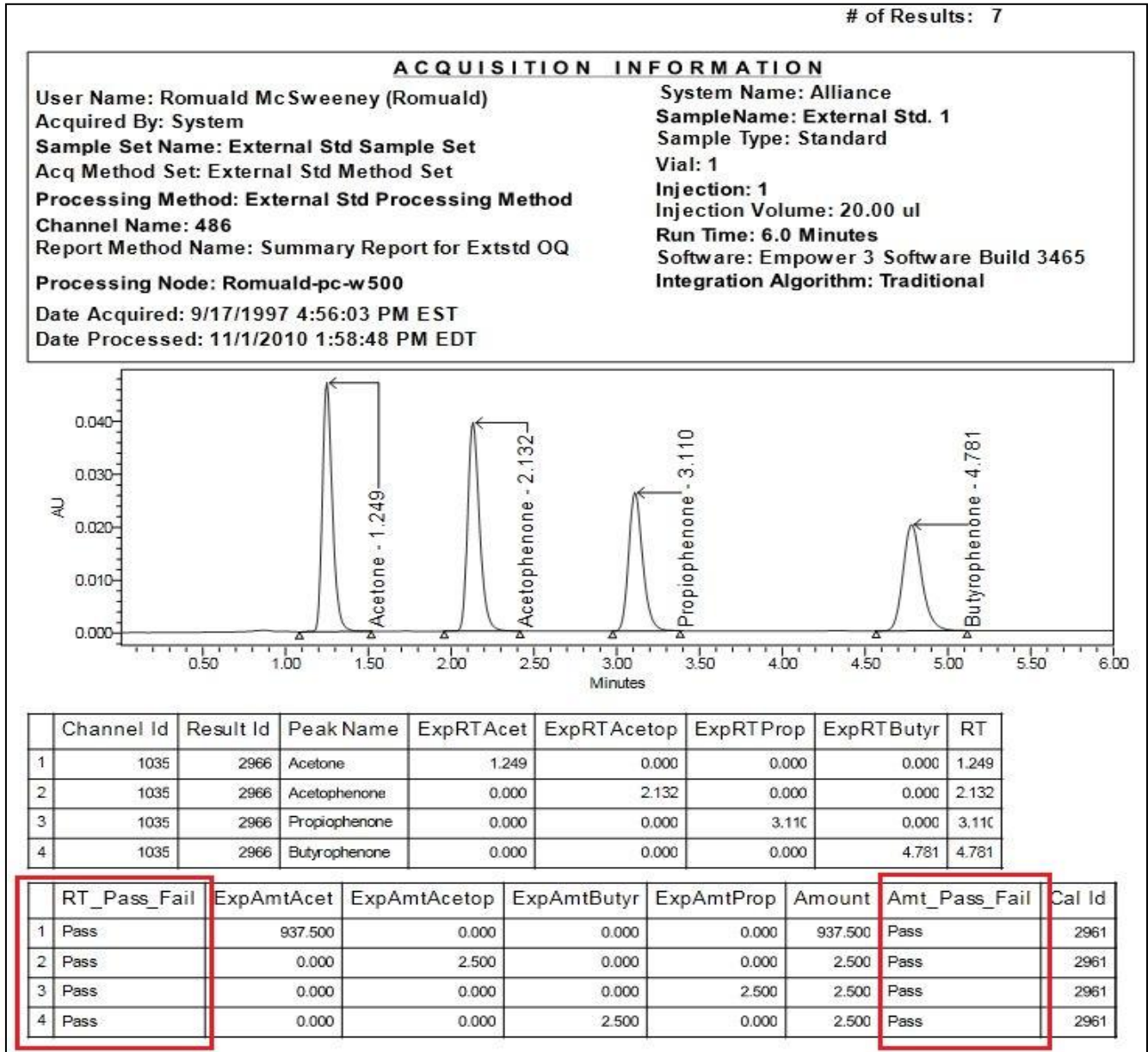
The minimum and maximum limits are set using custom fields for RT and Amount. When the actual RT or Amount falls within these limits, the OQ test returns a passing result. When "Fail" appears on any line, the RT or Amount falls outside these limits, and the test returns a failing result.

When the OQ test returns a passing result, the performer must initial the Pass line on the last page of the summary report. Then the performer and reviewer must sign and date the page, afterward filing it in the Waters binder under the Module Qualification tab.

Verifying the results of the OQ: the External Standard OQ Sample Summary Report

On the first seven pages of the External Standard OQ Sample Summary Report, ensure that "Pass" appears on each line of these two columns:

- RT_Pass_Fail
- Amt_Pass_Fail



When "Pass" appears on each line, no failures were found; all retention times (RT) equal the expected retention times (ExpRT), and the amount equals the expected amount (ExpAmt) indicated on each report page. Thus, this portion of the OQ has passed the test.

The minimum and maximum limits are set using custom fields for RT and Amount. When the actual RT or Amount falls within these limits, the OQ test returns a passing result. When "Fail" is printed on any line, the RT or Amount falls outside these limits, and the test returns a failing result.

When the OQ test returns a passing result, the performer must initial the Pass line on the last page of the summary report. Then the performer and reviewer must sign and date the page, afterward filing it in the Waters binder under the Module Qualification tab.

Operational qualification for ConnectionsAQT for Empower 3 with Method Validation Manager

If you activated the ConnectionsAQT for Empower 3 MVM qualification, the OQ uses the Valid_OQMVM project.

Requirement: You must manually restore the projects according to the integration technique specified in System Policies:

- When ApexTrack is the data processing technique, you must manually restore all three projects (Valid_OQ1, Valid_OQApex, and Valid_OQMVM) and generate a full set of OQ results and reports for each.
- When traditional integration is the data processing technique, you must manually restore only the Valid_OQ1 and Valid_OQMVM projects, and generate only two sets of OQ results and reports.

The Valid_OQMVM project is provided by Waters and is limited to verifying and documenting the ability of the Empower 3 Method Validation Manager to perform these tasks:

- Restore a validation working type project.
- Generate statistical validation results for all validation tests.
- Ensure the correct value is generated during validation processing.

When the OQ runs, the OQMVM summary report is sent to the printer. This summary report includes method validation results and protocol for these method validation tests:

- Linearity
- Linearity comparison
- LOD/LOQ
- Specificity
- Accuracy
- Repeatability
- Reproducibility
- Intermediate precision
- Intermediate precision DOE
- Robustness
- Stability
- Filter validation
- System precision

Verifying the results of the MVM OQ: the OQMVM Summary Report

On the OQMVM Summary Report you must ensure that "No" appears on each line of these columns:

- Faults
- Summary Faults

Specificity Results

Specificity Results								
	Validation Result Id	Component	Test Description	Area Mean Std Error	Retention Time Mean (min)	Retention Time Mean CI	Retention Time Mean Std Error	Faults
1	5352	Arg	AAA - Specificity	1257.164820	3.571633	0.007709	0.000607	No
2	5354	Cys	AAA - Specificity	1112.79189	6.612208	0.004641	0.000365	No
3	5353	Gly	AAA - Specificity	863.142274	3.687791	0.004877	0.000384	No

Accuracy Results

Accuracy Overall Results							
	Validation Result Id	Component	Test Description	Overall Mean % Recovery	% RSD	Calculated Validation Target	Faults
1	5329	EtP	Parabens - Acc 3 Preps 3 Injs	100.386495	1.107765	30.115945	No
2	5330	MeP	Parabens - Acc 3 Preps 3 Injs	100.222303	2.487046	25.055576	No

Per Level Accuracy Results
Component: EtP Validation Result Id: 5329

	Level	# Points	Mean % Recovery at Level	Standard Deviation	Summary Faults
1	Level 1	3	100.973593	0.033857	No
2	Level 2	3	101.268875	0.089926	No
3	Level 3	3	98.917017	0.115734	No

When "No" appears on each line, no faults were found. Thus, the OQ passed the test. When "Yes" appears on any line, the OQ has failed because the specific result differs from the target specified in the validation protocol.

When the OQ test returns a passing result, the performer must initial the Pass line on the last page of the summary report. Then the performer and reviewer sign and date the page, afterward filing it in the Waters binder under the Module Qualification tab.

When the OQ returns a failing result

When the ConnectionsAQT for Empower 3 software or Method Validation Manager OQ fail, do as follows:

1. In Configuration Manager, rename the Valid_OQ1, Valid_OQApex, or Valid_OQMVM project to Valid_OQ1_Failed, Valid_OQApex_Failed, or Valid_OQMVM_Failed.
2. Click File > Restore, to restore the Valid_OQ1, Valid_OQApex, or Valid_OQMVM project.

3. After the project is successfully restored, avoid making changes in the restored Valid_OQ1, Valid_OQApex, or Valid_OQMVM project, and then rerun the ConnectionsAQT for Empower 3 OQ again.

Tip: The OQ should then pass.

4. If required by your standard operating procedures (SOPs), compare the projects for the failed and passed results of the processing methods, to determine the cause of the failure. Additionally, review the project audit trail, to determine who made changes to the processing method.
5. (For MVM users only) If required by your SOPs, compare the projects for the failed and passed results of the processing methods, validation protocol methods, or chromatographic results of each of the validation tests to determine the cause of the failure. Additionally, review the project audit trail to determine who made changes to the methods.

To compare your results to those obtained by Waters technicians, use Microsoft XPS viewer to print these reports from the supplied CD:

- Internal Standard Data (Summary Report for IntStd OQ.pdf)
- External Standard Data (Summary Report for ExtStd OQ.pdf)
- Method Validation Data (OQMVM Summary Report.pdf)

Compare the data. The performer and reviewer must sign and date the page, afterward filing it in the Waters binder under the Module Qualification tab.