

Empower SystemsQT for Software

This protocol document describes the process for performing the Installation Qualification (IQ) and Operational Qualification (OQ) for Waters® Empower® SystemsQT™ for Software, with or without Method Validation Manager (MVM) software. This document applies to Empower 3 software with Feature Release 3 or higher.

Evaluate before qualification begins

Before qualification, the owner's management must review this protocol, the Empower SystemsQT for Software release notes (716003298), the *Waters Qualification Overview*, and the Empower 3 software release notes.

To perform the qualification, you must be running Empower 3 Feature Release 3, minimum.

Identify the scope:

- Personal, Workgroup, or Enterprise

Considerations for IQ or OQ execution:

- Execution for the Citrix® server requires that you list it as a node. If the Citrix server is not listed as a node, log in to the Citrix server and launch Empower. In Nodes, create a new node using the exact name of the Citrix server.
- If printing reports, you must have at least one printer configured and accessible.
- If using electronic signatures, you must configure the account privileges to use electronic signatures.
- Enable the Run Empower SQT privilege for your User Type.
- For use of electronic signatures, do the following:
 - o Enable the Sign Off Results 1 for your User Type.
 - o View the Result Sign Off tab in System Policies for Valid Sign Off 1 Reasons.
 - o Determine if Default Strings for Result Signoff 1 Meanings and Result Signoff 2 Meanings can be created. Create "Pass" and "Fail" default strings if possible.

In the Qualification Overview document, complete the following forms:

- Qualification Approval
- Identification of Performers and Reviewers

Overview

The Empower SystemsQT for Software uses a wizard to run the software IQ and OQ. The reports can be signed off electronically or printed. Reports that display the method parameters may contain blank fields because the parameters may not be enabled or populated in the method.

The data set used for IQ is a blank injection; with it, you can create the IQ report and use electronic signature. The IQ data set applies to Empower 3 FR3 or higher.

The data set used for internal standard calculations is identical to that used in Empower 2154, Empower 1154, and Millennium^{32®} v3.2, v3.05.01, or v3.05.

The data set used for external standard calculations is identical to that used in Empower 2154, Empower 1154, and Millennium³² v4.0 or v3.2.

The data set used for the method validation manager is identical to that used in Empower 2154 FR 3.

You need not enable ApexTrack™ integration if your organization uses traditional integration.

Installation qualification (IQ)

The IQ represents the installation qualification process for a Waters Empower 3 Personal, Workgroup, or Enterprise software system consisting of software and associated hardware components.

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

- Personal, Workgroup, or Enterprise software components are properly installed.
- Empower 3 software is properly installed.
- The Empower 3 files that you installed on the system are not corrupt, and they remain identical to the files shipped from Waters.
- Any Empower 3 software options are properly installed.
- The name of the operating system, the build number, and all service packs are correct.
- The total number of Empower 3 named user licenses and system licenses for Personal, Workgroup, and Enterprise.
- Any Empower 3 service releases or hot fixes are properly installed and verified.

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 the following file attributes:

- Cyclic Redundancy Checksum (CRC)
- File size
- File date and time stamp

To requalify the installation, you can rerun the utility at any time.

Rule: The software does not overwrite the original CHECKSUM.TXT file each time you run the Verify Files 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.

Operational qualification (OQ) for Empower SystemsQT for Software only

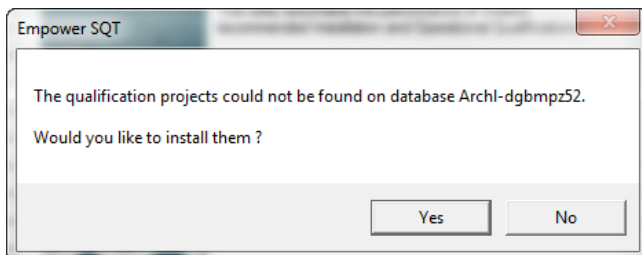
Determine if traditional integration or ApexTrack integration should be used when executing the OQ.

Restore the appropriate projects based on the integration type:

- Traditional integration – Restore the Valid_OQ1 project

- ApexTrack integration – Restore the Valid_OQ1 and Valid_OQApex projects

Ensure that all appropriate projects are restored. If all of the projects (Valid_OQ1, Valid_OQApex, and Valid_OQMVM) are not restored, the following message appears when you make requests from the SQT wizard:



You need not restore all of the projects, only those appropriate. If the appropriate projects are restored, click “No” and continue.

The projects provided by Waters are limited to verifying and documenting the ability of Empower 3 software to do the following:

- Restore projects
- Process standards
- Process unknowns
- Perform peak integration
- Perform quantification
- Perform calibration
- Generate a printed report or save a result to the database

Notes:

- When you use the ApexTrack Integration option and both the Valid_OQ1 and the Valid_OQApex projects are restored, the result sets for the Internal Std Sample Set and the External Std Sample Set are available in both projects when an OQ request is initiated.
- The reports contain an “Integration Algorithm” field that indicates if traditional or ApexTrack integration was used.

Operational qualification for Empower SystemsQT for Software with Method Validation Manager

If you activate the Empower SystemsQT for Software MVM qualification, the OQ uses the Valid_OQMVM project.

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

- Restore a validation working type project.
- Generate statistical results for all validation tests.
- Ensure that the correct value is generated during validation processing.
- Ensure that you restore the appropriate project folders for Empower 3 Feature Release 3.

The report includes results and protocol for the following method validation tests:

- Linearity

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

Node Properties

The SQT license enables additional tabs in the node properties: IQ Info and IQ/OQ.

1. In Configuration Manager, select Nodes, and then select a node to update its properties.
2. Right-click properties.
3. Select the IQ Info tab.
 - In the spaces provided, identify the computer components associated with this software IQ.
 - When you complete the Computer Components form, compare the information specified on it with the purchase order for the Empower 3 software system.
 - When you install software as part of a reloading operation or software support plan upgrade, the purchase order is sometimes unavailable. In such a case, type “RELOAD” or “UPGRADE” on the Purchase Order Number line of the Computer Component for that client.
4. Identify the documentation information required for qualification. When you complete the documentation information, identify each document as follows:
 - If the document was received, select Yes.
 - If the document was not received, select No.
 - If the document has a revision, type the revision.
 - If the document is missing or not applicable, type that information in the comments field.
5. Identify the components and peripherals of the Empower 3 system associated with this software IQ.
 - When you complete the Configuring the Computer and Peripherals section, select either “Installed” or “N/A” on the line corresponding to each device.
 - If any comments apply to the installation, type them in the comments section.

Note: If the Empower 3 system was purchased from Waters, you need not verify the configuration. Instead, in the configuring components and peripherals section, certify that the computer was configured at the factory by selecting Yes.

6. Click OK.

Running the Empower SystemsQT for Software

To run the Empower SystemsQT for Software, perform these tasks:

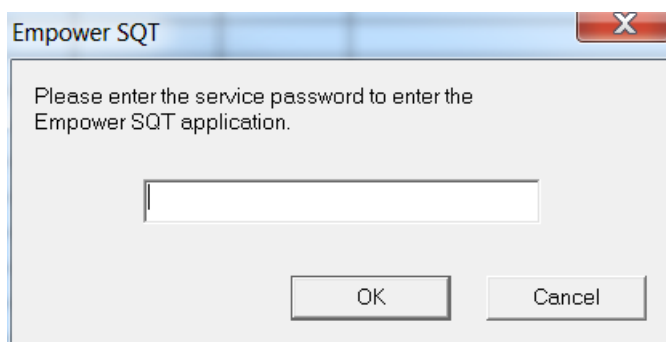
1. Using the Pro interface, log in to Empower as a designated user with a full name. Do not log in as one of the default users.
2. Before the qualification begins, ensure that the following conditions are met:
 - a. The owner's management reviewed the *Qualification Overview*, this protocol, and any applicable release notes.
 - b. The Qualification Protocol Approval Form 1-1 and the Identifying Performers and Reviewers Form 1-2 (both available in the *Qualification Overview* document) are completed and signed.
3. From the Empower Pro window, click Configure System, and then select Projects.

Requirements:

- To run the qualification, you must activate the Empower SQT for Software and the Empower SQT for Software MVM options, as applicable.
 - To run the Empower SystemsQT, you must enable the Run Empower SQT privilege for your User Type.
4. Insert the Empower SystemsQT for Software DVD into the DVD drive.
 5. From the menu bar, select File > Restore Project.
 6. Browse to the Empower SystemsQT for Software DVD, and select the appropriate Empower version and language folder.
 7. Depending on the type of integration algorithm to be used in Empower, restore the following projects:
 - For traditional integration, Valid_OQ1 project for IQ and OQ.
 - For ApexTrack integration, Valid_OQ1 project and Valid_OQApex project for IQ and OQ.
 - When using the Method Validation Manager with either integration algorithm, Valid_OQMVM project.
 8. In Configuration Manager, view the properties of the restored project or projects.
 9. Set the project access so that all required individuals can access the projects. If using owner and group access, ensure that the group access includes both the group in which you are a member and the groups of all other required individuals.

Requirement: The wizard requires specific project names to run the SQT. If you change the name of a project before initiating the SQT request, the request will not complete.
 10. In Configuration Manager, select Tools > EmpowerSQT.

11. In the service password dialog box, type the case-sensitive password, and click OK.

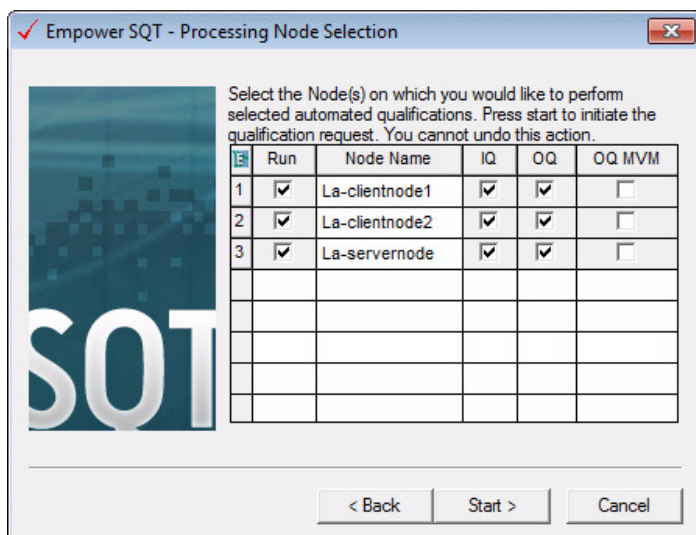


Result: When you correctly type the case-sensitive password and click OK, the Introduction wizard page appears.



12. Click Next.

Result: The Processing Node Selection wizard page appears.



13. Select the node or nodes on which you want to perform the automated qualification. You can select any node that has Empower software installed.

Notes:

- To clear the selection of all displayed nodes, clear the checkmark for the first node and then press Ctrl+D to extend the clearing for all displayed nodes.
- If the Citrix server is required but is not listed as a node, log in to the Citrix server and launch Empower. In Nodes, create a new node using the exact name of the Citrix server.
- Ensure that you select the appropriate qualification request:
 - o IQ: To perform the Empower software installation qualification on that node.
 - o OQ: To perform the Empower software operational qualification on that node.
 - o OQ MVM: To perform the Empower software operational qualification for Method Validation Manager on that node.

14. Click Start. This action initiates the selected qualifications and cannot be undone.

Result: Initiation of the qualification requests automatically populates the Date of Execution field in the node properties for the selected qualification requests. You cannot manually modify, enter, or delete the Date of Execution.

	Node Name	Node Location	Node Type	Owner	Node Comments	IQ Status	IQ Date	IQ Comment
1	Archl-dgbmpz52		Empower	System			12/17/2015 11:02:17 AM EST	

Node 'Archl-dgbmpz52' Properties

General | Instruments | Serial Ports | Configure DHCP | Access | IQ Info | IQ/OQ

IQ

Status: ☒ Date of Execution: 12/17/2015 11:02:17 AM EST

Comment:

OQ

Status: ☐ Date of Execution: 12/17/2015 11:02:24 AM EST

Comment:

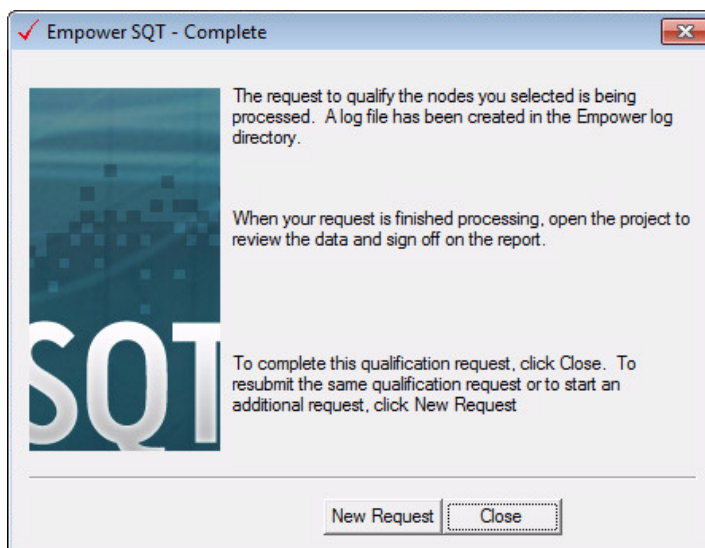
OQ MVM

Status: ☐ Date of Execution:

Comment:

OK Cancel Help

15. The Complete wizard page appears. Click Close if the qualification requests are complete. This closes the SQT wizard. Click New Request to resubmit, update, or create a new qualification request.



IQ Report

Perform the following steps:

1. From Configuration Manager, open the Valid_OQ1 project.
2. Select the Results Sets tab.
3. If multiple IQ qualification requests were performed, update the filtering by selecting Edit View and including IQ/OQ Node. This displays the node name associated with the result set created.
4. An individual IQ result set or multiple IQ result sets can be reported. Select multiple Result Sets by holding Ctrl and selecting each result or by selecting the first IQ Result set and using Shift to select a group of IQ Result Sets.
5. Once you select all of the required IQ Result Sets, right-click and select Preview/Publisher.
6. Select the appropriate report method.

Notes:

- Reports enabled for Electronic Signature are identified with the suffix “_RS”.
- When selecting a report, it is important to consider if it is appropriate to include the Empower Files because such inclusion increases the length of the report significantly, and electronic signatures require that each page be viewed prior to electronic signoff. All reports contain an Installation Qualification Summary.

Report Methods for an Individual IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ Individual Detailed	√	√	√		√

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ Individual Detailed_RS	✓	✓	✓	✓	
IQ Individual Summary	✓		✓		✓
IQ Individual Summary_RS	✓		✓	✓	

Report Methods for Multiple IQ Result Set:

Report Name	Installation Information	Empower Files	Installation Qualification Summary	Electronic Signature Enabled	Hand-written Signatures
IQ All Selected Detailed	✓	✓	✓		✓
IQ All Selected Detailed_RS	✓	✓	✓	✓	
IQ All Selected Summary	✓		✓		✓
IQ All Selected Summary_RS	✓		✓	✓	

7. Review the report.

Note: When reviewing the IQ report, you may notice that the result set time is not the same as the current time displayed on the report. When the result set is stored, the server provides the date and time associated with the result set. The current date and time comes from the node where the checksum report is created.

8. A node passes installation qualification if the Installation Qualification Summary states "no installation changes were detected". If another message appears (for example, "the following changes were detected:"), Waters recommends that you do the following:
 - a. Check for a standard operating procedure that notes the change and specifies if the change means the installation qualification passes or fails.
 - b. Evaluate the change and document the effects of these changes to determine if installation qualification passes or fails.
 - c. Reinstall the software and perform the IQ again.
9. When you find installation errors and the operational qualification fails, you must reinstall the Empower 3 software. Deactivate the options before reinstalling Empower 3.
10. For handwritten signatures, print the report or reports and then perform the following steps:
 - a. Complete the Qualification Status of the report and include the following: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the approver to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Installation Qualification tab.

11. For Electronic Signatures, use the Sign Off button after you review each page of the report.
12. Perform Sign Off 1 by typing the user name and password. Depending on the system policies, perform one of the following for the Reason:
 - Select the appropriate default string that includes the text “Pass” or “Fail”.
 - Select the appropriate default string and add the text “Pass” or “Fail”.

Note: Append additional comments to a Reason when appropriate. For example, if installation changes are detected but the changes are determined to be noncritical, reference this information as appended text in the Reason.
13. Notify the approver that he or she must electronically sign the results as “Sign Off 2”.
14. It is optional to update the IQ/OQ tab in the node properties with IQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

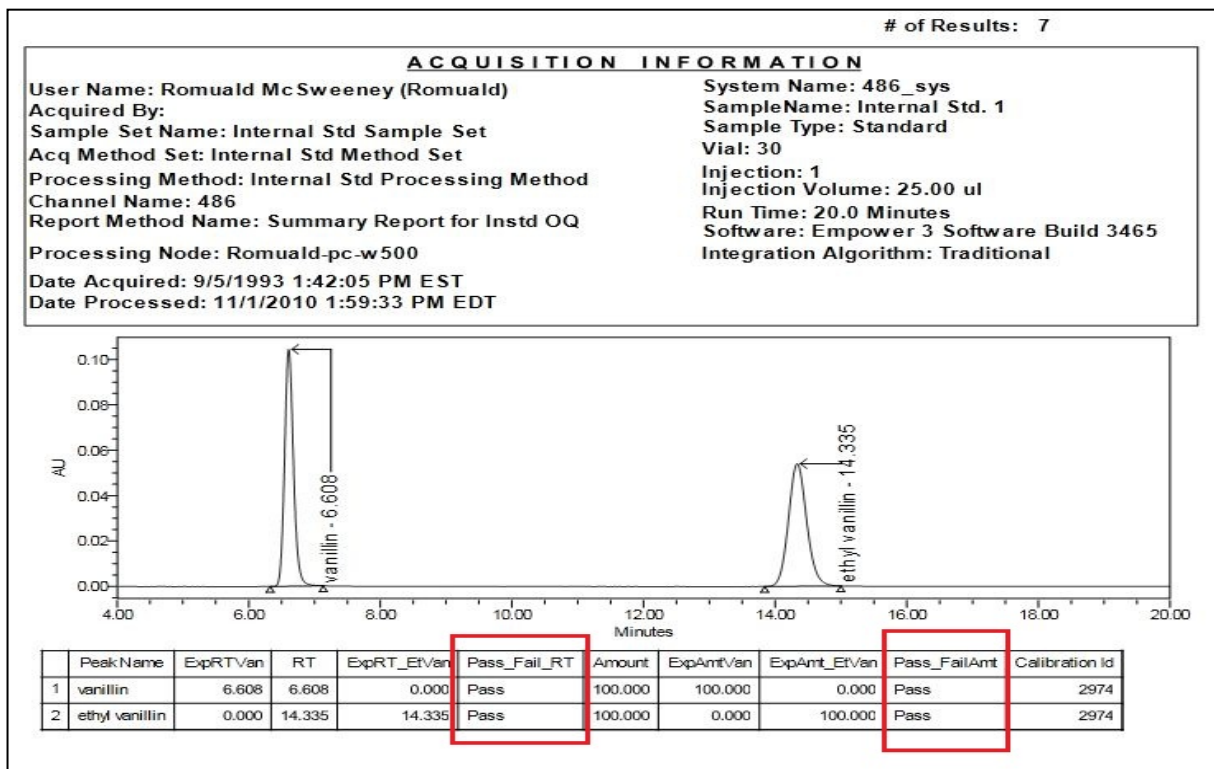
Verifying the results of the OQ: the Internal Standard OQ Sample Summary Report (Electronic or Printed)

Perform the following steps:

1. From Configuration Manager, open the Valid_OQ1 (Traditional Integration) or Valid_OQApex project (ApexTrack Integration).

Note: When the ApexTrack Integration option is enabled and both the Valid_OQ1 and Valid_OQApex projects are restored, result sets for the Internal Std Sample Set and External Std Sample Set will be available in both projects when an OQ request is initiated. Perform this procedure for both of the projects to evaluate Traditional and ApexTrack Integration.
2. Select the Result Set tab and select the appropriate “Internal Std Sample Set”.

Note: When multiple result sets are created, Waters recommends that you update the filtering by selecting Edit View and including the IQ/OQ Node. This displays the node name associated with the result set created.
3. Right-click and select Preview/Publisher.
4. Open the appropriate report method:
 - “Summary Report for Instd OQRS” for Electronic Signatures.
 - “Summary Report for Instd OQ” for Handwritten Signatures.
5. Review the report to ensure that “Pass” appears on each line of the following two columns:
 - Pass_Fail_RT
 - Pass_FailAmt



6. 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.
7. 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.
8. For handwritten signatures, print the report, and then do the following:
 - a. Complete the Certification section of the report and include the following: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the Reviewer to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Operational Qualification tab.
9. For Electronic Signatures use the Sign Off button after you review each page of the report.
10. Perform Sign Off 1 by typing the user name and password. Depending on the system policies, perform one of the following for the Reason:
 - Select the appropriate default string that includes the text "Pass" or "Fail".
 - Select the appropriate default string and add the text "Pass" or "Fail".

Note: Append additional comments to a Reason when appropriate.
11. Notify the Reviewer that he or she must electronically sign the results as "Sign Off 2".

12. It is optional to update the IQ/OQ tab in the node properties with OQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

Verifying the results of the OQ: the External Standard OQ Sample Summary Report (Electronic or Printed)

Perform the following steps:

1. From Configuration Manager, open the Valid_OQ1 or Valid_OQApex project.

Note: When the ApexTrack Integration option is enabled and both the Valid_OQ1 and Valid_OQApex projects are restored, result sets for the Internal Std Sample Set and External Std Sample Set are available in both projects when an OQ request is initiated. Perform this procedure for both of the projects to evaluate Traditional and ApexTrack Integration.

2. Select the Result Set tab and select the appropriate "External Std Sample Set".

Note: When multiple result sets are created, Waters recommends that you update the filtering by selecting Edit View and including the IQ/OQ Node. This displays the node name associated with the result set created.

3. Right -click and select Preview/Publisher.

4. Open the appropriate report method:

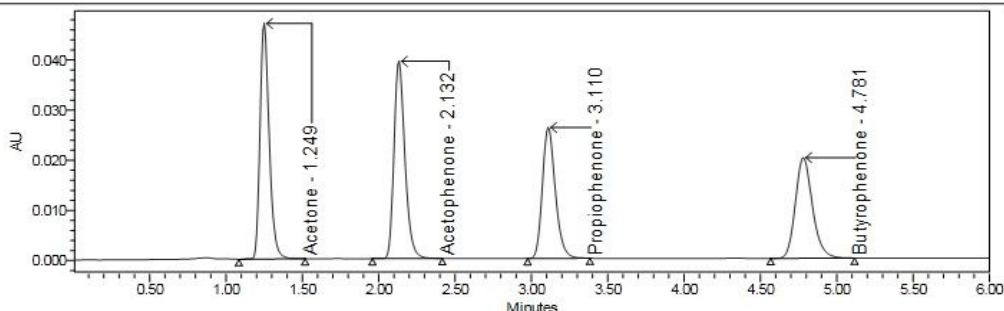
- "Summary Report for Exstd OQRS" for Electronic Signatures
- "Summary Report for Exstd OQ" for Handwritten Signatures

5. Review the report to ensure that "Pass" appears on each line of the following two columns:

- RT_Pass_Fail
- Amt_Pass_Fail

ACQUISITION INFORMATION

User Name: Romuald McSweeney (Romuald)	System Name: Alliance
Acquired By: System	SampleName: External Std. 1
Sample Set Name: External Std Sample Set	Sample Type: Standard
Acq Method Set: External Std Method Set	Vial: 1
Processing Method: External Std Processing Method	Injection: 1
Channel Name: 486	Injection Volume: 20.00 ul
Report Method Name: Summary Report for Extstd OQ	Run Time: 6.0 Minutes
Processing Node: Romuald-pc-w500	Software: Empower 3 Software Build 3465
Date Acquired: 9/17/1997 4:56:03 PM EST	Integration Algorithm: Traditional
Date Processed: 11/1/2010 1:58:48 PM EDT	



	Channel Id	Result Id	Peak Name	ExpRTAcet	ExpRTAcetop	ExpRTProp	ExpRTButyr	RT
1	1035	2966	Acetone	1.249	0.000	0.000	0.000	1.249
2	1035	2966	Acetophenone	0.000	2.132	0.000	0.000	2.132
3	1035	2966	Propiophenone	0.000	0.000	3.110	0.000	3.110
4	1035	2966	Butyrophenone	0.000	0.000	0.000	4.781	4.781

	RT_Pass_Fail	ExpAmtAcet	ExpAmtAcetop	ExpAmtButyr	ExpAmtProp	Amount	Amt_Pass_Fail	Cal Id
1	Pass	937.500	0.000	0.000	0.000	937.500	Pass	2961
2	Pass	0.000	2.500	0.000	0.000	2.500	Pass	2961
3	Pass	0.000	0.000	0.000	2.500	2.500	Pass	2961
4	Pass	0.000	0.000	2.500	0.000	2.500	Pass	2961

6. 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.
7. 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.
8. For handwritten signatures, print the report, and then do the following:
 - a. Complete the Certification section of the report and include the following: pass/fail status, any applicable comments, signature, and date.
 - b. Contact the Reviewer to review, sign, and date the report.
 - c. File all reports, passed or failed, in your Waters binder under the Operational Qualification tab.
9. For Electronic Signatures, use the Sign Off button after you review each page of the report.
10. Perform Sign Off 1 by typing the user name and password. Depending on the system policies, perform one of the following for the Reason:
 - Select the appropriate default string that includes the text "Pass" or "Fail".

- Select the appropriate default string and add the text “Pass” or “Fail”.

Note: Append additional comments to a Reason when appropriate.

11. Notify the Reviewer that he or she must electronically sign the results as “Sign Off 2”.
12. It is optional to update the IQ/OQ tab in the node properties with OQ status (Pass or Fail) and Comment. This information is for administrative purposes only. The status and comments are provided in the handwritten or electronically signed report.

Verifying the results of the MVM OQ: the OQMVM Summary Report (Electronic or Printed)

When OQMVM is requested, the project folder Valid_OQMVM contains a study name associated with the requested node. For example, the study name Valid_OQMVM Study: Node0013.

Perform the following steps:

1. Select the Valid_OQMVM project and open it.
2. On the Validation Studies tab, select the appropriate Study Name, and then right-click and select Preview/Publisher.

Note: Expect 62 validation results for a validation study. If multiple OQMVM are made to a node, in the Edit View include the Study Modified Date to clearly identify the appropriate validation study to select.

3. Open the appropriate report method:
 - “OQMVM Summary ReportRS” for Electronic Signatures
 - “OQMVM Summary Report” for Handwritten Signatures
4. On the report, ensure that “No” appears on each line of the following columns:
 - Faults
 - Summary Faults

Note: When “No” appears on each line, no faults were found and the OQ passed the test. When “Yes” appears on any line, the OQ has failed. “Yes” indicates that the specific result differs from the target specified in the validation protocol.

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

5. For handwritten signatures:
 - a. Print the report.
 - b. The performer must initial and date the Pass line on the last page of the summary report.
 - c. The performer and reviewer sign and date the page.
 - d. File the report in the Waters binder under the Operational Qualification tab.
6. For electronic signatures, review the report and electronically sign the results as "Sign Off 1".
7. Type the user name and password. Depending on the system policies, perform one of the following for the Reasons:
 - a. Select the appropriate default string that includes the text "Pass" or "Fail".
 - b. Select the appropriate default string and add the text "Pass" or "Fail".

Note: Append additional comments to a Reason when appropriate.
8. Notify the Approver that he or she must electronically sign the results as "Sign Off 2".
9. It is optional, as an administrative aid, to update the IQ/OQ tab in the node properties with the OQMVM status (Pass or Fail) and Comment. The status and comments are provided in the handwritten or electronically signed report.

When the OQ returns a failing result

When the Empower SystemsQT for Software or Method Validation Manager OQ fails, 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, respectively. You can also append a date and time after “_Failed”.
2. Click File > Restore, to restore the Valid_OQ1, Valid_OQApex, or Valid_OQMVM project.
3. After the project successfully restores, avoid making changes in the restored Valid_OQ1, Valid_OQApex, or Valid_OQMVM project, and then rerun the Empower SystemsQT for Software OQ.
Note: Expect a passing result.
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.
5. Review the project audit trail to determine who made changes to the processing method.
6. (For MVM users only) If required by your SOPs, compare the projects for the failed and passed results of the processing methods, the validation protocol methods, or the chromatographic results of each of the validation tests to determine the cause of the failure.
7. (For MVM users only) Review the project audit trail to determine who made changes to the methods.
8. (For MVM users only) Restore the correct project from the folder on the disk for Empower 3 FR3; otherwise, you will get failures.

For the printed OQ, the performer and the reviewer must sign and date the page. Afterwards, file the page in the Waters binder under the Operational Qualification tab.

For electronic OQ, update the IQ/OQ tab accordingly.

Protocol revision changes

The following changes were made to this protocol from Revision A to Revision B:

Page	Section	Change description
1	Introductory paragraph	A sentence is added to indicate that this document applies to Empower 3 software with Feature Release 3 or higher.
1	Evaluate before qualification begins	The previous list of Release Notes and part numbers is deleted. The second sentence is revised to specify Empower 3 Feature Release 3. The third and fourth bulleted items are added.
1	Overview	The first sentence of the first paragraph is revised to remove mention of Empower 3 FR1 and above. The second paragraph is revised to indicate that the IQ data set was collected for Empower 3 FR3 or higher.

Page	Section	Change description
2	Installation qualification (IQ)	The first paragraph and the first bulleted item are revised to remove mention of the LAC/E³² module. The sixth bulleted item is revised to add Empower Personal. The seventh bulleted item is revised to indicate "Any Empower 3 service releases or hot fixes are properly installed and verified."
2	Software file verification	The third paragraph is revised to remove mention of the installation being aborted.
7	Running the Empower SystemsQT for Software	The first sentence of step 13 is revised to remove mention of Empower 3 FR3. The second sentence is revised to specify that this applies to any node that has Empower software installed.
16	When the OQ returns a failing result	Step 8 is revised. The text below step 8 is revised.