

Test Descriptions and Specifications of SystemsQT for ACQUITY UPLC Systems with an ACQUITY PDA/PDA e λ /2996/TUV Detector with/without an ACQUITY ELS Detector

This document describes qualification tests and lists specifications for the Waters® Systems Qualification Tool (SystemsQT™). Use this SystemsQT with ACQUITY UPLC Systems that include an ACQUITY PDA, ACQUITY PDA e λ , ACQUITY 2996 PDA, or ACQUITY TUV detector with/without an ACQUITY ELS detector controlled by Empower™ (build 1154 with Service Pack L), Empower 2 (build 2154 with Feature Release 4 or 5), or Empower 3 software.

SystemsQT tests

The following manually performed and automated qualification tests are performed on this system dependent on configuration:

1. Manually performed OQ tests run before the automated tests
 - a. Quaternary solvent manager (QSM) flow rate accuracy
 - b. Binary solvent manager (BSM) flow rate accuracy
 - c. Sample manager - flow through needle (FTN) heater/cooler temperature accuracy
 - d. Sample manager heater/cooler temperature accuracy
 - e. Column manager, column heater/cooler, column heater, HT column heater, 30-cm column heater/cooler, column manager-A, or HT column heater-A temperature accuracy
 - f. Sample organizer heater/cooler sample compartment temperature
 - g. Sample organizer plate positioning
2. Automated tests
 - a. Test injections
 - b. System precision
 - c. Wavelength accuracy (ACQUITY PDA/PDA e λ /2996/TUV detector only)
 - d. UV detector linearity and sensitivity (ACQUITY PDA/PDA e λ /TUV detector only) and ELS response (ACQUITY ELS detector only)

- e. Injector linearity and accuracy
- f. Noise and drift (ACQUITY PDA/PDA eλ/2996/TUV detector only)
- g. Flow rate linearity
- h. Carryover
- i. Gradient performance

Manually performed OQ tests

Requirement: Run manually performed OQ tests before the automated SystemsQT tests. When doing so, refer to the manual OQ test procedures on the SystemsQT Projects/Documentation DVD.

QSM and BSM Flow Rate Accuracy

Flow rate accuracy is determined by timing the delivery of a set volume of mobile phase at a specified flow rate and system pressure into a certified volumetric flask. A calibrated stop watch and Class A volumetric flask are used for the measurements. The specification for flow rate accuracy includes the flask accuracy and operator error allowance.

Failing results

If the flow rate accuracy test results fail to fall within specifications, take these actions:

- Look for leaks in the fluid lines and inspect all tubing connections.
- Prime the solvent lines.
- Ensure the mobile phase is sufficiently degassed.
- Ensure the check valves are working properly.

Upon solving the problem, identify the cause and resolution in the system log. Then rerun the flow rate accuracy test. If you are unable to resolve the problem, log the failure in the system log.

Sample manager – FTN and sample manager heater/cooler temperature accuracy

Sample heater/cooler temperature accuracy is determined by measuring the temperature within the sample heater/cooler at a specific location (the sensor) and comparing it against the set-point programmed on the instrument. The test requires a calibrated temperature measuring device that is accurate to $\pm 1.0^{\circ}\text{C}$. Up to two temperature set-points may be tested.

Failing results

If the sample heater/cooler temperature accuracy test results fail to fall within specifications, take these actions:

- Ensure the probe of the temperature measurement device is in the proper location.
- Ensure the set temperature is at least 5.0°C above or below the ambient room temperature.

Column manager, column heater/cooler, column heater, HT column heater, 30-cm column heater/cooler, column manager-A, or HT column heater-A temperature accuracy

Temperature accuracy is determined by measuring the temperature within the instrument at a specific location (the sensor) and comparing it against the set-point programmed on the instrument. The test requires a calibrated temperature measuring device that is accurate to $\pm 1.0^{\circ}\text{C}$. Up to two temperature set-points may be tested.

Failing results

If the temperature accuracy test results fail to fall within specifications, take these actions:

- Ensure the probe of the temperature measurement device is in the proper location.
- Ensure the set temperature is at least 5.0°C above or below the ambient room temperature.

Sample organizer heater/cooler sample compartment temperature

Sampler organizer temperature is determined by measuring the temperature within the instrument at a specific location and comparing it against the set-point programmed on the instrument. The test requires a calibrated temperature measuring device that is accurate to $\pm 1.0^{\circ}\text{C}$.

Failing results

If the temperature test results fail to fall within specifications, take these actions:

- Ensure the probe of the temperature measurement device is in the proper location.
- Ensure the set temperature is at least 5.0°C above or below the ambient room temperature.

Sample organizer plate positioning

The sample organizer plate positioning test confirms that each of the four plates used in the test can correctly transfer from the sample organizer, to the sample manager, and then back to their original position in the sample organizer.

Failing results

If the plate positioning test fails, take these actions:

- Verify that the correct plate was configured.
- Verify that there are no obstructions.
- Verify that the plates are positioned correctly and not hanging off the edge of the shelf.
- Verify that the pressure on the Console is between 100 – 110 psi.

Automated tests

Requirement: Perform the automated tests after the manually performed OQ tests have successfully completed.

Test injections

Test injections are not part of the SystemsQT qualification. They merely ensure that the system is equilibrated and prepared for qualification.

Run a test-injections sample set before running any qualification sample sets. The test injections must indicate passing results before you continue with any qualification sample sets. The SystemsQT software selects the appropriate sample set based on the Empower project. The test injections sample set includes an equilibration step followed by two blank injections of mobile phase to equilibrate the system. Three injections of a caffeine solution follow, all at the same concentration and injection volume. Deviation in the area and height of the peaks is expressed by the percent relative standard deviation (%RSD) and should be minimal in a well-functioning system. The %RSD of the area and height gives the injection precision, and the standard deviation of the retention time is the measure of system precision.

The test-injections sample set for the UV detectors includes an equilibration step followed by two blank injections of mobile phase to equilibrate the system. Three injections of a caffeine solution follow, all at the same concentration and injection volume. Deviation in the area and height of the peaks is expressed by the %RSD and should be minimal in a well-functioning system. The %RSD of the area and height gives the injection precision, and the standard deviation of the retention time is the measure of system precision. Test injections are performed using the sample set that has the highest concentration from the detector linearity sample set (UV detectors). The test injections are used to ensure that detector linearity is verified over the range of 0.1 to 2.0 $\pm$ 0.2 absorbance units (AU).

Determining pass/fail criteria

For test injections, the results tables include custom fields called Area %RSD (for the %RSD of the area) and Height %RSD (for the %RSD of the height). The corresponding Boolean custom fields determine whether Area % Pass Fail and Height % RSD Pass Fail fall within specifications. When they do, the word Pass appears. When they do not, the word Fail appears.

For the retention time measure, the results table includes a custom field called Retention Time (sec) standard deviation. The corresponding Boolean custom field determines whether Retention Time (sec) standard deviation Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

For the peak height measure, the results table includes a custom field called Minimum Peak Height Pass Fail. The corresponding Boolean custom field determines whether Height (AU) falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

The compliance specialist must examine the test injection reports to ensure these conditions are met:

- ♦ Three caffeine peaks must be identified in the chromatograms. If they do not appear, the processing methods require updated retention times. When saving the revised methods, include a comment that retention times were updated based on test injections.

Processing Method Name	Component
Test Injections PM	Caffeine
System Precision PM	Caffeine
Wavelength Accuracy PM	Caffeine
Detector Height PM	Caffeine
Detector Area PM	Caffeine
Injector Lin Acc PM	Caffeine
Carryover PM	Caffeine

- ♦ The chromatographic peak results table names caffeine as a peak, and the peak appears in the table three times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).
- ♦ The test injections meet their specifications for retention time, area, and height reproducibility and minimum height before any other qualification test can run.

Failing results

When test-injection precision results fall outside specifications, take these actions:

- ♦ Inspect the injector for leaks or bubbles.
- ♦ Ensure the solvent reservoirs are not empty.
- ♦ Prime the pump lines.
- ♦ On the sample manager-FTN, prime the purge solvent.
- ♦ On the sample manager, prime the syringes and flush the needle.
- ♦ Perform leak tests of the sample manager – FTN or a static leak test of the sample manager.
- ♦ On the sample manager, recharacterize the sample manager's needle and loop volumes.

When test injections minimum peak height results fall outside specifications with a result <1.8 AU, take these actions:

- ♦ Click Abort on the Wait for User dialog box, and ensure the correct sample is in the correct vial location. If the sample and vial locations are correct, continue with the following step. If the correct sample is not in the correct vial location, correct it, restart the SQT, rerun test injections, and then continue with the following step.
- ♦ If the results fall outside specifications with a result <1.8 AU, take these actions:
 - Click Abort on the Wait for User dialog box.
 - Recycle power on the TUV/PDA/PDA eλ detector.
 - Manually calculate peak width using this formula: Peak width = (2 × Area)/Height.
 - If the manually calculated peak width is >2.6, take these actions:
 - Physically reset the column inlet/outlet and detector inlet fittings.

- Restart the SQT and rerun test injections.
- If test injections minimum peak height results again fall outside specifications, continue with Step A below.
- If the manually calculated peak width is ≤ 2.6 , take these actions:
 - (Step A) Verify the reference energy of the detector and, if needed, clean the flow cell.
 - Start flow, and reverify the reference energy of the detector.
 - Restart the SQT and rerun test injections.
- If test injections minimum peak height results again fall outside specifications, contact your Waters service representative for detector repair.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the test injections using the wizard.

System precision test

You determine system precision by running a sample set in Empower software and acquiring data in Run Samples. The SystemsQT software selects the appropriate sample set based on the project. The sample set performs an equilibration step and makes six injections of a caffeine solution, all at the same concentration and injection volume. The chromatograms should show the caffeine peak with the same retention time, area, and height. The deviation of these six chromatograms is expressed by the standard deviation and %RSD, which should be minimal in a well-functioning system. The %RSD is used to determine the precision of the injector and system, the %RSD of the area and height gives the injection precision, and the standard deviation of the retention time is a measure of the system precision.

Determining pass/fail criteria

For the system-precision test, the results table includes custom fields called Area %RSD (for the %RSD of the area) and Height %RSD (for the %RSD of the height). The corresponding Boolean custom fields determine whether Area % RSD Pass Fail and Height % RSD Pass Fail fall within specifications. When they do, the word Pass appears. When they do not, the word Fail appears.

For the retention time measure, the results table includes a custom field called Retention Time (sec) standard deviation. The corresponding Boolean custom field determines whether Retention Time (sec) standard deviation Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

The chromatographic peak results table names caffeine as a peak, and the peak appears in the table six times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).

Failing results

When system-precision test results fall outside specifications, take these actions:

- Inspect the injector for leaks or bubbles.
- Ensure the solvent reservoirs are not empty.

- ♦ On the sample manager – FTN, prime the purge solvent.
- ♦ On the sample manager, prime the syringes and flush the needle.
- ♦ Perform leak tests of the sample manager - FTN or a static leak test of the sample manager.
- ♦ On the sample manager, recharacterize the sample manager's needle and loop volumes.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the system-precision test using the wizard.

Wavelength accuracy test (UV detector only)

Wavelength accuracy with an ACQUITY PDA, PDA eλ, 2996, or TUV detector is determined by measuring the spectrum of a well-known compound, running the appropriate sample set in Empower software, and acquiring data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. The bands within caffeine— λ_{max} of 205 nm and 273 nm—are well defined. Empower software measures deviations from these wavelengths to determine the accuracy of the detector. For the ACQUITY PDA or PDA eλ detector, wavelength accuracy must fall within ± 2 nm to pass with two injections. For the ACQUITY TUV detector, wavelength accuracy must fall within ± 2 nm to pass with 14 injections.

Determining pass/fail criteria

For wavelength accuracy, the results table includes a custom field called Lambda Max. The corresponding Boolean custom field determines whether Lambda Max Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

In both wavelength accuracy result tables, ensure all seven lines report both area and height so the Lambda Max custom field reports correctly.

Failing results

When wavelength-accuracy test results fall outside specifications, take these actions:

- ♦ Ensure that the sample concentrations were correct.
- ♦ Confirm that the sample concentrations were in the correct sample tray positions in the sample manager – FTN or sample manager. For more information, see the SystemsQT Amounts PDF document called Amounts.pdf on the SystemsQT Projects/Documentation DVD.
- ♦ Clean the UV detector's flow cell.

If the failure persists, a Waters field service technician must service the detector's optics bench or you must return the optics bench to Waters for repair.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the wavelength-accuracy test using the wizard.

UV detector linearity and sensitivity test and ELS response test

The UV-detector-linearity test with an ACQUITY PDA, PDA e λ , or TUV detector determines whether a detector's response is linear within its absorbance range. The test involves running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. The sample set injects a series of standards at different concentrations using a constant injection volume. Empower software plots area and height against the sample amount and applies the coefficient of determination (r^2) to measure the linearity of the detector's response.

The UV detector's sensitivity with an ACQUITY PDA, PDA e λ , or TUV detector is determined by dividing the height and area by the amount, applying the standards used to determine detector linearity. The apparent sensitivity, S , varies over the dynamic range of the instrument, so the magnitude of the %RSD of the sensitivity is a good measure of the degree of variation. When sensitivities are measured at values of absorbance that fall on both the linear and curved portions of the calibration curve, the %RSD of the sensitivity is a good measure of the linear dynamic range.

The ELS-response test with an ACQUITY ELS detector determines whether an ELS detector has a log/log linear response within the range of sample concentration injected. The test involves running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. The sample set injects a series of standards at different concentrations using a constant injection volume. Empower software plots area and height against the sample amount and applies the coefficient of determination (r^2) to measure the linearity of the detector's response.

No sensitivity test exists for an ACQUITY ELS detector.

Determining pass/fail criteria for linearity or ELS response

For the UV-detector-linearity test or ELS-response test, the results table includes custom fields called Area Linearity Curve R^2 and Height Linearity Curve R^2 . The corresponding Boolean custom fields determine whether Area Linearity Curve R^2 Pass Fail and Height Linearity Curve R^2 Pass Fail fall within specifications. When they do, the word Pass appears. When they do not, the word Fail appears.

The chromatographic peak results table names caffeine as a peak, and the peak appears in each table seven times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).

Determining pass/fail criteria for sensitivity

For the UV-detector-sensitivity test, the results table includes custom fields called Area Sensitivity %RSD and Height Sensitivity %RSD. The corresponding Boolean custom fields determine whether Area Sensitivity %RSD Pass Fail and Height Sensitivity %RSD Pass Fail fall within specifications. When they do, the word Pass appears. When they do not, the word Fail appears.

The chromatographic peak results table names caffeine as a peak, and the peak appears in each table seven times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).

No sensitivity test exists for an ACQUITY ELS detector.

Failing results

When detector-linearity and -sensitivity test results or ELS-response test results fall outside specifications, take these actions:

- ♦ Ensure that the sample concentrations were correct.
- ♦ Check that the sample concentrations were in the correct sample tray positions in the sample manager – FTN or sample manager. For more information, see the SystemsQT Amounts PDF document called Amounts.pdf on the SystemsQT Projects/Documentation DVD.
- ♦ Ensure that solvent lines are at the bottoms of the reservoirs.
- ♦ Confirm that no air bubbles are in the flow cell.
- ♦ Confirm that the three test injection results fall within specifications.
- ♦ Confirm that the system precision test results fall within specifications.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the detector-linearity and -sensitivity test or ELS-response test, as applicable, using the wizard.

Injector linearity and accuracy test

The injector-linearity-and-accuracy test verifies whether a delivered injection volume is linear within specified criteria. The test involves running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. The sample set injects four different injection volumes of one concentration from the same vial. Empower software plots the area versus the volume injected to determine both the injector linearity and accuracy.

Determining pass/fail criteria

For the injector linearity, the results table includes a custom field called Linearity R^2 . The corresponding Boolean custom field determines whether Linearity R^2 Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

For the injector accuracy, the results table includes a custom field called Injector Accuracy. The corresponding Boolean custom field determines whether Injector Accuracy Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

The chromatographic peak results table names caffeine as a peak, and the peak appears in the table four times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).

Failing results

When injector-linearity-and-accuracy test results fall outside specifications, take these actions:

- ♦ Inspect the injector syringe and seals for leaks or bubbles.
- ♦ Ensure the solvent reservoirs are not empty.
- ♦ On the sample manager - FTN, prime the purge solvent.

- ♦ On the sample manager, prime the syringes and flush the needle.
- ♦ Perform leak tests of the sample manager - FTN or a static leak test of the sample manager.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the injector-linearity-and-accuracy test using the wizard.

Noise and drift test (UV detector only)

The noise and drift test is for ACQUITY PDA/PDA e λ /TUV detectors only. System detector noise is determined by running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the project. Data for noise and drift is collected for 15 minutes.

The average peak-to-peak noise (equivalent to ASTM 685-79) is calculated for 30-second intervals from 3 to 15 minutes. The detector average noise, in μ AU, is reported.

Detector drift is calculated for the 3 to 15-minute interval. The drift, in mAU/Hr, is reported.

Determining pass/fail criteria

For the noise test, the results table includes a custom field called Average Peak to Peak Noise (μ AU). The corresponding Boolean custom field determines whether "Noise Pass Fail" falls within specifications. When it does, the word "Pass" appears. When it does not, the word "Fail" appears.

For the drift test, the results table includes a custom field called Detector Drift (mAU/Hr). The corresponding Boolean custom field checks whether "Drift Pass Fail" falls within specifications. When it does, the word "Pass" appears. When it does not, the word "Fail" appears.

Failing results

If the test results fail to fall within specifications, take these actions:

- ♦ Ensure that you followed the SystemsQT Instrument and System Qualification Setup PDF procedure, which appears on the SystemsQT Projects/Documentation DVD.
- ♦ Look for baseline noise cycling (short term, 30 to 60 seconds).
- ♦ Look for flow fluctuations. Stabilize fluctuations by inspecting for leaks and repairing them.
- ♦ Look for radio frequency noise (short- or long-term cycling) and eliminate the interference.
- ♦ Look for ambient temperature fluctuations, and if present, stabilize the ambient temperature.
- ♦ Ensure the blank vial is in the correct position in the sample tray. (Refer to the SystemsQT Amounts PDF document on the SystemsQT Projects/Documentation DVD.)

Requirement: If repeating the noise and drift test, use a new blank vial containing fresh blank solution, and place it in the corresponding vial location.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the noise and drift test using the wizard.

Flow rate linearity test

The flow-rate-linearity test determines whether the QSM's flow rate is linear. The test involves running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. The sample set repeatedly injects a constant volume of sample and varies the flow rate. The plot generated is the plot of $1/t_r$ versus V_f (where t_r = caffeine retention time and V_f = flow rate), which measures flow rate linearity. Note that the X Value column in the results report represents the flow rate.

Determining pass/fail criteria

For the flow-rate-linearity test, the results table includes a custom field called Linearity R^2 . The corresponding Boolean custom field determines whether Linearity R^2 Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

The chromatographic peak results table names caffeine as a peak, and the peak appears in the table four times (so that caffeine is not identified based on only one peak and the Boolean custom field does not report Pass).

Failing results

When flow-rate-linearity test results fall outside specifications, look for a leak in the fluid lines. Inspect all tubing connections.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the flow-rate-linearity test using the wizard.

Carryover test

The carryover test determines the presence of sample carryover from one injection to the next. It involves running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project. Two preblank injections are performed to determine whether the system is clean enough to measure carryover. Three caffeine calibration injections follow at a concentration of $0.2 \mu\text{g/mL}$ which corresponds to 0.005% of the challenge injection concentration (4.0 mg/mL). These injections are followed by a challenge injection, which itself is followed by three postblank injections. Using the area calibration curve of the caffeine calibration standards, carryover in the post-blank injections is calculated and reported as a percentage of the challenge concentration.

Determining pass/fail criteria

For the carryover test, the results table includes a custom field called %Carryover. The corresponding Boolean custom field determines whether Carryover Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

In the "Peak Type" column of the chromatographic peak results table, ensure "Found" appears for all rows of sample type "Standard". If it does not, review the chromatography and determine the cause of the missing peak(s).

Failing results

When carryover test results fall outside specifications, take these actions:

- ♦ Ensure that you followed the SystemsQT Instrument and System Qualification Setup PDF procedure, which appears on the SystemsQT Projects/Documentation DVD.
- ♦ Ensure the solvent reservoirs are not empty.
- ♦ Ensure the solvent lines are not kinked or blocked.
- ♦ Ensure the blank vials are in the correct positions in the sample tray. For more information, see the SystemsQT Amounts PDF document called Amounts.pdf on the SystemsQT Projects/Documentation DVD.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the carryover test using the wizard.

Gradient performance test

The gradient-performance test determines whether a solvent management system can deliver a solvent mixture within acceptable criteria. A seven component mixture is injected six times. The gradient performance test is established by running a sample set in Empower software to acquire data in Run Samples. The SystemsQT software selects the appropriate sample set based on the Empower project.

Determining pass/fail criteria

For the gradient-performance test, the results table includes a custom field called Retention Time(seconds) Standard Deviation. The corresponding Boolean custom field determines whether Retention Time(seconds) Standard Deviation Pass Fail falls within specifications. When it does, the word Pass appears. When it does not, the word Fail appears.

The chromatographic peak results table names the seven components, and each component reports six retention times (so that the mean retention time and standard deviation are calculated for six injections).

Failing results

When gradient-performance test results fall outside specifications, look for leaking seals or failing check valves. Perform a diagnostic test on the QSM or BSM.

Upon solving the problem, print the Maintenance Log from the SystemsQT Projects/Documentation DVD, sign and date it, and file it under the maintenance log tab in the qualification binder. Then, rerun the gradient-performance test using the wizard.

Manual OQ test specifications

The following table lists the specifications for manually performed OQ tests completed before the automated tests.

Manual OQ test specifications (before)

Test Parameter	Specification	Unit of Measure
Quaternary solvent manager, or binary solvent manager flow rate accuracy	0.494 to 0.506	mL/min
Sample manager - FTN, or sample manager heater/cooler temperature accuracy	± 4.0 °C of set-point temperature	°C
Column manager-A, HT column heater-A, column manager, column heater/cooler, column heater, HT column heater, 30-cm column heater/cooler temperature accuracy	± 2.0 °C of set-point temperature	°C
Sample organizer heater/cooler sample compartment temperature	Between -2 and +4 °C of set-point	°C
Sample organizer plate positioning	Each of the four plates must correctly transfer from the sample organizer to the sample manager and then back to its original position in the sample organizer	N/A

Automated OQ test specifications

The following table lists the specifications for automated OQ tests.

Automated OQ test specifications

Test Parameter	Specification	Unit of Measure
Test injections standard deviation of RT (for ACQUITY UV detector)	≤ 1.5	seconds
Test injections area %RSD (for ACQUITY UV detector)	≤ 0.75	percent
Test injections height %RSD (for ACQUITY UV detector)	≤ 2.4	percent
Test injections minimum height (for ACQUITY UV detector)	≥ 1.8	AU
Test injections standard deviation of RT (for ACQUITY ELS detector)	≤ 1.5	seconds
Test injections area %RSD (for ACQUITY ELS detector)	≤ 6.0	percent
Test injections height %RSD (for ACQUITY ELS detector)	≤ 6.0	percent
System precision standard deviation of RT (for ACQUITY UV detector)	≤ 1.0	seconds
System precision area %RSD (for ACQUITY UV detector)	≤ 0.5	percent
System precision height %RSD (for ACQUITY UV detector)	≤ 1.1	percent
System precision standard deviation of RT (for ACQUITY ELS detector)	≤ 1.0	seconds
System precision area %RSD (for ACQUITY ELS detector)	≤ 5.0	percent
System precision height %RSD (for ACQUITY ELS detector)	≤ 5.0	percent
Wavelength accuracy (for ACQUITY PDA, PDA e λ , or TUV detector)	203 to 207 271 to 275	nm
Detector linearity R^2 area (for ACQUITY PDA or PDA e λ detector)	≥ 0.9990	N/A
Detector linearity R^2 height (for ACQUITY PDA or PDA e λ detector)	≥ 0.990	N/A
Detector sensitivity %RSD area (for ACQUITY PDA or PDA e λ detector)	≤ 3.5	percent
Detector sensitivity %RSD height (for ACQUITY PDA or PDA e λ detector)	≤ 4.5	percent

Test Parameter	Specification	Unit of Measure
Detector linearity R^2 area (for ACQUITY TUV detector)	≥ 0.9990	N/A
Detector linearity R^2 height (for ACQUITY TUV detector)	≥ 0.990	N/A
Detector sensitivity %RSD area (for ACQUITY TUV detector)	≤ 3.5	percent
Detector sensitivity %RSD height (for ACQUITY TUV detector)	≤ 4.5	percent
ELS detector response R^2 area	≥ 0.990	N/A
ELS detector response R^2 height	≥ 0.990	N/A
Injector linearity area R^2	≥ 0.9990	N/A
Injector accuracy	≤ 0.2	μL
Detector noise (for ACQUITY PDA or PDA e λ detector)	≤ 80	μAU
Detector noise (for ACQUITY TUV detector)	≤ 60	μAU
Detector drift (for ACQUITY TUV, PDA, or PDA e λ detector)	< 10	mAU/Hr
Flow rate linearity R^2	≥ 0.990	N/A
Carryover	≤ 0.005	percent
Gradient performance standard deviation of RT	≤ 1.0	seconds