Qualification Test Specification for Waters Acquity UPLC Systems

Test	Set Points/ Range	Acceptance Criteria
Flow Rate Accuracy and Precision	Flow Rate 1 = 0.5ml/min Flow Rate 2 = 1.0ml/min Flow Rate 3 = 5.0ml/min	Accuracy ≤ 1% from Set Point Precision ≤ 0.50%RSD
Column Compartment Temperature Accuracy	Temperature 1 = 35.0°C Temperature 2 = 90.0°C	±2°C
Sample Cooler Temperature Accuracy	Temperature 1 = 4°C	±4°C
Detector Accuracy (UV-Vis)	Wavelength 1 = 205nm (Max) Wavelength 2 = 273nm (Max)	±2nm
Gradient Composition Accuracy	7-component mix: 2-acetylfuran Acetophenone Valerophenone	SD Retention Time ≤ 1.0sec
Carryover	Blank Injection Caffeine Injection 0.20ug/mL Caffeine Injection 4mg/mL Blank Injection	Carryover ≤ 0.005%
Detector Linearity	Injection Concentration 1 = 0.01mg/mL Injection Concentration 2 = 0.03mg/mL Injection Concentration 3 = 0.04mg/mL Injection Concentration 4 = 0.05mg/mL Injection Concentration 5 = 0.08mg/mL Injection Concentration 6 = 0.10mg/mL Injection Concentration 7 = 0.16mg/mL	$R^2 \geq 0.9990$
Injection Linearity and Accuracy	Injection Volume 1 = 2µL Injection Volume 2 = 3µL Injection Volume 3 = 5µL Injection Volume 4 = 6µL	$R^2 \geq 0.9990$ Injector Accuracy ≤ 0.2uL
System Precision	Injection Concentration 1 = 0.16mg/mL	Area and Retention Time RSD ≤ 2.0%

Overview for Mentioned Tests

1. Flow Rate Accuracy and Precision

DESCRIPTION:

A calibrated flow meter is used to measure the flow at three set points.

ACCURACY CALCULATION:

$$\frac{\text{Abs (Flow Rate}_{\text{Set point}} - \text{Flow Rate}_{\text{measured}}) \times 100}{\text{Flow Rate}_{\text{Set point}}}$$

%RSD is calculated using 5 flow rate readings of each flow rate.

UNDERLYING PRINCIPLE:

Flow rate accuracy is important for transferring methods between systems. Flow rate precision is important for repeatability of the peak area.

2. Column Compartment Temperature Accuracy

DESCRIPTION:

The probe is attached to the column compartment so that it maintain direct contact to the heating element. A calibrated digital thermometer is used to measure the temperature.

ACCURACY CALCULATION:

$$\text{Abs (Temperature}_{\text{Set point}} - \text{Temperature}_{\text{measured}})$$

UNDERLYING PRINCIPLE:

Column compartment temperature accuracy is important for transferring methods between systems.

3. Sampler Cooler Temperature Accuracy

DESCRIPTION:

A calibrated digital thermometer meter is used to measure the temperature inside the sample cooler compartment.

ACCURACY CALCULATION:

$$\text{Abs (Temperature}_{\text{Set point}} - \text{Temperature}_{\text{measured}})$$

UNDERLYING PRINCIPLE:

Sampler Cooler Temperature accuracy is important for transferring methods between systems.

4. Detector Accuracy (UV-Vis)

DESCRIPTION:

The flow cell is flushed with traceable caffeine and the wavelength maxima are determined.

ACCURACY CALCULATION:

Abs (certified value – measured value)

UNDERLYING PRINCIPLE:

Detector accuracy is important for transferring methods between systems and for quantitative and qualitative analysis accuracy.

5. Gradient Composition Accuracy

DESCRIPTION:

Six injections of a standard 7-component mix are made onto a column.

GRADIENT CALCULATION:

Standard deviation for the retention time of 3 peaks is calculated.

UNDERLYING PRINCIPLE:

Gradient composition accuracy is important for transferring methods between systems. In addition proper solvent mixing is critical for qualitative analysis accuracy.

6. Injector Precision

DESCRIPTION:

Five injections of 20µl of traceable Caffeine are made onto a column.

PRECISION CALCULATION:

%RSD for retention time and %RSD for peak area are calculated by dividing the standard deviation of the peak area or the standard deviation of the retention time by the average of the peak area or the average of the retention time multiplied by 100.

UNDERLYING PRINCIPLE:

Injector precision is critical for quantitative analysis accuracy.

7. Carryover

DESCRIPTION:

A blank injection is made after injections of two different concentrations of a traceable Caffeine Standard.

CARRYOVER CALCULATION:

$$\text{Calculated \% Carryover} = \frac{\text{Caffeine Area (Post Challenged)}}{\text{Avg Caffeine Area (0.2ug/mL)}} \times \frac{0.002\text{mg/mL}}{4.0\text{ mg/mL}}$$

UNDERLYING PRINCIPLE:

To have low or no carryover is critical for quantitative and qualitative analysis accuracy and reliability.

8. Injector Linearity and Accuracy

DESCRIPTION:

Four injections of different injection volumes of a traceable Caffeine Standard are made onto a column.

ACCURACY CALCULATION:

RSQ and Injection Accuracy are calculated.

UNDERLYING PRINCIPLE:

Linearity is important for transferring methods between systems and for quantitative and qualitative analysis accuracy and reliability.

9. Detector Linearity

DESCRIPTION:

Seven injections of different concentrations of traceable Caffeine Standards are made onto a column.

LINEARITY CALCULATION:

RSQ is calculated.

UNDERLYING PRINCIPLE:

Linearity is important for transferring methods between systems and for quantitative and qualitative analysis accuracy and reliability.