

Qualification Test Specification for 500/600 Series Pump, 717 Series Autosampler HPLC 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 = 3.0ml/min	Accuracy $\leq 5\%$ from Set Point Precision $\leq 0.50\%RSD$
Column Compartment Temperature Accuracy	Temperature 1 = 30.0°C Temperature 2 = 45.0°C Temperature 3 = 60.0°C	$\pm 4^{\circ}C$
Sample Cooler Temperature Accuracy	Temperature 1 = 10°C	$\pm 3^{\circ}C$
Detector Accuracy (UV-Vis)	Wavelength 1 = 205nm (Max) Wavelength 2 = 273nm (Max)	$\pm 2nm$
Gradient Composition Accuracy for quaternary pumps	20% steps	Peak 2: $20 \pm 2\%$ Peak 3: $20 \pm 2\%$
Injector Precision (UV-Vis)	Injection Volume1 = 20 μ L	Area and Retention Time $RSD \leq 2.0\%$
Carryover	Injection Volume1 = 20 μ L	$\leq 0.2\%$
Injection/Detector Linearity	Injection Volume 1 = 5 μ L Injection Volume 2 = 10 μ L Injection Volume 3 = 25 μ L Injection Volume 4 = 50 μ L Injection Volume 5 = 100 μ L	$R^2 \leq 0.99900$

Overview for Above 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:
$$\frac{\text{Abs (Flow Rate Set point - Flow Rate measured)}}{\text{Flow Rate Set point}} \times 100$$

%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 maintains direct contact to the heating element. A calibrated digital thermometer is used to measure the temperature at three set points.

ACCURACY CALCULATION:

Abs (Temperature_{Set point} – Temperature_{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:

Abs (Temperature_{Set point} – Temperature_{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:

Two different mobile phases are used. One that has an acetone tracer and the other one does not. Then the pump is set up to show the composition changes at 20%.

ACCURACY CALCULATION:

$$\text{Relative Peak Height}_{(\text{Peak } 2)} = \frac{\text{Peak Height}_{(\text{Peak } 2)}}{\text{Peak Height}_{(\text{Peak } 1)}} \times 100$$

$$\text{Relative Peak Height}_{(\text{Peak } 3)} = \frac{\text{Peak Height}_{(\text{Peak } 3)}}{\text{Peak Height}_{(\text{Peak } 1)}} \times 100$$

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 the five precision injections.

CARRYOVER CALCULATION:

$$\% \text{ Carryover} = \frac{\text{Area Peak of Blank Injection}}{\text{Area Peak of Previous Injection}} \times 100$$

UNDERLYING PRINCIPLE:

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

8. Injector/Detector Linearity

DESCRIPTION:

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

ACCURACY CALCULATION:

RSQ is calculated

UNDERLYING PRINCIPLE:

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

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