Qualification Specifications for Agilent 1100/1200 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 = 5.0ml/min	Accuracy ±5.00% from Set Point Precision ±0.50%RSD
Column Compartment Temperature Accuracy	Temperature 1 = 30.0°C Temperature 2 = 45.0°C Temperature 3 = 60.0°C	±2.0°C
Sample Cooler Temperature Accuracy	Temperature 1 = 4°C	Difference from set point ≥-2.0°C, ≤5.0°C
Detector Accuracy (UV-Vis)	Wavelength 1 = 205nm (Max) Wavelength 2 = 273nm (Max)	±2nm
Detector Accuracy (FLD)	Wavelength 1 = 350nm (Max) Wavelength 2 = 397nm (Max)	±3nm
Gradient Composition Accuracy for isocratic and quaternary pumps	20% steps	Peak 2: 20.0% ±2.0% Peak 3: 20.0% ±2.0%
Gradient Composition Accuracy for binary pumps	25% and 75% steps	Peak 2: 25.0% ±2.0% Peak 3: 75.0% ±2.0%
Noise/Drift	Injection Volume1 = 20µL	Noise UV <0.10 RID ≤10.0 Drift UV ≤10.0 RID ≤400.0
Injector Precision (UV-Vis)	Injection Volume1 = 20µL	Area and Retention Time RSD≤ 1.00%
Injector Precision (RID only)	Injection Volume1 = 20µL	Area: RSD ≤ 3.00% Retention Time: RSD ≤ 2.00%
Carryover	Injection Volume1 = 20µL	≤ 0.20%
Carryover (FLD/RID)	Injection Volume1 = 5µL	≤ 1.00%

Test	Set Points/ Range	Acceptance Criteria
Injection/Detector Linearity	Injection Volume 1 = 5µL Injection Volume 2 = 10µL Injection Volume 3 = 25µL Injection Volume 4 = 50µL Injection Volume 5 = 100µL	$R^2 \leq 0.9990$ For RID: $R^2 \geq 0.99500$
RID Precision	Injection Volume 1 = 20µL	Retention Time: %RSD: ≤ 2.00% Peak Response: ≤ 3.00%
FLD Precision	Injection Volume 1 = 5µL	≤ 2.00%

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:

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

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

ACCURACY CALCULATION:

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

UNDERLYING PRINCIPLE:

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

3. Sampler Cooler Temperature Accuracy

DESCRIPTION:

Water is filled into vials that will be placed inside the Sample Cooler. A calibrated digital thermometer meter is used to measure the water temperature inside the vials at four different locations.

ACCURACY CALCULATION:

$-2°C \leq \text{Temperature}_{\text{measured}} \leq 5°C$

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. Detector Accuracy (FLD)

DESCRIPTION:

The flow cell is flushed with water and the excitation and emission wavelengths are determined.

ACCURACY CALCULATION:

Abs (theoretical value – measured value)

UNDERLYING PRINCIPLE:

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

6. 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% and/or 75% (for binary pumps only).

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.

7. Injector Accuracy

DESCRIPTION:

Six injection (50µl each) are made from a pre-weighed vial. Vial is weighed after injections.

ACCURACY CALCULATION:

$$\frac{\text{Weight (g)}_{\text{Before}} - \text{Weight (g)}_{\text{After}}}{6} \times 1000$$

UNDERLYING PRINCIPLE:

Injector accuracy is important for transferring methods between systems and is critical for quantitative analysis accuracy.

8. Injector Precision

DESCRIPTION:

Six injections of 20µl of traceable Caffeine (5µl of traceable Quinine Standard for FLD only) 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.

9. 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.

10. 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.

11. Noise/Drift

DESCRIPTION:

A single injection of traceable Caffeine Standard with no column.

ACCURACY CALCULATION:

ASTM noise and drift

UNDERLYING PRINCIPLE:

Large noise and drift can prevent small peaks from being detected.

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