Qualification Specifications and Test Points 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	±5.00% ±0.50%RSD (if applicable)
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	±3.0°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 quaternary pumps (UV)	20% steps	Peak 2: 20.0% ±2.0% Peak 3: 20.0% ±2.0%
Gradient Composition Accuracy for binary pumps (UV)	25% and 75% steps	Peak 2: 25.0% ±2.0% Peak 3: 75.0% ±2.0%
Noise/Drift	N/A	Noise / Drift UV ≤0.05 / ≤5.0 RID ≤10.0 / ≤400.0 ELSD ≤2.0 / ≤5.0
Injector Precision (UV-Vis)	Injection Volume = 20µL	Area and RT RSD ≤ 1.00%
Injector Precision (RID only)	Injection Volume = 20µL	Area: RSD ≤ 1.00% Retention Time: RSD ≤ 2.00%
FLD Precision	Injection Volume 1 = 5µL	≤ 1.00%
Carryover	Injection Volume = 20µL	≤ 0.20%
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: $R^2 \geq 0.99500$
Injector Accuracy (Optional)	6 injections at 50µL	50µL ± 2µL

Variance Allowed

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:

$$\frac{Abs(Flow_{setpoint} - Flow_{measured)}}{Flow_{setpoint}} \times 100$$

%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 $_{\text{Set point}}$ – 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:

$\text{Temperature}_{\text{measured}}$ = $\text{Temperature}_{\text{setpoint}}$ ±3°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:

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

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

UNDERLYING PRINCIPLE:

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

7. Carryover

DESCRIPTION:

A blank injection is made after the five precision injections.

CARRYOVER CALCULATION:

% Carryover = $\frac{Area_{Blank}}{Area_{Injection}} \times 100$

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:

R^2 is calculated

UNDERLYING PRINCIPLE:

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

9. Noise/Drift

DESCRIPTION:

A previous injection of traceable Caffeine Standard with a suitable area for calculating noise and drift, or a blank injection with no column.

ACCURACY CALCULATION:

ASTM noise and drift

UNDERLYING PRINCIPLE:

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

10. Injector Precision

DESCRIPTION:

Six injections of caffeine are made onto a column.

ACCURACY CALCULATION:

$$\frac{Standard\ Deviation_{Area/RT}}{Average_{Area/RT}} * 100$$

UNDERLYING PRINCIPLE:

Injector Precision is critical for quantitative analysis accuracy.

11. Injector Accuracy (Optional Test)

DESCRIPTION:

Six injection are made from a pre-weighed vial. Vial is weighed after injections.

ACCURACY CALCULATION:

$$\frac{(Weight_{Before} - Weight_{After}) \times 1000}{6}$$

UNDERLYING PRINCIPLE:

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

Pre-approval of Qualification for company: _____

The undersigned person(s) approve the following:

1. The use of a validated Excel Spreadsheet to calculate the test results.
2. The delivery of tests appropriate to the actual configuration of the systems covered by the services.
3. The specifications described in this document where the setpoints and possible optional tests follow:

Standard Setpoints

Name and Role	Signature and Date

This pre-approval is applicable to the following systems.

After signing; print this page (and the next if there are variances) to PDF and return it to Analytical@Transcat.com.

Variances (if applicable)

Ignore this section if you have selected to follow the standard setpoints.

Test	Setpoint	Standard	Variance	Units
Pump Flow	Flow Rate 1	0.5	No Variance	ml/min
	Flow Rate 2	1.0	No Variance	
	Flow Rate 3	5.0	No Variance	
Column Temp	Temperature 1	30	No Variance	°C
	Temperature 2	45	No Variance	
	Temperature 3	60	No Variance	
Sample Temp	Temperature 1	4	No Variance	°C
Injector Precision/Carryover (UV-Vis)	Injection Volume	20	No Variance	µL
Injector Precision/Carryover (RID)	Injection Volume	20	No Variance	µL
Injector Precision/Carryover (FLD)	Injection Volume	5	No Variance	µL
Injection/Detector Linearity	Injection Volume 1	5		µL
	Injection Volume 2	10		
	Injection Volume 3	25		
	Injection Volume 4	50		
	Injection Volume 5	100		

Optional Tests

Injector Accuracy (additional cost) ☐

Engineer completing service: sign here to acknowledge variances. Include this and previous page in report.