# Qualification Test Specification for Waters 2690/2695 HPLC Systems

| Test | Set Points/ Range | Acceptance Criteria |
|---|---|---|
| Flow Rate Accuracy and Precision | Flow Rate 1 = 0.5ml/min<br>Flow Rate 2 = 1.0ml/min<br>Flow Rate 3 = 3.0ml/min | Accuracy ≤ 5% from Set Point<br>Precision ≤ 0.50%RSD |
| Column Compartment Temperature Accuracy | Temperature 1 = 45.0°C<br>Temperature 2 = 60.0°C | ±2.0°C |
| Sample Cooler Temperature Accuracy | Temperature 1 = 10°C | ±4.0°C |
| Detector Accuracy (UV-Vis) | Wavelength 1 = 205nm (Max)<br>Wavelength 2 = 273nm (Max) | ±2nm |
| Gradient Composition Accuracy for quaternary pumps | 20% steps | Peak 2: 20.0±2.0%<br>Peak 3: 20.0±2.0% |
| Injector Precision (UV-Vis) | Injection Volume1 = 20µL | Area and Retention Time RSD≤ 2.00% |
| Noise/Drift | Injection Volume1 = 20µL | Noise ≤ 0.1mAU<br>Drift ≤ 10mAU/hr |
| Carryover | Injection Volume1 = 20µL | ≤ 0.20% |
| Injection/Detector Linearity | Injection Volume 1 = 5µL<br>Injection Volume 2 = 10µL<br>Injection Volume 3 = 25µL<br>Injection Volume 4 = 50µL<br>Injection Volume 5 = 100µL | $R^2 \leq 0.99900$ |
| Injector Accuracy (optional) | 5 Injections @ 50 µL | 50µL ± 2µL |

## 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 two 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.

**9. 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.

**10. Injection Accuracy**

DESCRIPTION:

6 injections of 50uL each of water are injection from a weighed vial.

ACCURACY CALCULATION:

Weight (before) - Weight (after) / 6 * 1000

UNDERLYING PRINCIPLE:

Ensures the injector is injecting desired amount

TRANSCAT®
Trust in every measure

35 Vantage Point Drive
Rochester, NY 14624

800.285.9822
Transcat.com