



Equipment Qualification Plan

Enterprise Edition

EQUIPMENT QUALIFICATION PLAN (1200_cds_EQP_001)

Overview and Purpose

Equipment Qualification Plans (EQP) are the quality control documents for instrument qualification services provided by Agilent's Enterprise Edition compliance service. This EQP is a specifically designed enhanced OQ protocol providing the tests & specifications for Agilent 1200 series HPLC on non-Agilent Chromatography Data Systems (CDS). The inventory of installed systems to be covered by the EQP is held separately and is the responsibility of instrument owner(s). IQ is also a separate document.

1200_cds_EQP_001 is for standard configurations of Agilent 1200 analytical scale HPLC systems with UV, FLD or RID detectors. Execution of the EQP provides evidence of operational and performance qualification and full control of the critical functions using the non-Agilent CDS. Verification of correct Signal Data collection by the non-Agilent CDS is provided by a separate test that can be attached to the Equipment Qualification Report (EQR) at the time of OQ execution.

Section 1 Test Specifications

All the tests are developed, tested and validated by Agilent Technologies Inc. as suitable for standard configurations of Agilent 1200 HPLC systems. These test specifications also may be used for qualification testing on most other similar HPLC systems at the discretion of the approvers of this EQP.

"1200cdsTestSpec01" comprises a default list of tests, set points and limits with an expanded range of pump flow testing and additional injection linearity tests. The test specifications represent the scope and depth of instrument testing recommended by Agilent based on industry experience, scientific research, and a risk-based analysis for 1200 on non-Agilent CDS.

Section 2 Report Definitions

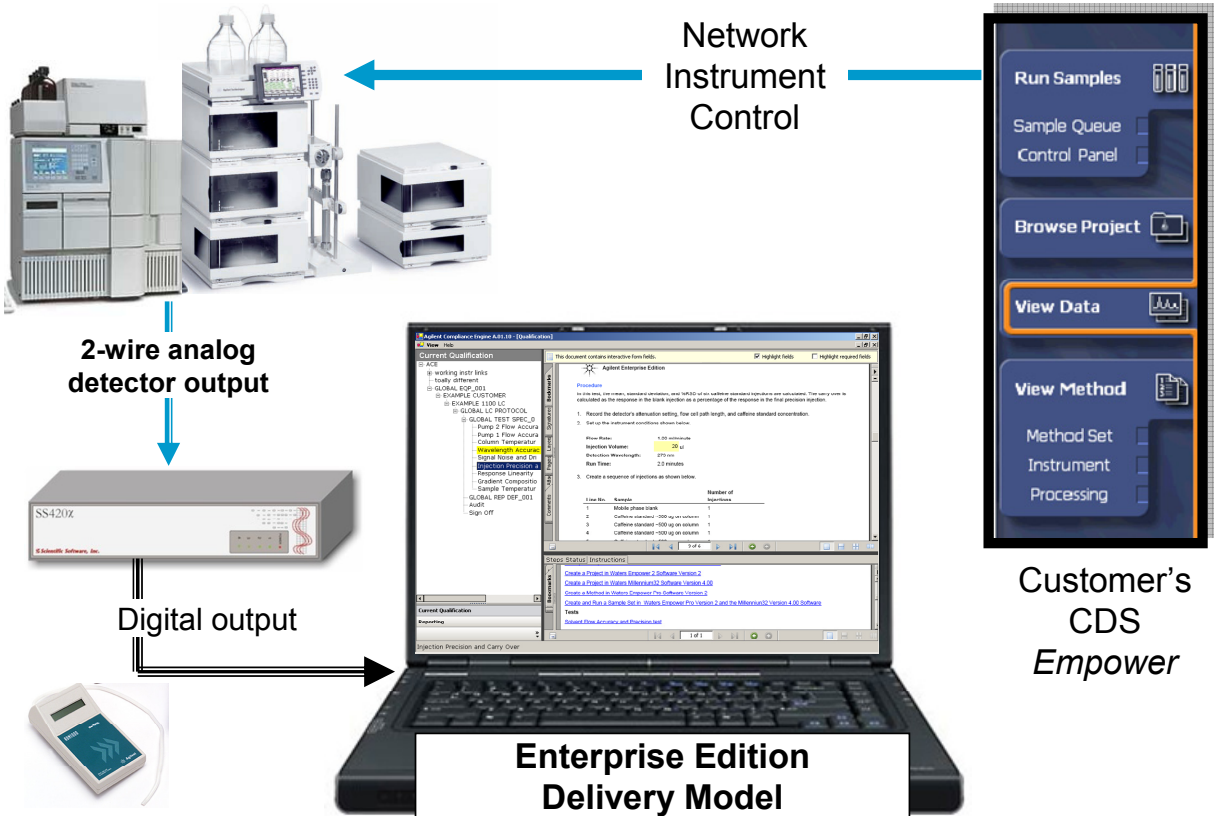
This section defines of the size and format of the final Equipment Qualification Reports generated after execution of the tests.

Agilent Compliance Engine

Agilent Compliance Engine is a validated, patent-pending commercial-off-the-shelf (COTS) software tool used in the automated execution of tests and reports. Agilent Compliance Engine ensures adherence to the EQP, eliminating the need for second-person checking of data entry and calculations and minimizing review of test execution against protocol. The tool provides complete, secure, auditable, and legible original records in Adobe Acrobat pdf format. Paper print-outs are complete and accurate copies of the original electronic records.

Agilent Compliance Engine includes an independent validated chromatography data analysis software for calculation of detector signal data generated in some of the OQ tests. A comparison of the results generated by the Agilent Compliance Engine against those generated by the non-Agilent CDS for the response linearity test allows validation of the CDS data collection process.

Brief Test Design Explanation



Why Enterprise Edition validates all critical control functions and data transfer of Agilent 1200 HPLC connected to non-Agilent CDS (e.g. Empower, Chromeleon, Atlas etc.)

- All OQ tests are run using the non-Agilent CDS to drive the 1200 HPLC hardware. Data is collected on CDS and Agilent Compliance Engine simultaneously.
- The enhanced OQ tests all critical control functions of auto sampler, pump, detector, column compartment.
- The optional data collection verification test compares integration results from non-Agilent CDS with the integration results from the independent validated integrator in Agilent Compliance Engine for the exact same injection runs.

Approval

Approver(s) of the EQP are approving:

- 1. The selection of tests (including set points and limits).
- 2. The use of Agilent Compliance Engine to manage the execution of tests and reports.
- 3. The use of recommended delivery tools (digital thermometers, flow meters, analog-to-digital converters etc.) when valid calibration certificates are included in the qualification reports.
- 4. Omission and/or repeat of a test at the time of testing in exceptional circumstances only when accompanied by an appropriate deviation report form included in the qualification reports.

Review and approval signatures may be kept separately as paper records or electronic approval using Acrobat 7 digital signature technology or electronic document management systems can be used.

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Ink signatures will not appear in the original electronic record of this EQP.

Name	Role	Hand-Written Signature	Date

EQUIPMENT QUALIFICATION PLAN (EQP)

Customer Details

Document Identifier

EQP Name:

EQP Author Name:

EQP Author Role:

EQP Comment:

Organization Details

Approval Date

Approval Date:

Section 1: Test Specification

Document Revision A.01.30

Software Release A.01.30

Technique Type:	HPLC - Analytical Scale - Operational Qualification
Test Specification Name:	1200cdsTestSpec01
Creation Date:	September 2006
Test Specification Comments:	Test for Agilent 1200 (in 1100 mode) installed on non-Agilent CDS

Purpose

This section records a suite of tests, setpoints, and limits that proves CDS control of all critical functions. The Agilent Technologies recommended limits and setpoints should meet user requirements for performance verification.

Pump Flow Accuracy and Precision

This test uses a calibrated digital flowmeter to determine the accuracy and precision of solvent flow rate. Flow accuracy is calculated as the absolute % difference the mean of the six flow readings and the setpoint, and flow precision is calculated as the %RSD of the six flow readings.

	Pump 1	Pump 2	Pump 3	Pump 4
Run the test?:	Run	Run	Not run	Not run
Customer Reference:	Not specified			
Flow Rate 1:	0.500	ml/minute		
Accuracy				
(Limit 1:)	<=	5.00	%	
(Limit 2:)	<=	5.00	%	
Precision				
(Limit 1:)	<=	0.50	%RSD	
(Limit 2:)	<=	0.50	%RSD	
Flow Rate 2:	5.000	ml/minute		
Accuracy				
(Limit 1:)	<=	5.00	%	
(Limit 2:)	<=	5.00	%	
Precision				
(Limit 1:)	<=	0.50	%RSD	
(Limit 2:)	<=	0.50	%RSD	

Column Temperature Accuracy and Stability

This test uses a calibrated digital thermometer to determine the accuracy and stability of column temperature. Column temperature accuracy is calculated as the absolute difference between the measured temperature and setpoint. Temperature stability is calculated as the absolute difference between the highest and lowest measured temperatures.

Run the test?:	Run
Customer Reference:	Not specified
Temperature 1:	80.0 °C
Accuracy	
(Limit 1:)	<= 3.0 °C
(Limit 2:)	<= 3.0 °C
Temperature 2:	40.0 °C
Accuracy	
(Limit 1:)	<= 2.0 °C
(Limit 2:)	<= 2.0 °C
Stability	
(Limit 1:)	<= 1.0 °C
(Limit 2:)	<= 1.0 °C

Wavelength Accuracy

This test uses a traceable standard or water to determine the wavelength accuracy. Wavelength accuracy is determined as the absolute difference between the measured and defined wavelengths.

Run the test?:	Run		
Customer Reference:	Not specified		
Detector:	UV or UV-Vis		
Wavelength 1:	205	nm	Maximum
Accuracy			
(Limit 1:)	<=	2 nm	
(Limit 2:)	<=	2 nm	
Wavelength 2:	245	nm	Minimum
Accuracy			
(Limit 1:)	<=	2 nm	
(Limit 2:)	<=	2 nm	
Wavelength 3:	273	nm	Maximum
Accuracy			
(Limit 1:)	<=	2 nm	
(Limit 2:)	<=	2 nm	
Wavelength 4:	Not applicable	nm	(Select an item)
Accuracy			
(Limit 1:)	<=	2 nm	
(Limit 2:)	<=	2 nm	

Signal Noise and Drift

This test determines signal noise and drift. Signal noise is calculated as the average peak-to-peak noise in a number of signal segments, and signal drift is calculated as the slope of the linear regression for the signal.

Run the test?:	Run		
Customer Reference:	Not specified		
Wavelength:	254 nm		
Noise			
(Limit 1:)	<=	0.100	units* * mAU or nRIU
(Limit 2:)	<=	0.100	units*
Drift			
(Limit 1:)	<=	10.000	units*/hour
(Limit 2:)	<=	10.000	units*/hour

Injection Precision

This test uses a traceable standard to determine injection precision.

Run the test?:	Run
Customer reference:	Not specified
Injection Volume On Column:	20 ul
Height RSD	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Area RSD	
(Limit 1:)	<= 1.00 %
(Limit 2:)	<= 1.00 %

Injection Carry Over

This test uses a traceable standard to determine injection carry over.

Run the test?:	Run
Customer reference:	Not specified
Injection Volume On Column:	20 ul
Height Carry Over	
(Limit 1:)	<= 0.40 %
(Limit 2:)	<= 0.40 %
Area Carry Over	
(Limit 1:)	<= 0.20 %
(Limit 2:)	<= 0.20 %

Signal to Noise

This test uses a traceable standard or water to determine signal to noise.

Run the test?:	Run
Customer reference:	Not specified
Detector:	UV or UV-Vis
Signal to Noise	
(Limit 1:)	>= 3,000
(Limit 2:)	>= 3,000

Response Linearity

This test uses a traceable standard to determine response linearity. Response linearity is calculated by determining the coefficient determination (r^2) of the peak areas versus concentration. In addition, the %RSD of response factors for all five peaks is calculated.

Run the test?:	Run		
Customer Reference:	Not specified		
Wavelength:	273 nm		
Coefficient of Determination (r^2)			
(Limit 1:)	>=	0.99900	
(Limit 2:)	>=	0.99900	
R/F Precision			
(Limit 1:)	<=	5.00	%RSD
(Limit 2:)	<=	5.00	%RSD

Gradient Composition

This test uses an acetone tracer to determine solvent gradient composition accuracy, stability and linearity. Accuracy is calculated as the absolute difference between the mean composition and each set composition. Stability is the slope of the linear regression of all composition versus time points in each composition step. Linearity is the coefficient of determination (r2) of the composition values versus time measured in three sections from 95% to 5% in the linear portion of the gradient.

Run the test?:	Run
Customer Reference:	Not specified
Step 1:	20.00 %
Accuracy	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Composition Noise	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Composition Drift	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Step 2:	40.00 %
Accuracy	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Composition Noise	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Composition Drift	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %
Step 3:	60.00 %
Accuracy	
(Limit 1:)	<= 2.00 %
(Limit 2:)	<= 2.00 %

Composition Noise

(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%

Composition Drift

(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%

Step 4: 80.00 %

Accuracy

(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%

Composition Noise

(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%

Composition Drift

(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%

High Correlation Start: 95.00 %

Coefficient of Determination (r2)

(Limit 1:)	>=	0.99900
(Limit 2:)	>=	0.99900

Mid Correlation Start: 75.00 %

Coefficient of Determination (r2)

(Limit 1:)	>=	0.99900
(Limit 2:)	>=	0.99900

Low Correlation Start: 25.00 %

Coefficient of Determination (r2)

(Limit 1:)	>=	0.99900
(Limit 2:)	>=	0.99900

Sample Temperature Accuracy

This test uses a traceable digital thermometer to determine sample temperature accuracy. Accuracy is determined as the difference between the measured temperature and the setpoint.

Run the test?:	Run
Customer Reference:	Not specified
Temperature:	4.0 °C
(Limit 1):	>= -2.0 °C
(Limit 2):	>= -2.0 °C
(Limit 1):	<= 5.0 °C
(Limit 2):	<= 5.0 °C

Pump Flow Accuracy and Precision (Additional Setpoint)

This test uses a calibrated digital flowmeter to determine the accuracy and precision of solvent flow rate. Flow accuracy is calculated as the absolute % difference between the mean of the six flow readings and the setpoint, and flow precision is calculated as the %RSD of the six flow readings.

	Pump 1	Pump 2	Pump 3	Pump 4
Run the test?:	Not run	Not run	Not run	Not run
Customer Reference:	Not specified			
Flow Rate:	0.800	ml/minute		
Accuracy				
(Limit 1:)	<=	5.00		%
(Limit 2:)	<=	5.00		%
Precision				
(Limit 1:)	<=	0.50		%RSD
(Limit 2:)	<=	0.50		%RSD

Column Temperature Accuracy and Stability (Additional Setpoint)

This test uses a calibrated digital thermometer to determine the accuracy and stability of the column temperature.

Run the test?:	Not run
Customer Reference:	Not specified
Temperature:	60.0 °C
Accuracy	
(Limit 1:)	<= 3.0 °C
(Limit 2:)	<= 3.0 °C
Stability	
(Limit 1:)	<= 1.0 °C
(Limit 2:)	<= 1.0 °C

Additional Pump Flow Accuracy and Precision

This test uses a calibrated digital flowmeter to determine the accuracy and precision of solvent flow rate. Flow accuracy is calculated as the absolute % difference between the mean of the six flow readings and the setpoint, and flow precision is calculated as the %RSD of the six flow readings.

Run the test?:	Not run		
Customer Reference:	Not specified		
Flow Rate 1:	1.000	ml/minute	
Accuracy			
(Limit 1:)	<=	5.00	%
(Limit 2:)	<=	5.00	%
Precision			
(Limit 1:)	<=	0.50	%RSD
(Limit 2:)	<=	0.50	%RSD
Flow Rate 2:	2.000	ml/minute	
Accuracy			
(Limit 1:)	<=	5.00	%
(Limit 2:)	<=	5.00	%
Precision			
(Limit 1:)	<=	0.50	%RSD
(Limit 2:)	<=	0.50	%RSD

Wavelength Accuracy (Additional Detector)

This test uses a traceable standard or water to determine the wavelength accuracy. Wavelength accuracy is determined as the absolute difference between the measured and defined wavelengths.

Run the test?:	Not run		
Customer Reference:	Not specified		
Detector:	FLD		
Wavelength 1:	350	nm	Maximum
Accuracy			
(Limit 1:)	<=	3	nm
(Limit 2:)	<=	3	nm
Wavelength 2:	397	nm	Maximum
Accuracy			
(Limit 1:)	<=	3	nm
(Limit 2:)	<=	3	nm
Wavelength 3:	Not applicable	nm	(Select an item)
Accuracy			
(Limit 1:)	<=	3	nm
(Limit 2:)	<=	3	nm
Wavelength 4:	Not applicable	nm	(Select an item)
Accuracy			
(Limit 1:)	<=	3	nm
(Limit 2:)	<=	3	nm

Signal Noise and Drift (Additional Detector)

This test determines signal noise and drift. Signal noise is calculated as the average peak-to-peak noise in a number of signal segments, and signal drift is calculated as the slope of the linear regression for the signal.

Run the test?:	Not run		
Customer Reference:	Not specified		
Wavelength:	Not applicable		nm
Noise			
(Limit 1:)	<=	0.100	units* * mAU or nRIU
(Limit 2:)	<=	0.100	units*
Drift			
(Limit 1:)	<=	10.000	units*/hour
(Limit 2:)	<=	10.000	units*/hour

Response Linearity (Additional Detector)

This test uses a traceable standard to determine response linearity. Response linearity is calculated by determining the coefficient of determination (r2) the peak areas versus concentration. In addition, the %RSD of response factors for all five peaks is calculated.

Run the test?:	Not run		
Customer Reference:	Not specified		
Wavelength:	Not applicable		nm
Coefficient of Determination (r2)			
(Limit 1:)	>=	0.99900	
(Limit 2:)	>=	0.99900	
R/F Precision			
(Limit 1:)	<=	5.00	%RSD
(Limit 2:)	<=	5.00	%RSD

Injection Linearity (Additional Test)

This test uses a traceable caffeine standard to determine injection linearity. Injection linearity is calculated by determining the coefficient of determination (r^2) of the peak areas versus injection volume. In addition, the %RSD of response factors for all five peaks is calculated.

Run the test?:	Run
Customer Reference:	Not specified
Standard Concentration:	5.0 ug/ml
Coefficient of Determination (r^2):	
(Limit 1:)	>= 0.99500
(Limit 2:)	>= 0.99500
R/F Precision:	
(Limit 1:)	<= 5.00 %RSD
(Limit 2:)	<= 5.00 %RSD

Injection Response (Additional Test)

This test uses a traceable standard to determine response based on injection volume.

Run the test?:	Not run		
Customer reference:	Not specified		
Injection Volume On Column:	20		ul
Average Area			
(Limit 1:)	>=	1,200,000	counts
(Limit 2:)	>=	1,200,000	counts
(Limit 1:)	<=	1,800,000	counts
(Limit 2:)	<=	1,800,000	counts

Sample Temperature Accuracy (Additional Setpoint)

This test uses a traceable digital thermometer to determine sample temperature accuracy. Accuracy is determined as the difference between the measured temperature and the setpoint.

Run the test?:	Not run		
Customer Reference:	Not specified		
Temperature:	10.0		°C
(Limit 1):	>=	-2.0	°C
(Limit 2):	>=	-2.0	°C
(Limit 1):	<=	5.0	°C
(Limit 2):	<=	5.0	°C

Injection Precision (Additional Setpoint)

This test uses a traceable standard to determine injection precision.

Run the test?:	Not run		
Customer reference:	Not specified		
Injection Volume On Column:	5	ul	
Height RSD			
(Limit 1:)	<=	2.00	%
(Limit 2:)	<=	2.00	%
Area RSD			
(Limit 1:)	<=	1.00	%
(Limit 2:)	<=	1.00	%

Injection Carry Over (Additional Setpoint)

This test uses a traceable standard to determine injection carry over.

Run the test?:	Not run		
Customer reference:	Not specified		
Injection Volume On Column:	50	ul	
Height Carry Over			
(Limit 1:)	<=	1.00	%
(Limit 2:)	<=	1.00	%
Area Carry Over			
(Limit 1:)	<=	1.00	%
(Limit 2:)	<=	1.00	%

Injection Response (Additional Test, Additional Setpoint)

This test uses a traceable standard to determine response based on injection volume.

Run the test?:	Not run
Customer reference:	Not specified
Injection Volume On Column:	10 ul
Average Area	
(Limit 1:)	>= 600,000 counts
(Limit 2:)	>= 600,000 counts
(Limit 1:)	<= 900,000 counts
(Limit 2:)	<= 900,000 counts

Signal to Noise (Additional Detector)

This test uses a traceable standard or water to determine signal to noise.

Run the test?:	Not run
Customer reference:	Not specified
Detector:	FLD
Signal to Noise	
(Limit 1:)	>= 400
(Limit 2:)	>= 400

Section 2: Report Definition

Document Revision A.01.30

Software Release A.01.30

Report Definition Name:	Full_OQ_RepDef_001
Creation Date:	Sep 2006
Report Definition Comment:	Defines a standard, full size report with standard nomenclature.

Purpose

This section defines the required format of a Qualification Report.

This information will be applied to all Qualification Reports with the same Report Definition Name in this EQP.

Limit Names

Each test's pass/fail status is based on a one- or two-limit model for evaluating limits. Limits 1 and 2 are the same in an Agilent fixed EQP.

Agilent recommends a one-limit model based on Agilent recommended limits.

Default Name and Description

User-Specified Limit Name

Limit 1: This name describes the Limit 1 selectable value. If a two-limit evaluation model is used, this limit should be the more stringent requirement.

User Limit

Limit 2: This name describes the Limit 2 selectable value. If a two-limit evaluation model is used, this limit should be the less stringent requirement.

Recommended Limit

Status Names

Default Name and Description

User-Specified Status Name

Pass: If test result meets applicable limit(s), report test status as:

PASS

Pass Recommended Limit Only: If test result meets less (but not more) stringent user limit, report test status as:

PASS recommended limit only

Fail: If test result does not meet applicable limit(s), report test status as:

FAIL

Report Format

Cover Page	Include in report
Report Details	Include in report
Concise Revision History	Include in report
Detailed Revision History	Do not include in report
Scope and Purpose	Include in report
Glossary	Include in report
Qualification Details	Include in report
Instrument Details	Include in report
Protocol, Materials, and Calibrated Tools Details	Include in report
General Procedure	Include in report
Calculation Formulas	Include in report
Test Summary	Include in report
Declaration of Change Control	Include in report
Regulatory Disclaimer	Include in report
Tests	Include in report
Attachments	Include in report