EQUIPMENT QUALIFICATION PLAN

Agilent CrossLab Compliance Services

Agilent CrossLab
From Insight to Outcome

EQP Name:	DISS.02.55_PQ_R213H0
Service Type:	PQ
Company Name:	__________
Customer Name/Title:	__________
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Test program as reflected in EQP agreement.

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Scope and Purpose

Overview

An Equipment Qualification Plan (EQP) documents the work performed during qualification services provided using the Agilent Automated Compliance Engine (ACE) software. The EQP must be approved before the work is performed (see customer responsibilities) and the results are reported in an Equipment Qualification Report (EQR), which documents the following.

-Tests performed during the qualification work
-Setpoints used (for example, wavelength, temperature, and flow settings, as applicable)
-Limits (acceptance criteria) applied to tests and setpoints
-Test descriptions and rationales for tests performed (these and test parameters are also reported EQR)
-Traceability of the Agilent qualification protocol

EQP PDF review documents support customer review and approval and are digitally produced directly from the electronic EQP contained within ACE. Two different EQP approval formats can be created.

-Concise: standard format, typically used for Agilent-recommended EQPs
-Tabular: expanded format, typically used for configured EQPs

Many customers approve the Agilent-recommended EQP in the concise format. The tests, setpoints, and limits applied are typically organized in a concise table format (see information below and the Operational Qualification (OQ) test suite). The table can also display which qualification tests can be configured, which Agilent designates as variance (see Glossary).

In a concise EQP approval document used for Agilent-recommended EQPs, the test, setpoints and parameters, and limits (as applicable) are displayed in a concise abbreviated format as shown below.

NOTE This section is used by all ACE techniques, but only LC examples are provided for illustrative purposes.

Key:	Fixed HPLC setpoints/limits	UHPLC setpoints (primary module)	Variance allowed

Test	Setpoints and Parameters	Limits
CDS Logon Verification	N/A	Evidence of logon used to collect qualification data
Pump Flow Accuracy and Precision (Pump)	Flow Rate 1: 0.500 ml/minute Flow Rate 2: 5.000 ml/minute Flow Rate 2: 2.000 ml/minute (G4220B) Flow Rate 2: 1.500 ml/minute (with ULD kit)	Accuracy Ò3.00% Precision RSD Ò0.50%

By design, ACE EQPs can be configured to align the qualification work to laboratory use of the system and / or satisfy user requirements such as range of use for parameter settings (for example, HPLC flow). This requires close collaboration with Agilent to align the configured EQP with laboratory requirements and may include additional optional tests and/or changes to test setpoints and limits. With configured EQPs, an expanded tabular test format is used. Changes from the Agilent-recommended EQP are displayed at the individual test level (so the test section of a tabular EQP document is longer). The electronic EQP file used to create the customer configured EQP is displayed on front page of the EQP. When the qualification work is complete, the results will be reported in the Equipment Qualification Report (EQR) for review and approval.

Understanding the Test Specification Section in Tabular Review Documents

Tabular formatted EQP PDF review documents are typically used for configured EQPs (or if this format is requested by customers). When this EQP approval format is used, which applies to hardware qualifications only, tests are displayed in an expanded tabular arrangement, where the setpoints and limits are explicitly displayed for each test. Agilent-recommended setpoints and limits and the range of allowable values are designated as L (for low) and H (for high). Changes are noted relative to these limits é W (changes within the Agilent range) and O (changes outside the Agilent range). Where dual reporting limits are enables, these are designated as DW (within the Agilent limits) and DO (outside the Agilent limits). Optional tests that are enabled are included and marked as such. Additionally, any required tests that are disabled at customer request are included and marked as such. The EQP documents changes that are within the Agilent variance range as well as any out of variance range tests (see Glossary).

Note: (1) Agilent is NOT responsible for test failures for O (out of range) setpoints and limits. (2) Limit ranges must be more tightly managed than setpoint ranges because they often reflect physical measurement limits and are directly linked to the testing method. Therefore *within range* user limits are subject to best effort repairs if they cannot be met. In particular, Agilent is not be responsible for test failures for limits tighter (more demanding or challenging) than the recommended values. (3) Changes from the Agilent-recommended EQP are also displayed in the Test Summary section of the EQR. (4) For hyphenated systems (for example, LC-LCMS), an EQP for each system needs to be approved.

In a tabular EQP approval document, the test, setpoints and parameters, and limits are typically displayed in the following representative format.

Pump Flow Accuracy

Flow 1

	Analytical Agilent and non-Agilent pump							
	Setpoint:	0.500	mL/min		L:	0.100	H:	5.000
W	Setpoint:	0.200	mL/min					
	Limit:	<=	5.00	%	L:	5.00	H:	10.00

Injection Precision Additional FLD

This optional test is enabled for this EQP.

Agilent or non-Agilent injector with FLD detector							
Vial verification performed?	No						
Injection Volume on Column:	5	uL		L:	1	H:	5
Area RSD Limit:	<=	1.00	%	L:	1.00	H:	5.00
Height RSD Limit:	<=	1.00	%	L:	1.00	H:	5.00

Column Temperature Accuracy

This standard default test is disabled for this EQP.

Customer Responsibilities

To perform ACE instrument qualification services, requirements associated with instrument control and use of ACE software on site need to be understood and satisfied.

- Instrument control to perform the qualification tests.
- ACE software access by the field service engineer (FSE) to load the electronic EQP, run the qualification workflow, and publish the EQR.

ACE is designed to satisfy ALCOA+ data integrity requirements and provide qualification tests that are independent of the instrument control software. This Agilent qualification design philosophy facilitates a harmonized approach to analytical instrument qualification and ensures consistent application of validated algorithms (such as those used to perform gradient pump HPLC testing), independent of instrument and software manufacturer. Additional documentation is available to provide further information on these subjects.

Agilent recommends that the software routinely used in the lab to control the instrument is used by the FSE to perform qualification tests. Therefore, appropriate access to the instrument control software, such as the customer data system (CDS), needs to be set up for the Agilent representative before they arrive on site. For ACE software access on site, Agilent recommends installation of Network ACE to load the electronic EQP, run the qualification workflow, and publish the EQR.

Customers need to address the following responsibilities.

- EQP review
  - Review the EQP supplied (standard or configured).
  - Request changes to the EQP if required (to meet user requirements such as testing range of use) or approve the supplied EQP (that satisfies user requirements).
  - Return an electronic copy of the EQP to Agilent prior to qualification delivery.

- Agree and set up instrument control access to perform the work (provide a CDS logon for the FSE).
- Agree and approve ACE usage on site (Network ACE).
- For configured EQPs, maintain change control and revision history of the specific approved EQP.
- Safely store and archive an approved copy of this EQP.
- Review and sign the EQR when the qualification work is complete and reported.

NOTE: If Agilent representatives use customer software such as a CDS account to acquire test data during the qualification, they log off from the CDS account at the end of test acquisition. Account credentials created for FSE CDS access are a customer responsibility (that is, some labs disable the account when the work is complete).

Agilent Responsibilities

Agilent representatives follow an approved structured training process, which is represented by the training certificates included in the EQR. Additionally, any customer-specific training that is required to perform the work should be specified and complete before the work is scheduled and can be optionally added as a PDF attachment to an EQR, if required. Agilent representatives do the following.

- Deliver the approved services following the test programs described in the approved EQP;
- Provide a locked and e-signed EQR upon completion of the service;
- If requested, provide an optional ink-signed EQR CD to the customer.

Statement of Intent

The qualification is delivered according to the approved EQP. The standard EQP is followed unless a configured EQP has been requested and approved. If a configured EQP has been created and approved, Agilent defines variances as changes to the default recommended values (stated in the standard EQP) that fall within a well-defined range. These changes are considered to be within the intended use range of the system under test.

Customizations are (a) values that subject the system to limits that exceed the typical operational range or (b) additional tests that are not considered part of the core program required for completion of the selected service. Because user-defined setpoints and limits may exceed the operational envelope of the equipment, Agilent reserves the right to warrant conformance only to the closest variance value. The user is notified of this stipulation at EQP setup time and the qualification report (EQR) reflects this situation.

The service is delivered according to the terms and conditions stated in the corresponding service exhibit. After approval, it is recommended that this EQP be archived with the electronic EQP file.

General Statements on the Testing Program

The hardware OQ tests described within this EQP are designed to satisfy analytical instrument qualification (AIQ) requirements for regulated laboratories. The laboratory is responsible for documenting that analytical instruments are suitable for the analytical procedures they use and the decisions they make on the reportable values / quality attributes being measured. Diligent application of an instrument life cycle framework such as USP <1058> help define and satisfy this requirement.

Agilent-recommended EQPs are derived from Agilent's interpretation of the analytical instrument life-cycle framework defined in USP <1058> and authoritative literature requirements from sources such as ISO9001, FDA, GAMPÉ, PIC/S, ASTM 2500, and others. User requirements and intended use can vary from laboratory to laboratory. Therefore, it is recommended that prior to EQP approval, laboratories determine if additional set points and/or optional additional tests are required to test their user requirements. Additional charges may apply to any changes. This can be accommodated in a configured or customized EQP. In line with the USP <1058> requirements, Agilent qualification services include Installation Qualification (IQ) and Operational Qualification (OQ). Typically, the range of instrument use should be tested in the OQ. Laboratories are responsible for addressing PQ requirements of the USP <1058> life cycle.

Agilent CrossLab Compliance uses a balanced selection of direct metrology and chemical-based tests to directly determine the performance of the systems without unnecessary reliance on graphical extrapolation, interpolation, inferred or derived results. For example, for HPLC qualification, direct metrology measurements are used to test pump flow rate accuracy and precision, and thermal-controlled column compartment and autosampler modules. Holistic chemical testing is used for the evaluation of the following critical instrument characteristics: linearity, precision, signal to noise, and carry over.

EQP Revision History

ACE qualification protocols follow a standardized software development life cycle within Agilent. The electronic EQP files used by ACE are managed under change control within this life cycle. Changes to the core electronic EQP are recorded in the Agilent EQP Revision History and are available on request. Change control processes vary between organizations; therefore, although Agilent maintains a revision history for electronic EQPs contained within ACE, it is recommended that, for configured EQPs, laboratories maintain EQP-independent revision history information appropriate to their own policies and procedural requirements.

CDS Software Pre-requisites for Hardware Qualifications

The software used to control instruments during hardware qualification needs to be suitable. Agilent recommends that software used during the qualification has been qualified within the qualification period specified by the customer s software qualification SOP.

Glossary

Agilent EQP
ACE: Agilent Automated Compliance Engine or Agilent software used to provide qualification services

EQP:

Equipment Qualification Plan that documents qualification work to be performed

EQR:

Equipment Qualification Report that documents qualification results

CDS:

Customer data system

Network ACE:

ACE is installed on a network node within the laboratory LAN infrastructure

Local ACE:

ACE resides on an independent external drive connected to the LAN infrastructure

Alternative Method:

ACE is installed and run from a PC not connected to the laboratory network

Standard EQP:

EQP pre-defined by Agilent that includes default tests, setpoints, and limits

Configured EQP:

EQP that has been changed based on user requirements

Variance, Range:

The range of operating values for a test parameter within ACE (flow, temperature, and so on) that were defined and tested when the test was first developed and set up

Variance, W:

Change to a test parameter that is within the Agilent variance range

Variance, O:

Change to a test parameter that is outside the Agilent variance range

Variance, DW:

Dual reporting limits within the Agilent supported range

Variance, DO:

Dual reporting limits outside the Agilent supported range

Optional Test:

An optional additional test that is not included in the standard EQP

Additional Setpoint:

Additional measurement value for a test parameter (flow, temperature, and so on)

Qualification Life Cycle Stages

URS:

User Requirement Specification that documents intended instrument use

DQ:

Design Qualification that documents suitability of instrument for intended use

IQ:

Installation Qualification that documents the installation of the instrument

OQ:

Operational Qualification that tests the range of use

PQ:

Performance Qualification that tests the system under conditions of use

RQ:

Repair Qualification that tests the instrument after an instrument repair

PM:

Planned Maintenance for scheduled preventive maintenance

Reference Sources

ASTM:

American Society for Testing and Materials

FDA:

United States Food and Drug Administration

GAMPÉ:

Good Automated Manufacturing Practice

ISO:

International Organization for Standardization

ISO9001:	ISO Standard for Quality Management Systems
PIC/S:	Pharmaceutical Inspection Cooperation Scheme
USP:	United States Pharmacopeia

Dissolution Test Design and Rationale

Standard Preparation

Description: This test describes how to prepare standards for the PQ tests.

Procedure: Refer to prednisone certificate for details.

Filter Validation

Description: This test validates the filters used for sample and standard preparation.

Procedure: This test compares absorbance readings of three filtered aliquots of working standard. The % recovery for each filtered aliquot must be between 98% and 102%.

Prednisone Qualification - Single Stage

Description: This chemical test verifies the performance of the dissolution tester.

Procedure: Refer to prednisone certificate for details.

Prednisone Qualification - Two Stage

Description: This chemical test verifies the performance of the dissolution tester.

Procedure: Refer to prednisone certificate for details.

Dissolution Test Specification

DISS.02.55

This section includes (1) Agilent-recommended default setpoints and limits and (2) any customer requested change directly beneath the default. Requested changes are marked in the left margin with (1) W if within the Agilent-recommended setpoint or limit range or (2) O if outside the range. If dual limits are selected, changes are marked DW or DO. Agilent is NOT responsible for test failures for out of range setpoints and limits; they are limited to meeting the closest published allowable variance value (marked L or H) that has been exceeded. Under no conditions will Agilent be held responsible for qualification test failures that result from these user defined limits, which are therefore also excluded from the coverage of service contracts. A similar statement will also be included on the cover of related equipment qualification reports (EQRs). NOTE: Limit ranges must be more tightly managed than setpoint ranges since they often reflect physical measurement limits and are directly linked to the testing method. Therefore, *within range* user limits are subject to best effort repairs if they cannot be met. In particular, Agilent is NOT responsible for test failures for limits tighter (that is, within range but more demanding or challenging) than the recommended values.

Standard Preparation

Standard Preparation1

(A working standard and a control standard are required to calculate % Absorptivity for each standard; if the customer does not want to create a control standard, % Absorptivity is NOT calculated.)

Always scheduled for supported dissolution testers: Apparatus: 1 or 2

% Absorptivity Low Limit:	>=	99.0	L:	99.0	H:	99.0
% Absorptivity High Limit:	<=	101.0	L:	101.0	H:	101.0

Filter Validation

Filter Validation1

Always scheduled for supported dissolution testers: Apparatus: 1 or 2

	Recovery Low Limit:	>=	98	%	L:	98	H:	98
O	Recovery Low Limit:	>=	99	%				
	Recovery High Limit:	<=	102	%	L:	102	H:	102
O	Recovery High Limit:	<=	101	%				

Prednisone Qualification - Single Stage

Prednisone Qualification - Single Stage1

(Limits may change with new prednisone standards. A custom EQP for the current USP lot is available. Also, the number appended to the end of subheading does not correspond to the number of stages; it is required for ACE processing.)

Apparatus: 1; number of vessels tested 6, 7 or 8; user defined USP limits

	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Geometric Mean Low Limit:	>=	81	%	L: 81	H: 81
O	Geometric Mean Low Limit:	>=	77	%		
	Geometric Mean High Limit:	<=	92	%	L: 92	H: 92
O	Geometric Mean High Limit:	<=	90	%		
	Coefficient of Variation Limit:	<=	4.6	%	L: 4.6	H: 4.6
O	Coefficient of Variation Limit:	<=	4.4	%		
	Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Temperature Low Limit:	>=	36.5	ÁC	L: 36.5	H: 36.5
	Temperature High Limit:	<=	37.5	ÁC	L: 37.5	H: 37.5
	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2

* Apparatus: 1 Number of vessels tested: 7 User Defined USP Limits

	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Geometric Mean Low Limit:	>=	81	%	L: 81	H: 81
O	Geometric Mean Low Limit:	>=	77	%		
	Geometric Mean High Limit:	<=	92	%	L: 92	H: 92
O	Geometric Mean High Limit:	<=	90	%		
	Coefficient of Variation Limit:	<=	4.5	%	L: 4.5	H: 4.5
O	Coefficient of Variation Limit:	<=	4.3	%		
	Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Temperature Low Limit:	>=	36.5	ÁC	L: 36.5	H: 36.5
	Temperature High Limit:	<=	37.5	ÁC	L: 37.5	H: 37.5
	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2

* Apparatus: 1 Number of vessels tested: 8 User Defined USP Limits

	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Geometric Mean Low Limit:	>=	82	%	L: 82	H: 82
O	Geometric Mean Low Limit:	>=	78	%		
	Geometric Mean High Limit:	<=	92	%	L: 92	H: 92
O	Geometric Mean High Limit:	<=	90	%		
	Coefficient of Variation Limit:	<=	4.4	%	L: 4.4	H: 4.4

O	Coefficient of Variation Limit:	<=	4.2	%				
	Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2
	Apparatus: 2 Number of vessels tested: 6 User Defined USP Limits							
	Elapsed Time Setpoint:	30	minutes		L:	30	H:	30
	Geometric Mean Low Limit:	>=	46	%	L:	46	H:	46
O	Geometric Mean Low Limit:	>=	43	%				
	Geometric Mean High Limit:	<=	59	%	L:	59	H:	59
O	Geometric Mean High Limit:	<=	54	%				
	Coefficient of Variation Limit:	<=	6.2	%	L:	6.2	H:	6.2
O	Coefficient of Variation Limit:	<=	7.1	%				
	Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2
*	Apparatus: 2 Number of vessels tested: 7 User Defined USP Limits							
	Elapsed Time Setpoint:	30	minutes		L:	30	H:	30
	Geometric Mean Low Limit:	>=	46	%	L:	46	H:	46
O	Geometric Mean Low Limit:	>=	43	%				
	Geometric Mean High Limit:	<=	59	%	L:	59	H:	59
O	Geometric Mean High Limit:	<=	54	%				
	Coefficient of Variation Limit:	<=	6.1	%	L:	6.1	H:	6.1
O	Coefficient of Variation Limit:	<=	6.9	%				
	Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2
*	Apparatus: 2 Number of vessels tested: 8 User Defined USP Limits							
	Elapsed Time Setpoint:	30	minutes		L:	30	H:	30
	Geometric Mean Low Limit:	>=	46	%	L:	46	H:	46
O	Geometric Mean Low Limit:	>=	43	%				
	Geometric Mean High Limit:	<=	59	%	L:	59	H:	59

O	Geometric Mean High Limit:	<=	53	%				
	Coefficient of Variation Limit:	<=	6.0	%	L:	6.0	H:	6.0
O	Coefficient of Variation Limit:	<=	6.8	%				
	Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2

Prednisone Qualification - Two Stage

Prednisone Qualification - Two Stage1

(Limits may change with new prednisone standards. A custom EQP for the current USP lot is available. Also, the number appended to the end of subheading does not correspond to the number of stages; it is required for ACE processing.)

Apparatus: 1; number of vessels tested: 6 or 7 user defined USP limits

	Elapsed Time Setpoint:		30	minutes	L:	30	H:	30
	Stage 1 Geometric Mean Low Limit:	>=	83	%	L:	83	H:	83
O	Stage 1 Geometric Mean Low Limit:	>=	80	%				
	Stage 1 Geometric Mean High Limit:	<=	90	%	L:	90	H:	90
O	Stage 1 Geometric Mean High Limit:	<=	87	%				
	Stage 1 Coefficient of Variation Limit:	<=	3.4	%	L:	3.4	H:	3.4
O	Stage 1 Coefficient of Variation Limit:	<=	3.3	%				
	Stage 1 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Stage 2 Geometric Mean Low Limit:	>=	81	%	L:	81	H:	81
O	Stage 2 Geometric Mean Low Limit:	>=	77	%				
	Stage 2 Geometric Mean High Limit:	<=	92	%	L:	92	H:	92
O	Stage 2 Geometric Mean High Limit:	<=	90	%				
	Stage 2 Coefficient of Variation Limit:	<=	4.5	%	L:	4.5	H:	4.5
O	Stage 2 Coefficient of Variation Limit:	<=	4.4	%				
	Stage 2 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2

* Apparatus: 1 Number of vessels tested: 7 User Defined USP Limits

	Elapsed Time Setpoint:		30	minutes	L:	30	H:	30
	Stage 1 Geometric Mean Low Limit:	>=	83	%	L:	83	H:	83

O	Stage 1 Geometric Mean Low Limit:	>=	80	%				
	Stage 1 Geometric Mean High Limit:	<=	90	%	L:	90	H:	90
O	Stage 1 Geometric Mean High Limit:	<=	87	%				
	Stage 1 Coefficient of Variation Limit:	<=	3.4	%	L:	3.4	H:	3.4
O	Stage 1 Coefficient of Variation Limit:	<=	3.3	%				
	Stage 1 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Stage 2 Geometric Mean Low Limit:	>=	81	%	L:	81	H:	81
O	Stage 2 Geometric Mean Low Limit:	>=	77	%				
	Stage 2 Geometric Mean High Limit:	<=	92	%	L:	92	H:	92
O	Stage 2 Geometric Mean High Limit:	<=	90	%				
	Stage 2 Coefficient of Variation Limit:	<=	4.4	%	L:	4.4	H:	4.4
O	Stage 2 Coefficient of Variation Limit:	<=	4.3	%				
	Stage 2 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5
	Sampling Accuracy Limit:	<=	2	%	L:	2	H:	2

Apparatus: 1 Number of vessels tested: 8 User Defined USP Limits

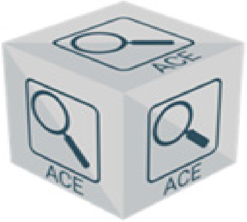
	Elapsed Time Setpoint:	30	minutes		L:	30	H:	30
	Stage 1 Geometric Mean Low Limit:	>=	83	%	L:	83	H:	83
O	Stage 1 Geometric Mean Low Limit:	>=	80	%				
	Stage 1 Geometric Mean High Limit:	<=	90	%	L:	90	H:	90
O	Stage 1 Geometric Mean High Limit:	<=	87	%				
	Stage 1 Coefficient of Variation Limit:	<=	3.4	%	L:	3.4	H:	3.4
O	Stage 1 Coefficient of Variation Limit:	<=	3.3	%				
	Stage 1 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Stage 2 Geometric Mean Low Limit:	>=	82	%	L:	82	H:	82
O	Stage 2 Geometric Mean Low Limit:	>=	78	%				
	Stage 2 Geometric Mean High Limit:	<=	92	%	L:	92	H:	92
O	Stage 2 Geometric Mean High Limit:	<=	90	%				
	Stage 2 Coefficient of Variation Limit:	<=	4.3	%	L:	4.3	H:	4.3
O	Stage 2 Coefficient of Variation Limit:	<=	4.2	%				
	Stage 2 Standard Difference Limit:	<=	2.0	%	L:	2.0	H:	2.0
	Temperature Low Limit:	>=	36.5	ÁC	L:	36.5	H:	36.5
	Temperature High Limit:	<=	37.5	ÁC	L:	37.5	H:	37.5

	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2
*	Apparatus: 2 Number of vessels tested: 6 User Defined USP Limits					
	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Stage 1 Geometric Mean Low Limit:	>=	48	%	L: 48	H: 48
O	Stage 1 Geometric Mean Low Limit:	>=	45	%		
	Stage 1 Geometric Mean High Limit:	<=	57	%	L: 57	H: 57
O	Stage 1 Geometric Mean High Limit:	<=	52	%		
	Stage 1 Coefficient of Variation Limit:	<=	4.6	%	L: 4.6	H: 4.6
O	Stage 1 Coefficient of Variation Limit:	<=	5.3	%		
	Stage 1 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Stage 2 Geometric Mean Low Limit:	>=	46	%	L: 46	H: 46
O	Stage 2 Geometric Mean Low Limit:	>=	43	%		
	Stage 2 Geometric Mean High Limit:	<=	59	%	L: 59	H: 59
O	Stage 2 Geometric Mean High Limit:	<=	54	%		
	Stage 2 Coefficient of Variation Limit:	<=	6.1	%	L: 6.1	H: 6.1
O	Stage 2 Coefficient of Variation Limit:	<=	7.1	%		
	Stage 2 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Temperature Low Limit:	>=	36.5	ÁC	L: 36.5	H: 36.5
	Temperature High Limit:	<=	37.5	ÁC	L: 37.5	H: 37.5
	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2
*	Apparatus: 2 Number of vessels tested: 7 User Defined USP Limits					
	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Stage 1 Geometric Mean Low Limit:	>=	48	%	L: 48	H: 48
O	Stage 1 Geometric Mean Low Limit:	>=	45	%		
	Stage 1 Geometric Mean High Limit:	<=	57	%	L: 57	H: 57
O	Stage 1 Geometric Mean High Limit:	<=	51	%		
	Stage 1 Coefficient of Variation Limit:	<=	4.6	%	L: 4.6	H: 4.6
O	Stage 1 Coefficient of Variation Limit:	<=	5.3	%		
	Stage 1 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Stage 2 Geometric Mean Low Limit:	>=	46	%	L: 46	H: 46
O	Stage 2 Geometric Mean Low Limit:	>=	43	%		
	Stage 2 Geometric Mean High Limit:	<=	59	%	L: 59	H: 59
O	Stage 2 Geometric Mean High Limit:	<=	54	%		
	Stage 2 Coefficient of Variation Limit:	<=	6.0	%	L: 6.0	H: 6.0

O	Stage 2 Coefficient of Variation Limit:	<=	6.9	%		
	Stage 2 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Temperature Low Limit:	>=	36.5	ÁC	L: 36.5	H: 36.5
	Temperature High Limit:	<=	37.5	ÁC	L: 37.5	H: 37.5
	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2
*	Apparatus: 2 Number of vessels tested: 8 User Defined USP Limits					
	Elapsed Time Setpoint:	30	minutes		L: 30	H: 30
	Stage 1 Geometric Mean Low Limit:	>=	48	%	L: 48	H: 48
O	Stage 1 Geometric Mean Low Limit:	>=	45	%		
	Stage 1 Geometric Mean High Limit:	<=	57	%	L: 57	H: 57
O	Stage 1 Geometric Mean High Limit:	<=	51	%		
	Stage 1 Coefficient of Variation Limit:	<=	4.6	%	L: 4.6	H: 4.6
O	Stage 1 Coefficient of Variation Limit:	<=	5.3	%		
	Stage 1 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Stage 2 Geometric Mean Low Limit:	>=	46	%	L: 46	H: 46
O	Stage 2 Geometric Mean Low Limit:	>=	43	%		
	Stage 2 Geometric Mean High Limit:	<=	59	%	L: 59	H: 59
O	Stage 2 Geometric Mean High Limit:	<=	53	%		
	Stage 2 Coefficient of Variation Limit:	<=	5.9	%	L: 5.9	H: 5.9
O	Stage 2 Coefficient of Variation Limit:	<=	6.8	%		
	Stage 2 Standard Difference Limit:	<=	2.0	%	L: 2.0	H: 2.0
	Temperature Low Limit:	>=	36.5	ÁC	L: 36.5	H: 36.5
	Temperature High Limit:	<=	37.5	ÁC	L: 37.5	H: 37.5
	Sampling Accuracy Limit:	<=	2	%	L: 2	H: 2

HOW AGILENT CROSSLAB COMPLIANCE SERVICES INTEGRATE WITH QUALITY SYSTEMS AND REGULATIONS

Agilent CrossLab Compliance Services

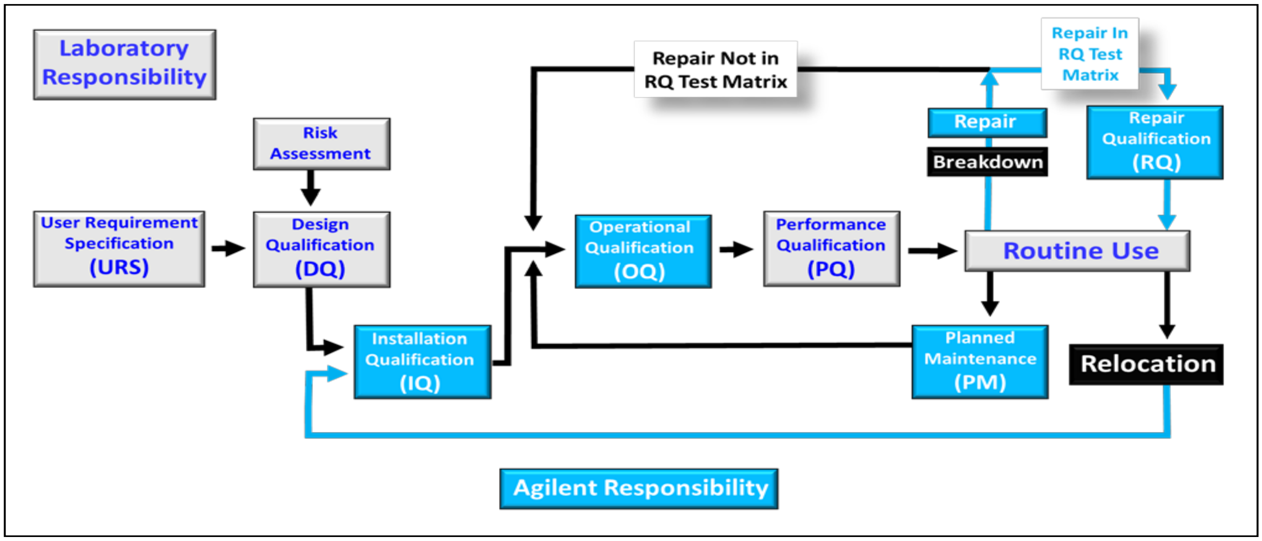


Agilent CrossLab
From Insight to Outcome

Agilent CrossLab Compliance Services

Agilent CrossLab Compliance Services are designed to seamlessly integrate with traditional quality systems used by firms and recognized by regulatory agencies worldwide. Analytical instruments must be suitable for their intended use. This requirement is good science in all laboratories and a regulatory requirement in pharma and biopharma laboratories. A life-cycle process for documenting and testing the suitability of laboratory instruments should be followed and Agilent recommends the life cycle framework defined in USP General Chapter <1058> on Analytical Instrument Qualification (AIQ). USP <1058> defines the governing framework and requirements that need to be satisfied, but the laboratory is responsible for how they satisfy these requirements.

- The United States Pharmacopoeia (USP) is the only major pharmacopeia with a general chapter dedicated to analytical instrument qualification, making <1058> an important global regulatory reference. The information is provided in a scientific, risk-based approach to analytical instrument qualification (AIQ). However, the life-cycle framework contained within USP <1058> is not prescriptive in its implementation, making the embedded scientific and risk-based principles flexible and universally applicable.
- The scientific process followed by CrossLab uses the Agilent's Automated Compliance Engine (ACE) to deliver paperless electronic qualification. The life-cycle stages Agilent perform are highlighted in the life-cycle diagram below. As part of this life-cycle, Agilent can configure the qualification tests performed to align with user requirements.


Laboratory Responsibility
Repair Not in RQ Test Matrix
Repair In RQ Test Matrix
Risk Assessment
Repair
Breakdown
Repair Qualification (RQ)
User Requirement Specification (URS)
Design Qualification (DQ)
Operational Qualification (OQ)
Performance Qualification (PQ)
Routine Use
Installation Qualification (IQ)
Planned Maintenance (PM)
Relocation
Agilent Responsibility

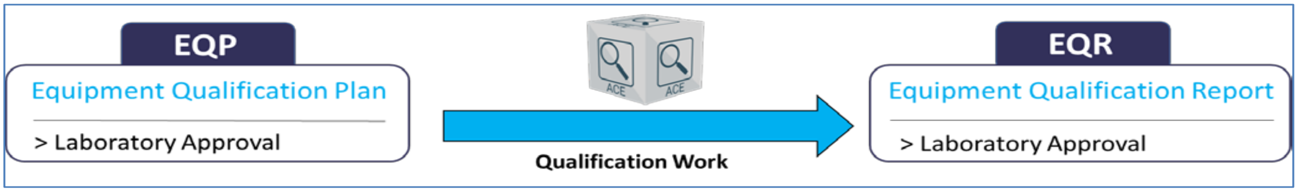
USP <1058> AIQ Framework

***NOTE**: RQ services, described later in this document, can be added to standard qualification services.*

ACE Workflow and Equipment Qualification Plans (EQPs)

Overview

Within the ACE workflow, the qualification tests, setpoints, and limits are defined in an EQP that can be configured to ensure that testing satisfies user requirements. When the qualification work is complete, an Equipment Qualification Report (EQR) is issued. The electronic workflow used within ACE has significant data integrity advantages over traditional paper or Excel-based qualification protocols, as validated calculations can be performed directly using electronic data such as chromatograms and metrology test values. Several of the instrument life-cycle stages are the responsibility of the laboratory, Agilent can provide compliance consultancy services and documentation which can help customers satisfy these requirements. These additional services are not included in our typical qualification offering.



High-level ACE Qualification Workflow

Standard and User-defined Limits

(Hardware qualifications only)

EQPs are available for download and approval as standard documents with Agilent recommended tests, setpoints, and limits, or they can be electronically configured by approved personnel to align with user requirements and intended range of use requirements. The degree of configuration depends on the analytical technology, but most EQPs can be configured to some degree, and one feature that can typically be changed is test limits.

EQPs are designed to be configurable (dependent on the analytical technology and standard requirements), but including additional tests or setpoints can impact the qualification time and associated cost. If a test limit is changed, ACE includes the capability to report results against the Agilent approved limit and any customer required limits (that is, both can be reported simultaneously).

If a user-defined test limit is more stringent than an Agilent recommended limit, Agilent makes no guarantee or obligation regarding the instrument passing the tighter test specification requirements. It is important to appreciate that tests performed under conditions of use (that is, to satisfy pharmaceutical monograph and application requirements) can have different limits than those defined in the OQ. It is the continuum of the combined OQ, PQ, and any point of use testing performed each time the instrument is used that together satisfy regulatory requirements.

User Requirements Specification (URS)

The purpose of user requirements is to document the intended use of the instrument within the life-cycle process and quality management system (QMS) being followed. Therefore, the URS is a customer / laboratory responsibility. Defining user requirements is often used to guide the customer in instrument selection and is stated as the first activity that should be followed in <1058>. The URS is important for two main reasons.

- It is a regulatory requirement for FDA and EU GMP that the intended use of the instrument and any software must be specified.
- Investment protection perspective means getting the right instrument for the right job.

Qualification protocols should test the instrument against any limits or specifications listed in the URS, which should document the intended range of use. Depending on the instrument complexity and how it is classified, a separate URS document may not be needed, but the URS requirements of the <1058> framework must be satisfied. A separate URS is almost always recommended for computerized systems.

An instrument performance specification is a product of the instrument development process by the supplier. It typically documents the performance the instrument can achieve. The URS should be based on intended use of the instrument and not the instrument specification. Additionally, if the intended use of a system changes, this may trigger a need to review the URS and associated qualification testing (for example, to ensure range of use is tested if used with a new analytical procedure).

Agilent offers compliance consultation services and documentation that can help customers address URS requirements.

Design Qualification (DQ)

The main function of the DQ stage of the laboratory instrument life-cycle process is to document why the selected instrument is suitable. Typically, this includes consideration of the instrument specification, how the instrument will be qualified, and the QMS followed by the instrument manufacturer. All together, these confirm that instrument performance is capable of satisfying user requirements. Depending on laboratory instrument life-cycle policy or SOPs being followed, instrument requirements and the relationship between the URS and DQ stages may vary – but as long as the <1058> framework principles are satisfied, this is not a problem, as it is left to each laboratory to justify and document its specific approaches.

The responsibility for satisfying DQ requirements primarily lies with the laboratory, with support from the supplier.

Agilent's approach to satisfying DQ requirements of USP <1058> includes the following.

- All Agilent hardware and software laboratory products, including the ACE software used to deliver qualification services, are designed, manufactured, and tested according to Agilent internal quality life-cycle development procedures.
- Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and similar certification can be provided for ACE software.
- Agilent is capable of installation, support, preventive maintenance, on-going qualification, and re-qualification after repair and user training worldwide.

Agilent offers a compliance consultation service that can help customers with DQ documentation.

Installation Qualification (IQ)

The main functions of the IQ stage are to document that laboratory is suitable (for example, critical systems typically include a site inspection / checklist), that the instrument is installed correctly in the environment, and IQ checks such as module start up are completed. IQ is provided and automated by ACE, which collects, checks, and tests Agilent hardware and software products for the following.

1. Purchase Order Details: Allows the customer to verify that the instrument being qualified matches their design requirements (if available) and purchase order.
2. Preparation and Installation Details: Gathers and records information about preparation and installation documents.
3. Documentation: Gathers and records information about reference and user manuals for initial installations.
4. Product Quality Assurance Details: Collects and records certificates and other forms that verify that the vendor has developed and built the product according to internal standards.
5. Startup: Verifies that all modules/components start up properly.
6. Installation Verification (software only): Verifies the correctness of all installation-related files.

Operational Qualification (OQ)

The main function of the OQ stage is to evaluate and document instrument performance at the intended operational range of use. OQ protocols should include a mix of metrology, functional, and operational tests. ACE qualification protocols include information about the test description and rational, setpoints, and the limits (acceptance criteria) for each technique, category, and instrument configuration.

OQ is provided and automated by ACE. ACE checks and tests for Agilent hardware and software products include the following.

- Metrological tests such as flow, temperature, pressure, and so on that ensure that the system is performing within Agilent (or user) specifications.
- Qualification results are reported in the EQR, which can include details of all test certificates, standards, and training information for the engineer performing the work. (Note that the EQR can be configured to customer requirements.)
- System or “holistic” tests verify the combined functions of the various system components
- The qualification testing can be configured to ensure URS requirements, such as range of use are tested.

For software qualification, the OQ consists of automated diagnostics regression testing and verification of the software installation. This supports continued use of the software in regulated environments (at install and as part of supporting periodic review).

In line with regulatory requirements, the EQPs should be approved before work is performed and the EQR should be reviewed and approved when the work is complete (as illustrated in Figure 2). The EQR contains all the raw data, results, and relevant information and attachments for complete compliance and traceability.

Mechanical Qualification (MQ)

(Dissolution systems only)

The main function of the MQ stage is to document that the mechanical performance of the instrument meets specifications and is functioning properly.

Performance Qualification (PQ)

The main function of the PQ stage is to document that the instrument is fit for purpose under conditions of intended use and to create an approved framework that ensures the instrument continues to perform as required. Because instrument range of use is tested within the OQ stage, it is usually not necessary to test this during PQ. It should be noted that requirements for instrument maintenance and repair fall within the PQ life cycle stage within the USP <1058> framework, as they are components of ensuring the continued performance of the instrument.

The customer is responsible for satisfying PQ requirements. (NOTE: Agilent can provide a PQ for Dissolution systems only.)

It is important to note that PQ is a lifecycle activity and not a one-time event. PQ tests may include activities such as method validation or system suitability tests (SST), but in Agilent’s opinion, SSTs contribute towards ensuring continued performance of the instrument (that is, PQ testing), but do may not fully satisfy <1058> PQ requirements.

Repair Qualification (RQ)

After an instrument is repaired, tests should be performed to evaluate the effectiveness of the repair and document that repaired instrument satisfies performance requirements. Agilent offers a service called Repair Qualification (RQ), which refers to the requalification of laboratory instrument hardware after a repair. For some laboratory systems, to document the performance after repair may require a full OQ. However, for some modular or component-based systems, such as HPLC and GC for example, partial qualification testing can be justified. This is accomplished by performing the qualification tests that are applicable to only the module or system component related to the repair, reducing the time the instrument is out of service. Re-qualifying the instrument after repair is a regulatory requirement defined in USP <1058>.

Agilent offers service contracts to repair and requalify an instrument during the period between scheduled annual OQs.

The level of retesting is prescribed in the RQ section of ACE: a form is displayed for the operator showing all types of repairs possible and the retesting required. Part of an example form for an LC system is shown below.

Re-Qualification After Repair		
Pump Strategies		
Repair/Replace Strategy	Modules	OQ Testing
Internal pump head parts, active inlet valve (or AIV cartridge), (parts of) check valves, reference valves, inlet manifold or pump drive, or taking pump head apart to clean (versus repair)	Any pump	Flow Accuracy & Precision
Pulse damper, pressure transducer	Any pump	Flow Accuracy & Precision
Multi-channel gradient valve	Quaternary	Flow Accuracy & Precision Gradient Composition

The full list of RQ repair and retest guidance is available for customer review.

www.agilent.com/chem/qualification

USP REFERENCE STANDARD CERTIFICATE

DISSOLUTION PERFORMANCE VERIFICATION STANDARD - PREDNISONE

(10 mg nominal prednisone content per tablet)

USP Catalog No.: 1222818
USP Lot No.: R213H0

Valid Use Date	30-SEP-2026
Storage/Handling	As per the label.
Uses	General Chapter <711> Dissolution, Performance Verification Test (PVT), Apparatus 1 and Apparatus 2

Dissolution <711>

Medium: 499 g of degassed purified water maintained at 37° ± 0.5°

Medium degassing: Recommended degassing procedure: Heat a suitable amount of water, while stirring gently to about 41-45°. Filter under vacuum through a 0.45-µm-porosity filter into a suitable filtering flask equipped with a stirring device. Seal the flask and continue to apply vacuum while stirring for an additional five minutes. Measured vacuum should be less than 100 mbar.

Note: Other validated degassing methods that reduce the total dissolved gas in the media can also be used.

Apparatus: Apparatus 1 (Basket) or Apparatus 2 (Paddle) at 50 RPM

Note: If equipment is dedicated for use with only one apparatus (basket or paddle), then performance verification is only required for that apparatus.

Time: 30 minutes

Standard solution: A known concentration of USP Prednisone RS in Medium.

Note: An amount of methanol or ethanol not to exceed 5% of the total volume of the standard solution may be used to bring the prednisone reference standard into solution.

Sample solution: Laboratory can choose either Single-Stage Test or Optional Two-Stage Test scheme to obtain Sample Solutions.

A filtered portion of the solution under test, suitably diluted, if necessary, with Medium to obtain a concentration similar to that of the Standard solution.

Note 1: The filtering method must not cause adsorptive loss of drug (using 0.45-µm PVDF material or equivalent).

Note 2: Bias introduced by automated methods is to be avoided.

Analysis: UV at 242 nm

USP REFERENCE STANDARD CERTIFICATE

Dissolution <711>

Procedure: Determine the quantity of prednisone, $C_{21}H_{26}O_5$, dissolved at 30 minutes in each vessel expressed as percent of the labeled amount.

Single-Stage Test Instructions and Acceptance Criteria

1. For each position in the assembly, test one USP Dissolution Performance Verification Standard – Prednisone (DPVS – Prednisone) RS tablet, and record the percent dissolved at the sampling time point specified. Transform the percent dissolved results to the natural log scale, determine the mean and variance. For assemblies with 12 or 14 dissolution vessels, no further testing is required.
2. For assemblies with fewer than 12 positions, repeat Step 1 with an additional set of tablets. Transform the percent dissolved results to the natural log scale, determine the mean and variance.
3. Calculate the average of the two means and of the two variances obtained in Steps 1 and 2.
   Use the results from Step 1 alone for assemblies that have 12 or 14 positions.
4. Convert the results of Step 3 to a geometric mean (GM) and percent coefficient of variation (%CV). See Calculation Example for details.
5. Compare the results of Step 4 to the Single-Stage acceptance criteria in Table 1. The GM must not fall outside the limits, and the %CV must not be greater than the limit. If both meet the criteria, the assembly has passed the PVT.

Table 1. Performance Verification Test Acceptance Criteria for Single-Stage Test

Apparatus	No. of vessels per run	Geometric Mean, % Prednisone Dissolved	%CV
1 (Basket)	6	77-90	4.4
	7	77-90	4.3
	8	78-90	4.2
	12	77-90	4.3
	14	77-90	4.2
2 (Paddle)	6	43-54	7.1
	7	43-54	6.9
	8	43-53	6.8
	12	43-54	7.0
	14	43-54	6.9

USP REFERENCE STANDARD CERTIFICATE

Optional Two-Stage Test Instructions and Acceptance Criteria

A laboratory may choose to implement the PVT as a Two-Stage test in case of assemblies with less than 12 positions. The Two-Stage test is a statistically valid means of allowing the possibility of stopping the test at the first stage using more stringent acceptance criteria. The following are step-by-step instructions for the two-stage test.

1. For each position in the assembly, test one USP DPVS – Prednisone RS tablet, and record the percent dissolved at the sampling time point specified. Transform the percent dissolved results to the natural log scale, determine the mean and variance.
2. Convert the results of Step 1 to a GM and %CV and compare to the 1st Stage of Two Stages acceptance ranges in Table 2. The GM must not fall outside the limits, and the %CV must not be greater than the limit. For calculation of the GM and %CV, see Calculation Example for details.
3. If results of Step 2 satisfy both acceptance criteria, the assembly has passed the PVT. Otherwise continue to Step 4. Prior to proceeding to Step 4, see Futility Factor section.
4. Repeat Step 1 with an additional set of tablets. Transform the percent dissolved results to the natural log scale determine the mean and variance for the data obtained at this step.
5. Average the two means and two variances obtained in Steps 1 and 4.
6. Convert the results of Step 5 to a geometric mean (GM) and percent coefficient of variation (%CV). For calculation of the GM and %CV, see Calculation Example for details.
7. Compare the results of Step 6 to the 2nd Stage of Two Stages acceptance ranges in Table 2. The GM must not fall outside the limits, and the %CV must not be greater than the limit. If both meet the acceptance criteria, the assembly has passed the PVT.

Table 2. Performance Verification Test Acceptance Criteria for Two-Stage Test

Apparatus	No. of vessels per run	First Stage of Two-Stage Test		Second Stage of Two-Stage Test	
		Geometric Mean, % Prednisone Dissolved	%CV	Geometric Mean, % Prednisone Dissolved	%CV
1 (Basket)	6	80-87	3.3	77-90	4.4
	7	80-87	3.3	77-90	4.3
	8	80-87	3.3	78-90	4.2
2 (Paddle)	6	45-52	5.3	43-54	7.1
	7	45-51	5.3	43-54	6.9
	8	45-51	5.3	43-53	6.8

Futility Factor

If optional Stage-Two test is chosen, there are circumstances when the %CV after the First Stage of Two-Stage test equals or exceeds the value in the Futility Factor table (without rounding). In such cases it is impossible to meet the %CV criterion after the Second Stage of the Two-Stage test. The lab can stop after the First Stage run. However, after any adjustments to equipment, test procedure, and so on, the PVT must be restarted with a new first run (Step 1 of the two-stage test instructions).

Futility Factor, %CV at or above value given, second stage testing will not produce passing result

Apparatus	Number of Vessels		
	6	**7**	**8**
1	6.2	6.1	5.9
2	10	9.8	9.6

Refer to this website for the USP Calculation Tool: https://apps.usp.org/app/USPNF/pvtCalculationTool/

Calculation Example (expressed as Microsoft Excel® worksheet functions)**:**

Run 1: $x_1, x_2, ..., x_n$ in natural log scale: Ln x_1, Ln x_2, ..., Ln x_n

Run 2: $x_{n+1}, x_{n+2}, ..., x_{2n}$ in natural log scale: Ln x_{n+1}, Ln x_{n+2}, ..., Ln x_{2n}

1st Stage of Two-Stage for n=6, 7, 8 and Single-Stage for n=12, 14:

GM1 = exp(average (Ln x_1:Ln x_n))

%CV1 = 100*sqrt(exp(var(Ln x_1:Ln x_n)) -1)

Single-Stage or 2nd Stage of Two-Stage for n= 6, 7, 8:

GM = exp(average((average (Ln x_1:Ln x_n)), (average (Ln x_{n+1}:Ln x_{2n})))) = exp(average (Ln x_1:Ln x_{2n}))

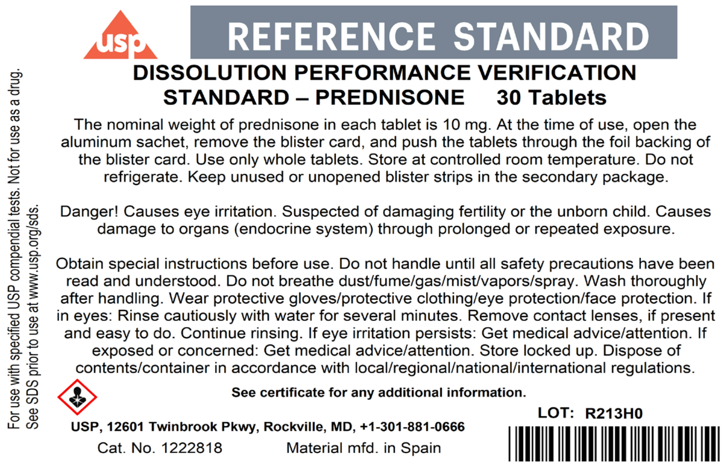
%CV= 100*sqrt(exp(average((var(Ln x_1:*Ln* x_n)),(var(Ln x_{n+1}:Ln x_{2n})))) -1)

exp: exponential (e^x) var: variance sqrt: square root *: multiply 100: conversion factor to percentage

For more information and guidelines about how to complete the performance verification test refer to the following website: https://www.usp.org/small-molecules/pvt

USP REFERENCE STANDARD CERTIFICATE

Label



REFERENCE STANDARD

DISSOLUTION PERFORMANCE VERIFICATION STANDARD – PREDNISONE 30 Tablets

The nominal weight of prednisone in each tablet is 10 mg. At the time of use, open the aluminum sachet, remove the blister card, and push the tablets through the foil backing of the blister card. Use only whole tablets. Store at controlled room temperature. Do not refrigerate. Keep unused or unopened blister strips in the secondary package.

Danger! Causes eye irritation. Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention. Store locked up. Dispose of contents/container in accordance with local/regional/national/international regulations.

See certificate for any additional information.

For use with specified USP compendial tests. Not for use as a drug.
See SDS prior to use at www.usp.org/sds.

USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666

Cat. No. 1222818 Material mfd. in Spain

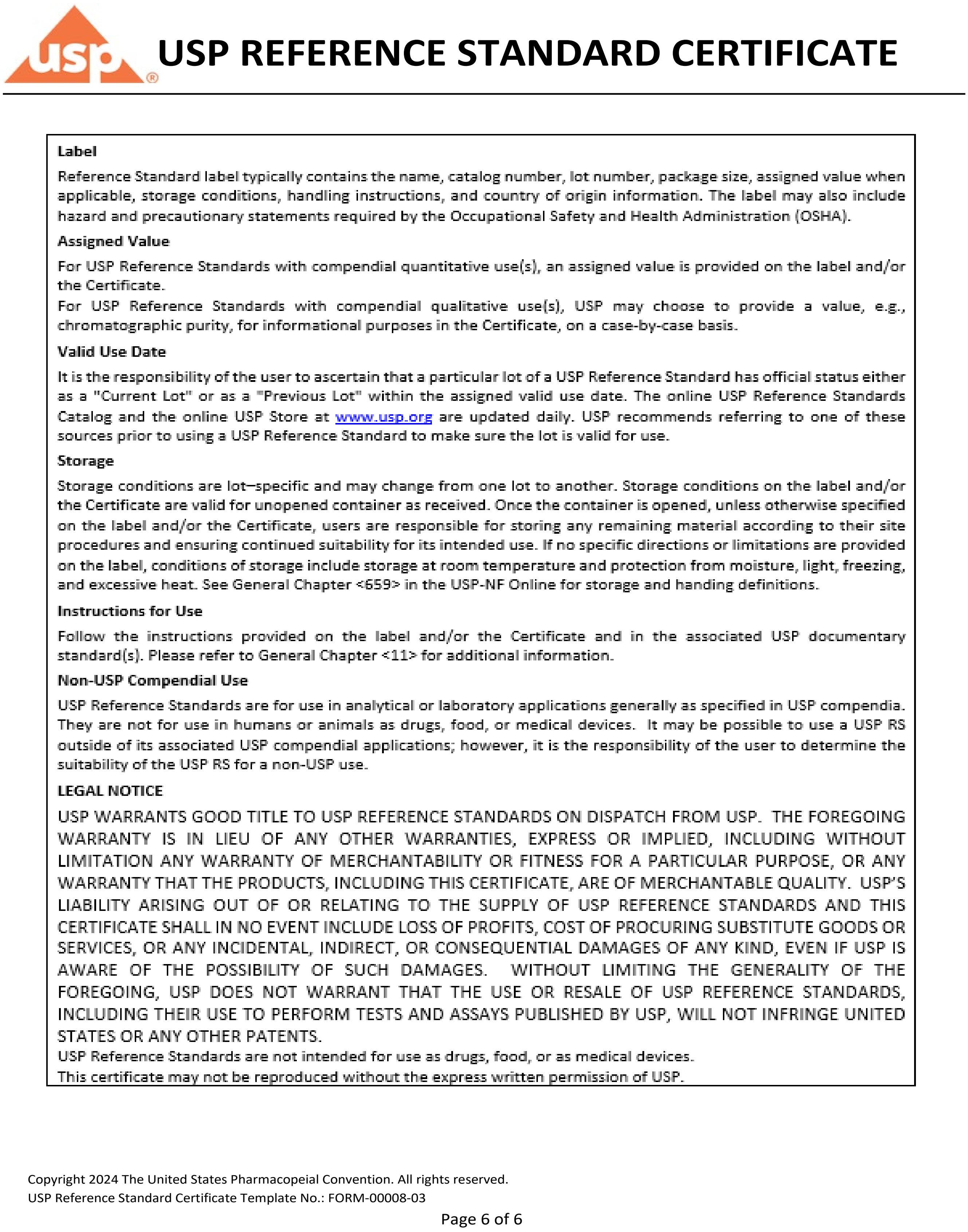
LOT: R213H0

Danielle A. Vattimo

Quality Assurance

Certificate Version History

Version Number	Date	Reasons for Change
00	04-SEP-2025	First issue



USP REFERENCE STANDARD CERTIFICATE

Label

Reference Standard label typically contains the name, catalog number, lot number, package size, assigned value when applicable, storage conditions, handling instructions, and country of origin information. The label may also include hazard and precautionary statements required by the Occupational Safety and Health Administration (OSHA).

Assigned Value

For USP Reference Standards with compendial quantitative use(s), an assigned value is provided on the label and/or the Certificate.

For USP Reference Standards with compendial qualitative use(s), USP may choose to provide a value, e.g., chromatographic purity, for informational purposes in the Certificate, on a case-by-case basis.

Valid Use Date

It is the responsibility of the user to ascertain that a particular lot of a USP Reference Standard has official status either as a "Current Lot" or as a "Previous Lot" within the assigned valid use date. The online USP Reference Standards Catalog and the online USP Store at www.usp.org are updated daily. USP recommends referring to one of these sources prior to using a USP Reference Standard to make sure the lot is valid for use.

Storage

Storage conditions are lot–specific and may change from one lot to another. Storage conditions on the label and/or the Certificate are valid for unopened container as received. Once the container is opened, unless otherwise specified on the label and/or the Certificate, users are responsible for storing any remaining material according to their site procedures and ensuring continued suitability for its intended use. If no specific directions or limitations are provided on the label, conditions of storage include storage at room temperature and protection from moisture, light, freezing, and excessive heat. See General Chapter <659> in the USP-NF Online for storage and handing definitions.

Instructions for Use

Follow the instructions provided on the label and/or the Certificate and in the associated USP documentary standard(s). Please refer to General Chapter <11> for additional information.

Non-USP Compendial Use

USP Reference Standards are for use in analytical or laboratory applications generally as specified in USP compendia. They are not for use in humans or animals as drugs, food, or medical devices. It may be possible to use a USP RS outside of its associated USP compendial applications; however, it is the responsibility of the user to determine the suitability of the USP RS for a non-USP use.

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USP Reference Standard Certificate Template No.: FORM-00008-03

DISSOLUTION SYSTEMS PERFORMANCE QUALIFICATION

Agilent CrossLab Compliance Services

Agilent CrossLab
From Insight to Outcome

Standard PQ Test Suite

This document describes the test program for qualifying dissolution instruments, and the following tables list all PQ tests. PQ affirms that your dissolution apparatus performs in accordance with current USP requirements. The USP Dissolution Performance Verification Test (PVT) is performed as required in the current USP General Chapters, Dissolution <711> and Drug Release <724>, in accordance with cGMPs.

Note: The actual test limits are subject to change when a new prednisone standard is released. A custom EQP is available with limits for the current USP lot.

Test	Setpoints and Parameters	Limits
Standard Preparation	N/A	% Absorbtivity ≥ 99.0% and ≤ 101.0% for working and control standards (calculations are performed only if the control standard is used)
Filter Validation	N/A	Recovery ≥ 98% and ≤ 102% for each filtered aliquot
Prednisone Qualification (All variations of test)	Vessel temperature: 37.0°C Elapsed time: 30 minutes (target window from tablet drop to sampling)	See current USP lot's Certificate of Analysis

Consumables, Supplies, and Parts Used for Qualification

All parts, supplies, standards and consumables specified by the Agilent qualification protocol are provided by the customer. Agilent does not provide Prednisone standards due to the impact of improper storage, which can adversely affect the potency and/or purity of the standards and put the integrity of the qualification at risk. Agilent will provide equipment necessary for the measurement of physical parameters (e.g., thermometer, level, tachometer, wobble gauge, etc.). Any additional parts for maintenance or repair needed to affect qualification will be billed to customer unless otherwise covered by Agilent service and support agreement.

Test Design and Rationale

PQ service does not include physical testing (e.g., measurements of speed, wobble, centering, level, etc.). Because the physical condition of the Dissolution tester can affect the outcome of the Performance Qualification, it is recommended that an inspection of the equipment and measurements of physical parameters are performed prior to the service to ensure that the equipment conforms to pharmacopeia requirements.

Standard Preparation

Description: This test describes how to prepare standards for the PQ tests.

Procedure: Refer to prednisone certificate for details

Filter Validation

Description: This test validates the filters used for sample and standard preparation.

Procedure: This test compares absorbance readings of three filtered aliquots of working standard.

Prednisone Qualification

Description: These chemical tests verify the performance of the dissolution tester.

Procedure: Refer to prednisone certificate for details.

www.agilent.com/chem/qualification

Report and Delivery Options

This list below includes options selected for inclusion in the EQR. By default, repeated run logs and transaction logs are always included; all other options can be included or excluded.

(For hyphenated system types only) If different options are chosen for the primary and supported system types, the primary system options are used for both techniques.

- Show chromatograms
- Show header and footer on cover
- Include repeated run logs
- Include Transaction logs

Selected Signature Options

Status: EQP is not locked

- Reporting variance is allowed in this EQP

Customer Approval

Name:
Title:
Date:
Signature:

Name:
Title:
Date:
Signature:

Name:
Title:
Date:
Signature:

Name:
Title:
Date:
Signature:

Legal Notice

Agilent CrossLab Compliance and its primary components (ACE software tool, procedures, test design, metrology tools, chemical reference standards, and operator training materials) have been designed, tested, validated, and released for commercial use following Agilent's Life Cycle Development Quality Assurance methodology. A review of the following life cycle stages is a key part of the ACE software and associated protocol development process.

-Product Description / Specification
-Life Cycle Phases / Transition Approval
-Quality Assurance / Testing
-Documentation and Change Management
-Source Code

Validation certificates for the ACE software and associated protocols are generated automatically as part of the life cycle process, prior to software release, and are available on request. The certificate includes a declaration of intent statement, including Annex 11 and 21 CFR Part 11, and is representative of the life cycle process followed.

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