EQUIPMENT QUALIFICATION PLAN





Agilent CrossLab Compliance Services

9 E D'BUa Y. ÖÖÙÙÈEŒĬÍ ´ÚÛ ´ÜFÌ GÜ€

GYfj]WY'HmdY. ÚÛ

7 ca dUbmiBUa Y.

7 i ghca Yf BUa Y#HJhY.

9 E D':] Yb Ua Y. ÖÖÜÜÈEGĚÍ Í ´ÚÛ ´ÜFÌ GÜ€È`]

9 E D'Di V']g\'8 UhY. Œ ¦ā ĒŒŒ ÂK Œ JÁŒ

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Ú¦^å}ã[}^ÁÛ`æţãã&æqã}}Æd√,[ÁÚæt^	FÍ
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FGGG FÌ ËÜFÌ GÜ€″ FÍ Ö^&GÍ	СН
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OḤĀÒˇªJ{^}ơĐÛˇæṭāææāt}}ÁÚ|æþÁQÒÛÚDÁs[&č{^}ơÁœÁÇ!\Á,^!+{!{^åÁsˇ!ā,*Áˇæṭāææāt}}Á^!çæð^•Á;!çæã^åÁ•ā,*ÁœÁŒā?}c ¦^•][]•ãā āāāā•DÁsa•) a Ás@Á√•`|œÁsa•^Á^][¦&°åÁsaþÁsò•) ÁÖ`ĭā[{^}œÁū æāā8ææā]}ÁÜ^][¦αÁçÒÛÜDÁÉ, @38.@Ás[8č{^}œÁs@Áf||[_ā*È

Ë/^•o•Á,^¦-{¦{ ^åÁå`¦ã,*Áo@ Á`æþãã&ææã[}Á,[¦\ EÜ^d|[ā]o•Á.•^å.AG|¦Án¢æ{||^EÃ;æe^|^}}*c@ÉÁn{||^!æeč¦^EÁæ}åÁ|[.Án^cæ]*•ÉÁæ•Áæ]||a&æà|^D ËŠājār•ÁQa&&\]caa}&\Á&jāe\jāeDÁed;]jā\åÁqfÁe\•@Áed;åÁ\^d;[āj@ Ë/^•ơśā^•&¦a̞qā̞}•Áṣæ̞åÁææą̞}æ∤•Á̞¦Áx•ơÁ̞∧-Á̞¦{ ^åÁ眕^Áṣæ̞åÁx•ơʎæ∉ ^৫¦•Ásæ̞^Áṣæ̞[Á^][¦৫åÁÒÛÜD $\ddot{E}/\$ $\frac{1}{2}$ $\frac{1}$

ÒÛÚÁÚÖØÁ^çã\ Á\$[&`{^}œÁ*]][¦ơÁx`•q{^\Ánçã\ Ása}]¦[çæÁsa}åÁsa}]¦[çæÁsa}åÁsa}Åsäāæa|^Á;¦[å`&^åÁsā^&q^Á;[{Ás@Ár|^&d[}&BÁÒÛÚ &[}œaaj^åÁ, ão@ajÁoÆÔÒÆV、[Á&ã-^\^}oÁÔÛÚÁædj];[çædÁ[;{æærÁ&æ)Áa^Á&\^æe^åÈ

EÔ[}&ã^kácæ}åæåÁ{;{æeÊác}ã&æ|^Á•^åÁ;¦ÁOEã^}dE^&{{ ^}å^åÅÔÛÚ• $E^{\prime}/2\pi \hat{a}^{\prime}/2\pi \hat{b}^{\prime}/6\pi \hat{c}^{\prime}/2\pi \hat{c}^{\prime$

T æ)^Á&`•q[{^\•Áæ}];|[ç^ÁœÁDÊā^}dË^8[{{^}å^åÁÖÛÚÁ§ÁœÁ8[}&ã^ÁÇi{ædÊV@Áo•œÊ^q[ā,œÊæ}åÁā[āœÁæ]]āðáÁæ}^Ác]ā&æ}^ åãi]|æîÁ, @38.@Á`æṭáā8ææāi}}Ár∿•orÁsæ)Ás^Ás[}-ã`¦^åЁÁ, @38.@ÁOĽā/}oÁs^•ã}æx°•Ásæ Áçæ≿æe)&^ÁG,^^ÃÖ|[••æ;∩È

Q ÁsaÁKI}&@^ÁÒÛÚÁse}]¦[çæbÁs[&`{^}c^*•^åÁ;|ÁOE*ā^}dĒ*&!{{^^}å^åÁÖÛÚÚ•ĒÁS@^Ác^•dĒ*^d]ā;o~Áse}åÁ;æbæ;^c°!•ĒÁse}åÁā[ão Áçæ ad;]|a8aaa;|^DÁad^Ásaa;]|aê^åÁsiÁsaÁsi;}8aa*^Áaaàà;^çãæe^åÁs;;{ æeÁsæ Ása;}Aá;\;

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Ú`{]ÁØ[¸Á038&`¦ ÇÚ`{]D	æ&^Áæ)åÁÚ!^&@a{i}}	Ø[, ÁÜæe^ÁFHÁEĒE €€Á, HEP ā, ° c^ Ø[, ÁÜæe^ÁGHÁ ÈE€€Á, HEP ā, ° c^ Ø[, ÁÜæe^ÁGHÁGÈE€€Á, HEP ā, ° c^Á, Ø[, ÁÜæe^ÁGHÁFĒE€Á, HEP ā, ° c^Á,		OBS&* 28&^ Ám Ú ^&&# 4[} ÁÜ</td><td>ÁsÍECÃ ÙÖÁnÁGÉÍEÃ</td></tr></tbody></table>	

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I bXYfgHUbX]b['h\ Y'HYgh'GdYW]Z]WUH]cb'GYW]cb']b'HUVi `Uf'FYj]Yk '8 cW a Ybhg

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Di a d': `ck '5 WW fUWn

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V@ā Á[] cá[} æþÁc∿• cÁsē ÁN} æà|^å Á[¦Ás@ā ÁÖÛÛÈ

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7 c'i a b'HYa dYfUhi fY'5 WW fUWn

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7 i glca Yf F Ygdcbg]V]`]lj]Yg

 $V[\acute{A}^{+}]_{+}^{+} (\acute{A}OEO) \acute{A}_{5} \circ d^{+} (^{+} \circ \acute{A}_{5} \circ \acute{A}_{5}$

ËÄQQ•d~{^}oÁs{}d[|Ág[Áj^\-¦-{|{Ás@∧Á~adjãa8aæaa[}}Ás^•o•È

EXODÊÒÁ [~; zd^Áz688^••ÁzîÁz@Ázî|åÁ^¦;z8x^Ár}*ji^^¦ÁgZÙÒDÁ[Á[zoáÁz@Ár|^8d[}38AÒÛÚÉÄ`}Áz@Á`zotá38zozá]}Á;[¦\√[; ÉbodyåÁ;`à|ā @Áz@ ÒÛÜÈ

 $\begin{array}{l} \text{CEO}\hat{\Delta} & \hat{\Delta}_{0} & \hat$

 $CE_{A}^{\circ} \circ A^{\circ} \circ$

ËÄÒÛÚÁ^çã\

ËÄÜ^çã\ Ás@ ÁÒÛ ÚÁ`]]|ā\åÁÇ æ; åæ;åÁ;¦Á&[}-āt`¦^åDÈ

ÊÜU^``^•ơ&@æ)*^•Áq Áx@ ÁÒÛÚÆAÁ^``ā^åÁQq Á; ^^ơÁ•^¦Á^``ā^{ ^}œÁ`&@&æ Áx••ɑ]*Áæ)*^Á;-Á•^DÆ;¦Áæ]]¦[ç^Áx@Á`]]|∂råÁÒÛÚ Ç@ænÁææã-3r•Á•^¦Á^``ā^{ ^}œ1È

ËÄÜ^č¦}ÁsejÁ^|^&d;[} &&ÁsejÁ^|^&d;]^Á;~Ás@ÁÒÛÚÁqÁOE*ã^\}oÁ;¦ã;¦ÁqÁ*æã&æãā;}Ás^|ãç^¦^È

ÊÍOE*;^^Áse) åÁs^ÓÁ]ÁS,•d*{ ^}óÆ[}d[|Áse&&&^••Á[Á,^\;-[;{ Ás@Á, [;\ÁG;:[çãs^ÁseÁÔÖÙÁ[*[}Á;;Ás@ÁØÙÒŪÈ ÊÍOE*;^^Áse) åÁse}];[ç^ÁOEÔÒÁ•æ*^Á;}Árão^ÁDp^ç;[;\ÁOEÔÒDÈ ÊÍO[;ÁS[}-ª*;^åÁÒÛÚ•ÊÍ(æs) cæs) Æs@e)*^Æ[}d[|Áse) åÁ^çã•ã[}Á@e(;^Á;Æs@Á]^&ãæ&Áse];[ç^åÁÒÛÚÈ ÊÍÛæ^|^Átd;|^Áse) åÁse&®iç^Áse) Áse];[ç^åÆ[]^Á;Æs@e ÁÖÛÚÈ ÊÍÚ^çã°,Áse) åÁsâ}Áse&®iç^Áse) Áse) Ás@Á*æ}Ásææã[}Á;[;\ÆsÆs[{]|^«Ase) åÁ^][;«åÈ

5 [] YbhF Ygdcbg]V]]h]Yg

 $\begin{array}{l} CE^*a^{\ } \circ A^{\ } | \cdot \circ \circ A^{\ } \circ A^{\ } | \cdot \circ \circ A^{\ } \circ A^{\ }$

ËÄÖ^|ãç^¦Ás@Ásē}]¦[ç^åÁs^\;çæ&^•Áq||[¸ãj*Ás@Ás^•ơÁ;¦[*¦æq•Ás^•&¦æa^åÁsjÁs@Ásē}]¦[ç^åÅÖÛÚL ËÄÚ¦[çæā^ÁseÁn[&\^åÁse)åÁsĒð}}åÁsĒð}}åÁÖÛÜÁ][}Ás[{]|^œā;}ÁsÆóÁs\éAs&\æAs} ËÄOÁ^~``^•ơåĒÁ;¦[çæā^Áse)Ás]æā{s}æÁs[\Ēðt}^åÁÖÛÜÁÔÖÁ;Ás@Ás`•d;{^\È

GHUHYa YbhcZ±bhYbh

 $\hat{O} \cdot \text{d} \left\{ \tilde{a} \text{ assaff} \right\} \cdot \hat{A} \text{sch} \hat{A}_{\text{path}} \hat{A}_{\text{path}}$

 $V@\acute{A}^{|c|} = A^{|c|} + A^{|c|} +$

; YbYfU`GHUHYa Ybhg`cb`h\ Y`HYgh]b[`Dfc[fUa

 $V@A@dd_{add} \Rightarrow AUUAe^{A} \otimes Au_{ad} \Rightarrow AUUAe^{A} \otimes Au_{ad} \Rightarrow Au_{a$

 $\begin{array}{l} CP a^{\lambda} dP^{\lambda} dP^{\lambda}$

9EDFYj]g]cb'<]glcfm

 $\begin{array}{l} \text{OEOOÁ} \stackrel{`}{\sim} \text{afastaceta}_{\dot{A}}^{\dagger}, & \text{i}_{\dot{A}}^{\dagger}, & \text{i}_{\dot{A}}^{\dagger},$

78 G'GcZtk UfY'DfY!fYei]g]hYg'Zcf'<UfXk UfY'Ei U']Z]WUh]cbg

 $V@\acute{A}[-\varsigma, 3e^{\acute{A}} \bullet ^a \mathring{A}_{i} \mathring{A}_{i}] d[/\mathring{A}_{i} \bullet d^{*}\{ ^{*} \bullet ^a \mathring{A}_{i} \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \mathring{A}_{i} \mathring{A}_{i} \bullet ^a \mathring{A}_{i} \mathring{A}_$

; `cggUfm

5[] Ybh9ED

ŒÔÒK

 $CE^{\frac{1}{4}} \circ hCE^{\frac{1}{4}} = \frac{h}{h} \circ hCE^{\frac{1}{4}} \circ hCE$

ÖOÙÙÈEGĂÍ ′ÚÛ′ÜFÌGÜ€ ÖOÙÙÈEGĂÍ ′ÚÛ′ÜFÌGÜ€È^] Úæť^ÁľÁÐÁHG

OE,¦ã/ ÉÃG€GÍ KIIKGÏÁDET

ÒÛÚK

 $\dot{O}^* = \frac{1}{4} \left\{ ^{\circ} \dot{A} + \dot{A$

ÒÛÜK

 \mathring{O}^{*} \mathring{a} { $^{\wedge}$ } \mathring{A} \mathring{U}^{\wedge}] [\mathring{A} \mathring{A} \mathring{U}^{\wedge}] [\mathring{A} $\mathring{$

ÔÖÙK

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Þ^c [¦\ÁŒÔK

OEÔÒÁna Áng • cæn|\^åAn() ÁnænÁ,^c; [¦\Án([å^Á, ãn@an) Án@.Álænà[¦æne[¦^ÁŠOEÞÁng, √æ∙d`&c'¦^

Š[&#ÁŒÔÒK

CEÔÒÁ^•ãå^•Á;}Áṣà Áṣã^]^}å^}oÁ\¢¢'\}æþÁsiãç^Ás[}}^&&\åA[}\$

O‡c^¦}ancãç^ÁT^co@tåK

OEÔÒÁsarÁsj•cæl|^åÁsæ}åÁ*}Á¦[{ÁsæÁÚÔÁ;[cÁs[}}^&c^åÁ(Ás@^Áæà;[læe[l^Á;^c, [l\

Ùæ) åæ\åÁÖÛÚK

ÒÛÚÁ,¦^Ëå^-ã,^åÁà^ÁOE ã^} oÁs@ædá, &|`å^•Áå^-æĕ|oÁs^•œÆ^d, [ã,œÆæ) åÁã, ãœ

Ô[}-at~¦^åAÒÛÚK

ÒÛÚÁs@æÁ@æÁs^^}Á&@æ)*^åÁsæ^åÁj}Á•^¦Á^~~¦Á^~~ã^{ ^} @

Xælãæ) & ^ÊÄÜæ) * ^ K

 $V@Aa)*^{A_{-}}^{A_{-$

Xælåæn) & ^ÉAY K

Ô@e) * ^ Át ÁseÁc^• oÁ, ædæ (^ c^ \ Ás@eseÁs Á, ãs@ã, Ás@ ÁCE ã^) oÁsædãe) & ^ Áæ) * ^

Xælåæn) & MÉÄUK

Ô@a) *^Át ÁæÁr^• OÁ ælæt ^c^!Ás@ænÁæ Át o ãa^Ás@ ÁCE ā^} OÁsælãæ) &^Áæ) *^

Xælæel & ÉÄÖYK

Xælæn) & ÉÄÖUK

 \ddot{O}^* $a\phi \dot{A}^*$][$c\ddot{a}$ * $\dot{A}\ddot{a}$ $\ddot{a}\sigma \dot{A}$ * $\sigma \ddot{a}\sigma \ddot{A}$ * $\sigma \ddot{a}\sigma \ddot{A}$

U] a[{} a A/^• dK

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O5ååããã{}æ∮ÁÛ^d][ãjdK

Ofāåããã} a aḥÁ; ^æe ˇ ¦^{ ^} oÁṣæ ţ ˇ ^Á[¦ÁæÁs^• oÁ;æææ { ^c^¦Áç-|[Ébē^{] ^ |æe ˇ |^ Ébæ} å Á• [Á; } D

Ei U]Z[WUt]cb @ZY7 mWY GtU[Yg

WÜÙK

 $W^{\bullet} \wedge AU^{\circ} \tilde{a} \wedge \{ \wedge \} \circ AU \wedge \tilde{a} = A \otimes AU \wedge \tilde{a} = AU \wedge \tilde{a}$

ÖÛK

ŴΚ

UÛK

 $U]^{+}$ area A^{+} area A^{-} are A^{-} area A^{-} are A^{-} a

ÚÛK

 $\dot{U}^{+} + \left\{ \begin{array}{c} (a) & (A^{-})^{-} & (A^$

ÜÛK

 $\ddot{U}^{\ } = \frac{1}{2} \frac{1}{4} \frac{1}{4}$

ÚT K

FYZYfYbWY'GcifWYg

OT)VT K

OE, ^¦a8æ) ÁÙ[&ã\c`Á[¦Á/^•cā] *Áæ) åÁTæc\¦ãæ;•

ØÖŒK

W}ãa^åÁÛcæaa^•ÁA2[[åÁse)åÁÖ¦**ÁOEå{ãjãrdæaãi}

Ռ Úî K

 $\tilde{O}[[\mathring{a}AOE ({æe^\mathring{a}ATæ})^*-æ&c^\mathring{a}*AÚ|æ&c@k^)$

ФUК

Q(c') and A(c') and A(c'

ÒÙUJ€€FK

QÙU ÁÙ cæ) åæ å Á[¦ÁÛ * æþãc ÁT æ) æ* ^{ ^} cÁÛ * e^{ •

ÚÔĐÙK

 $\dot{U}@ed{ \ ask^* \ asked} \dot{Q} \bullet] ^8 call{} \dot{A} \dot{Q} [] ^1 ascall{} \dot{A} \dot{U} \& @e{ \ } ^0$

WÙÚK

W}ãr^åÁÙæær^•ÁÚ@æd{æ&[]^ãæ

8]ggc`i hjcb'HYgh8 Yg][b'UbX'FUhjcbUY

GHUbXUfX'DfYdUfUfjcb

Ö^•&{a} cai} kÁ/@a kố·• chán·• &{aà^• ká@, ká[kí] æh^kaæ} åæåå• kí[kk@ kÚÛ kố·• œ È

Ú¦[&^a* \^KÁÜ^-\^\Á[Á]\^a\}ā*[}^Á&^\cãa&æe^Á[\Á\^cæa*È

:] hyf J U JXUhjcb

Ú¦[&^å`¦^kÁv@ákv•oks[{]æh^•Áæà•[¦àæ}&^Án^æåā]*•Á;Áœ^^Á⢦^åÁæd^î`[o•Á;Á;[¦\ā]*Áaæ}åæåàÈV@ÁÃÁn^&[ç^¦^Á;¦Áræ&@Áā¢\¦^å æ#ã`[oÁ;ઁ•oÁs^Ás^ç ^^}Ái)ìÃÁæ}åÆF€GÃÈ

DfYXb]gcbY'Ei U']ZWUIjcb'!'G]b['Y'GIU[Y

Ö^•&|a] aa[} káv@a Á&@{ a&adÁx•• aÁx•! ã㻕 Áx@ Á, ^; -{; { a} &^Á, Áx@ Á&ã•[| ` aa[} Áx• a*) È

Ú¦[&^å`¦^kÁÜ^-^¦Áq[Áj¦^å}ãr[}^Á&^¦cãã&æe^Áq[¦Áså^cæá‡•È

DfYXb]gcbY'Ei U']ZJWUh]cb'!'Hk c'GhU[Y

Ö^•&|a] a[} kk/@a k&@{ a&adkv•oko^|aan•ko@k]^|-{|{ ag &^k/a-ko@kaa•[|`a]} kkv•o'|E

Ú¦[&^å`¦^kÁÜ^~^¦Á{[Á, |^å}ã[] ^Á&^¦çãã&æc^Á[¦Áå^cæã•È

8]ggc`i hcb HYghGdYVJZJWUhcb

8 =GG'\\$&'\))

GHUbXUfX'DfYdUfUficb

GHUbXUfX'DfYdUfUf]cb%

ÇDEÁ, [¦∖ā) *Án cæ) 忦åÁæp) åÁæÁs[}d[|Án cæ) 忦åÁæ¦^Á∧``āl^åÁs[Ásæ4s`|ææ^Áà ÁOEa•[¦]cãpãôÁ[¦Án æ&o@Án cæ) 忦åLÁsÁnc@Ás`•d[{ ^¦Ás[^•Á,[cÁ,æ)oÁs[&¦^ææ^ÁæÁs[}d[|Án cæ) 忦åÉÃÃÁOEa•[¦]cãpãôÁsiÁr>UVÁsæ4s`|ææ^åÈD

ÁŒ, æê•Á&@åˇ ^åÁ[¦Áˇ]][¦ơ^å	Áåã•[ˇdā[}Ás∿	• c^¦• kÁOJ[]ælæcč• kÁFÁ[¦ÁG		
ÃÁOEa•[¦]cāçācÁŠ[¸ÁŠā[ādK	NM	JJÈ€	ŠK JJÈ€	PK JJÈ€
ÃÁOEa∙[¦]cãçãcÁPãt@ÁŠãĮãdK	ŁM	F€FÈ€	ŠK F€FÈE	PK F€FÈ€

:]`hYf`JU]XUh]cb

:]`HYf`JU]XUHcb%

	ÁŒ, æê•Á&@å* ^åÁ[¦Á*]][¦ơ\åÁåã•[ča[}Áe^∙o	^:\•KÁOE]]	ælæeč•KafrÁj¦ÁG		
	Ü^&[ç^¦^Æ6[¸Æ6ā[ãdK	NM	JÌ	Ã	ŠK JÌ	PK JÌ
С	Ü^&[ç^¦^Æs[¸Æsā[ādK	NM	JJ	Ã		
	Ü^&[ç^¦^ÁPā*@ÁŠā[ādK	ŁΜ	F€G	Ã	ŠK F€G	PK F€G
С	Ü^&[ç^¦^ÁPā*@ÁŠā[ābK	ŁΜ	F€F	Ã		

DfYXb]gcbYEi U]ZWUHcb'!'G]b[`Y'GHU[Y

DfYXb]gcbY'Ei U']ZJWUf]cb'!'G]b[`Y'GHU[Y%

ÁOE[]ælæeč•KÁFLÁ,~{à^\Á,~Áç^••^ •/	Ág∧∙c∧åÁiĤÁiÁÁi	¦ Â , L Á •∧¦	Á§^~ã^åÁNÙÚÁãã®		
)\(\alpha\) \\\\\^\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	H€	{ ā , `		 ŠK H€	PK H€
Ő^[{ ^dækÁT ^æ}ÁS[, ÆSā[ãnK	NM	ÌF	Ã	ŠK ÌF	PK ÌF
Õ^[{^da&ÁT^aa}ÁPa*@KŠã[ãdK	ŁM	JG	Ã	ŠK JG	PK JG
Õ^[{^da&ÁT^aa}ÁPa*@KŠã[ãdK	ŁM	JI	Ã		
Õ^[{ ^da&AT ^a+) AP aT@AŠa[aŭK Ô[^~a&a*}o/qiAXa+àaæaqi}AŠa[aŭK	ŁM	ΙĒ	Ã	ŠK IĒ	PK IË
Ô[^~a&a}}o4j.~ÁXæiāæaāj}Æšāj.ãiK	ŁM	ΙÈ	Ã		
ÙœàåæååÄÖã-^\^}&^ÆãijãtK	ŁM	GÈ€	Ã	ŠK CÈE	PK QÈ€
V^{]^¦æeč¦^AŠj(, ÁŠājānK	NM	HÎĚ	»Ô	ŠK HÎĒ	PK HÎĚ
V^{]^¦æeč¦^ÁPâ*@AŠãa[ãaK	ŁM	Η̈́Ḗ	»Ô	ŠK HÏĒ	PK HÏĚ
Ùæ{] ā]*Á018&*¦æ&?ÁŠā[ãnK	ŁM	G	Ã	ŠK G	PK G
ÁQŢ]ælæcč•KÁFÁÞ*{à^\Á,Áç^••^ •Á					
Ò æ]•^åÁ/ą̄ ^ÁÙ^d̞ [ạ̄ dK	H€	{ ā j ~ (6å	ŠK H€	PK H€
Õ^[{^dã&ÁT^æ},ÆĞ[,ÆĞā[ãdK	NM	ÌF	Ã	ŠK ÌF	PK ÌF
Õ^[{^dä&ÁT^aa}ÁPā*@ÄŠāĮãnK	ŁM	JG	Ã	ŠK JG	PK JG
Õ^[{^dã&ÁT^æ}ÁPã*@ÁŠã;ãaK	ŁM	JI	Ã		
Ô[^~a&a}}oÁ;Áxædaæaāj}ÁšājātK	ŁM	ΙĚ	Ã	ŠK IĚ	PK IĚ
Ô[^~a8an}on[-Áxætaeaaa]}ÁŠa[atK	ŁM	ΙÈΗ	Ã		
Ùœ) 忦åÄÖã-^¦^} &^ÆŠã[ãtK	ŁM	GÈ€	Ã	ŠK CHÈ€	PK GÈ€
V^{] ^ æeč ^ Æs̃[¸ Æsã[ãnK	NM	HÎĚ	»Ô	ŠK HÎĚ	PK HÎĚ
V^{]^¦æeč¦^ÁPār@AŠāįāŭK	ŁM	Η̈́Ē	»Ô	ŠK HÏĒ	PK HÏĚ
Ùæ{] āj*Á018&*¦æ&°ÁŠā[ādK	ŁM	G	Ã	ŠK G	PK G
ÁO[[]ælæeč•MaFÁÞ*{à^\Á;^••^ •Á	έ∧• c^å kΩ ÁΛ•^	¦ÁÖ^-ãj^:	åÁNÙÚÁŠĄã ar		
Ò æ]•^åÁ/ā[^ÁÛ^d] [ā] dK	H€	{ ā j ~	g ∿•	ŠK H€	PK H€
Õ^[{ ^dã&ÁT ^æ},ÁŠ[,ÁŠã[ãK	NM	ÌG	Ã	ŠK ÌG	PK ÌG
Õ^[{ ^da&ÁT^aa}ÁŠ[, ÁŠā[ādK	NM	ÌF	Ã		
Õ^[{^dã&ÁT^aa}ÁPã*@ÆãaĮãnK	ŁM	JG	Ã	ŠK JG	PK JG
Õ^[{^da&ÁT^aa}ÁPa*@ÆŠaįãnK	ŁM	JI	Ã		
$\hat{O}[\ ^{\sim}$ -38-20 $\)$ $O(\ ^{\sim}$ X act area () AS at a to	ŁM	ΙÈ	Ã	ŠK IÈ	PK IÈ
$\hat{O}[\ ^{\sim}\widehat{a}\widehat{s}\widehat{a}^{\alpha}\}\ o\widehat{A}\ \widehat{A}X\ \widehat{a}\widehat{e}\widehat{a}\widehat{a}\widehat{e}\widehat{a}\widehat{a}\ \widehat{a}K$	ŁM	ΙÈG	Ã		
Ùœ) åæ\åÁÖã-^\^}&^Æãį ãtK	ŁM	Œ	Ã	šk ŒE	PK GÈ€
ÖOÙÙÈEGEĬÍ′ÚÛ′ÜFÌGÜ€ ÖOÙÙÈEGEĬÍ′ÚÛ′ÜFÌGÜ€ÈÈ`]			Úæt^Áπ-HÁÐÁ-IG	Oʦ‡ ặÀ ÉĞ €G	ÂKIKGÏÁŒT

V^{]^¦æeč¦^ÁG[¸ÆGā[ãdK V^{]^¦æeč¦^ÁPā*@AGā[ãdK	NM ŁM	HÎĚ	»Ô	ŠK	HÎĚ	PK HÎĚ
•	ŁΜ	. : *				
		Η̈́Ḗ	»Ô	ŠK	Η̈́Ě	PK HÏĚ
Ùæ{] ā]*ÁOB&&`¦æ&îÁŠā[ãnK	ŁM	G	Ã	ŠK	G	PK G
ÁCE[]ælæeč•kÁCÁÞ~{à^¦Á;Áç^••^ •Ág^	∙c^åk¶ÂÁV∳^	¦ÁÖ^-ãj^å	àÁWÙÚÆãą ão			
Ò æ]•^åÁvã[^ÁÙ^d][ā]dK	H€	{ ā j ~ c	y •	ŠK	H€	PK H€
Õ^[{^dã&ÁT^æ}ÁŠ[¸ÁŠã[ãK	NM	ΙÎ	Ã	ŠK	ΙÎ	PK IÎ
Õ^[{^dã&ÁT^æ}ÁŠ[¸ÁŠã[ãK	NM	ΙÍ	Ã			
Õ^[{^dã&ÁT^æ}ÁPãã@ÁŠãįãaK	ŁM	ĺJ	Ã	ŠK	ÍJ	PK ÍJ
Ő^[{^dã&ÁT^æ}ÁPã*@ÁŠãįãaK	ŁM	ĺÏ	Ã			
$\hat{O}[^{\sim}382^{\circ}]$ $o\hat{A}$ \hat{A}	ŁM	ÎÈG	Ã	ŠK	ÎÈG	PK ÎÈG
$\hat{O}[\ \sim -3820^{\circ}] $ $O(\hat{A} - \hat{A}) $ $CO(\hat{A} + \hat{A}) $ $CO(\hat{A} $	ŁM	ÍÈ	Ã			
Ùœ) 忦åÄÖã-^¦^}&^Æãį ãnK	ŁM	GÈ€	Ã	ŠK	Œ	PK GÈ€
V^{]^¦æeč¦^Æõ[¸Æõã[ãaK	NM	HÎĚ	»Ô	ŠK	HÎĚ	PK HÎĚ
V^{]^¦æeč¦^ÁPâŤ@ÁŠãĮãnK	ŁM	Η̈́Ē	»Ô	ŠK	Η̈́Ě	PK HÏĚ
Ùæ{] ã;*Á078&*¦æ&^Ášã;ãtK	ŁM	G	Ã	ŠK	G	PK G
ÁCE[]ælæeč•kÁCÁÞ~{à^¦Á;Áç^••^ •Ág^	• c^åk¶.ÁW•^	¦ÁÖ^-ãj^å	ÁVÙÚÁŠĄ ão			
Ò æ]•^åÁ/ã[^ÁÙ^d] [ā]dK	H€	{ ā j ~ c	y •	ŠK	H€	PK H€
Õ^[{^da&ÁT^aa}ÁŠ[¸ÁŠã[ãK	NM	ΙÎ	Ã	ŠK	ΙÎ	PK IÎ
Ő^[{^dã&ÁT^æ},ÁŠ[,ÁŠã[ãaK	NM	ΙÍ	Ã			
Õ^[{^dã&ÁT^æ}ÁPãã@ÉŠãĮãdK	ŁM	ĺJ	Ã	ŠK	ĺJ	PK ÍJ
Ő^[{^dã&ÁT^æ}ÁPãã@ÁŠãĮãdK	ŁM	ĺÏ	Ã			
$\hat{O}[\ ^{\sim}=382\hat{a}^{\circ}\)$ $O(\hat{a},\hat{a})$ $A(\hat{a})=\hat{a}$ $A(\hat{a})=\hat{a}$ $A(\hat{a})=\hat{a}$	ŁM	ÎÈ	Ã	ŠK	ÎÈ	PK ÎÈ
$\hat{O}[\ ^{\sim} - \hat{a}\hat{b}\hat{a}^{\circ}\} O(\hat{a} - \hat{A}\hat{x}) \approx \hat{a}\hat{a}\hat{a}\hat{a}\hat{a}\hat{a}) \hat{A}\hat{S}\hat{a}\hat{a} \hat{a}\hat{b}\hat{A}$	ŁM	ÍÈH	Ã			
Ùœa)åæååÄÖã=^¦^}&^ÄŠãĮãdK	ŁM	Œ	Ã	ŠK	Œ	PK CHÈ
V^{]^¦æcč¦^Æc̃[¸Æcã[ãdK	NM	Η̈́Ē	»Ô	ŠK	HÎĚ	PK HÎĚ
V^{]^¦æcč¦^ÁPā*@ÁŠāįãdK	ŁM	Η̈́Ē	жÔ	ŠK	Η̈́Ě	PK HÏĚ
Ùæ{] ā]*Á018&*¦æ&?ÁŠā[ãdK	ŁM	G	Ã	ŠK	G	PK G
ÁO[[]ædæcĕ•KÁCÁÞ*{à^¦Á[Áç^••^ •Ág^	∙c^åkÂÁW•^	¦ÁÖ^-ãj,^å	àÁVÙÚÆŠĄ ão			
Ò æ]•^åÁ/ã[^ÁÙ^d][ā]dK	H€	{ ā j ~ c	^•	ŠK	H€	PK H€
Õ^[{^dã&ÁT^aa)ÁŠ[¸ÁŠã[ãdK	NM	ΙÎ	Ã	ŠK	ΙÎ	PK IÎ
Õ^[{^dã&ÁT^aa)ÁŠ[¸ÁŠã[ã£K	NM	ΙÍ	Ã			
Õ^[{^dã&ÁT^æ}ÁPãã@ŐŠãĮãdK	ŁM	ĺJ	Ã	ŠK	ÍJ	PK ÍJ
Ő^[{^dã&ÁT^æ}ÁPãã@ÉŠãĮãdK	ŁM	ĺÎ	Ã			
$\hat{O}[\ ^{\sim}\!\!\!\!-\!\!\!\!\!\!-\!$	ŁM	ÎÈ€	Ã	ŠK	ÎÈ€	PKÎÈ€
			Úæť^ÁFIÁÐÁHG	077	ur A Mosoí	ÂIKIIKGÏÁOET

С	Ô[^~a&a^}o4j~ÁXæbäæeaj}ÁŠājāiK	ŁM	ÍÈG	Ã		
	Ùœ);åælåÁÖã^\^}&^AŠã(ãtK	ŁM	Œ	Ã	ŠK GÈ€	PK GÈ€
	V^{] ^ aeč ^ AŠ[¸ AŠā[ādK	NM	ΗÎĚ	»Ô	ŠK HÎĚ	PK HÎĚ
	V^{]^¦æc°¦^ÁPāt@AŠāĮānK	ŁM	Η̈́Ē	»Ô	ŠK HÏĒ	PK HÏĚ
	Ùæ[] ā]*Á018&*¦æ&?ÁŠā[ãuK	ŁM	G	Ã	ŠK G	PK G

DfYXb]gcbYEiU]ZJWUr]cb'!'Hkc'GHU[Y

ÖOÙÙÈEGĚÍÍÚÚÚÍÜFÌGÜ€È`]

$DfYXb]gcbY`Ei\ U`]Z]WUJ]cb`!`Hk\ c`GIU[\ Y\%$

	ÁŒŢ]æbæcč•kÁFLÁ¸ˇ{à^\Á¸Áç^••^ •Ác^•c^åkÂ,Á;\Á; Ò æ}•^åÁVą̄^ÂĹVq̄[ā]dK	,⁄⊈ ,⁄ H€			 ŠK H€	PK H€
			{ ā ~			
	Ùœt^ÁFÁÕ^[{ ^dæÁT ^æ; ÁŠ[, ÁŠā; ãtK	NM	ÌΗ	Ã	ŠK ÌH	PK ÌH
	Ùœt^ÁFÁÕ^[{ ^dæAT ^æ}ÁPã @Æãį ãK	ŁM	J€	Ã	ŠK J€	PK J€
	Ùœt^ÁFÁÕ^[{^dā&ÁT^æ), ÁPã @ÁŠã, ãdK	ŁM	JF	Ã		
	Ùœt^ÁFÁÔ[^~~3828}o4jÁxætāæaāj}ÁšājādK	ŁM	HÈ	Ã	ŠK HĒ	PK HÈ
	Ùcæt^ÁrÁÔ[^~&&aN}oÁ;Áxætãææāj}ÁŠājātK	ŁM	HÈH	Ã		
	Ùcet ^ÁrÁÙce) åæåÁÖã-^\^} &^ÁŠãį ãtK	ŁM	Œ	Ã	ŠK GÈ€	PK GÈ€
	Ùcæ*^ÁGÃÕ^[{^dā&ÁT^aa)ÃĞ[,ÃĞā[ãdK	NM	ÌF	Ã	ŠK ÌF	PK ÌF
	Ùcæ*^ÁGÁÖ^[{^da&ÁT^æ)ÁPā*@ÁSā;ānK	ŁM	JG	Ã	ŠK JG	PK JG
	Ùcae*^ÁGÁŐ^[{^dā&ÁT^aa)ÁPā*@ÁSā;ādK	ŁM	JI	Ã		
	$\dot{\mathbf{G}}^{A} = \mathbf{A} \hat{\mathbf{G}}^{A} \hat{\mathbf{G}} \hat{\mathbf{G}} \hat{\mathbf{G}} \hat{\mathbf{G}}^{A} + \mathbf{A} \hat{\mathbf{G}}^{A} $	ŁM	ΙĚ	Ã	ŠK IĚ	PK IĚ
	$\dot{U}_{\text{Cat}} \wedge \dot{A}_{\text{C}} \dot{O}_{\text{C}} \wedge \sim 382) \circ \dot{A}_{\text{C}} $	ŁM	ΙÈ	Ã		
	Ùœt^ÁGÁÙœa) åælåÁÖã-^\^} &^ÁŠãĮ ãdK	ŁM	Œ	Ã	šk GÈ€	PK GÈ€
	V^{]^¦æcੱ¦^Áō[¸ÁōãįãnK	NM	ΗÎĚ	»Ô	ŠK HÎĒ	PK HÎ Ĕ
	V^{]^¦æc'¦^ÁPâ'@ÁSã ãnK	ŁM	Η̈́Ē	»Ô	ŠK HÏĒ	PK HÏÈ
	Ùæ[] ā]*Á1028&*¦æ&?Á6ã[ãnK	ŁM	G	Ã	ŠK G	PK G
	ÁCH;]ælæce*•KÁFÁÞ~{à^\Á;^•••^ •Ác^•c^åKÁiÁN•^	\¦ÁÖ^~āj^åÁWÙI	ÚÁŠãĮ ão			
	Ò æ]•^åÁVā[^ÁÙ^d] [ā]dK	H€	{ ā ř	6 å	ŠK H€	PK H€
	Ùcæt^ÁrÁÕ^[{^da&ÁT^æa}ÁŠ[¸ÁŠā[ãaK	NM	ÌΗ	Ã	ŠK ÌH	PK ÌH
	Ùcæt^ÁrÁÕ^[{^da&ÁT^æa)Ár?ã@KŠã[ãdK	ŁM	J€	Ã	ŠK J€	PK J€
	Ùcæt^ÁrÁÕ^[{^da&ÁT^æa)Ár?ã@KSã[ãdK	ŁM	JF	Ã		
	Ùœet^ÁFÁÔ[^~a3&at\}oÁ(Axasiānenā)}ÁSā(ānK	ŁM	HÈ	Ã	ŠK HĒ	PK HÈ
	$\dot{V}_{cet} \wedge \dot{A}_{F} \dot{A} \hat{O}[\ \wedge \sim 3820) \circ \dot{A}_{F} \dot{A}_{K} \approx 3820 \cdot \dot{A}_{K} \times 3820 \cdot \dot{A}_{K} $	ŁM	HÈH	Ã		
;	ÖQÙÙÈEGĚÍ′ÚÛ′ÜFÌGÜ€	l Ílæ*	^ÁFÍÁÐÁH	3	OE,¦ājÁìÉjG€GÍA	ברוא באוא ב
•	343241 00 011 000	500	יוועם נווי.	•	04 14 1 20CO 1	

ÖOÙÙÈEŒĂÍ′ÚÛ′ÜFÌŒÜÈČ`]

	Ùœt^ÁFÁÙœ)åæååЮã-^\^}&^ÆãįãtK	ŁM	Œ	Ã	ŠK GÈ€	PK CHÈ
	Ùœet^ÁGÁŐ^[{^dā&ÁT^æa}ÁS[¸ÁSã[ãK	NM	ÌF	Ã	ŠK Ì F	PK ÌF
	Ùœe*^ÁGÁŐ^[{^dā&ÁT^æa}ÁPā*@ÁŠāĮādK	ŁM	JG	Ã	ŠK JG	PK JG
С	Ùœet^ÁGÁŐ^[{^dā&ÁT^æa}ÁPāt@ÁŠāĮādK	ŁM	JI	Ã		
	Ùœt^ÁGÁÔ[^~=3828}}ơÁ;-Áxætāæcā[}ÁŠā[ãtK	ŁM	ΙÈ	Ã	ŠK IĖ	PK IÈ
С	Ùœt^ÁGÁÔ[^~=3828}}ơÁ;-Áxætāæcā[}ÁŠā[ãtK	ŁM	ΙÈΗ	Ã		
	Ùœt^ÁGÁÙœa)åædåÁÖã=^\^}&^ÁSãĮãiK	ŁM	Œ	Ã	ŠK GÈ€	PK GÈE
	V^{]^¦æc°¦^Á5[¸Á5ã[ãnK	NM	ΗÎĚ	»Ô	ŠK HÎĒ	PK HÎĚ
	V^{]^¦æc'¦^ÁPa"@ÁŠa[ãdK	ŁM	Η̈́Ē	»Ô	ŠK HÏĒ	PK HÏĚ
	Ùæ[] ā]*Á028&*¦æ&?ÁŠā[ãnK	ŁM	G	Ã	ŠK G	PK G
	ÁCU[]ælæe:•HÁRÁÞ~{à^\Á;^••^ •Áe^•c^åHÂÁV•^\ÁÖ^	- ą ^åÁWÙl	ÚÁŠĄ ão			
	Ò æ]•^åÁVą ^ÂÛ^d] [ā] dK	Н€	{ ā j ~	6 å	ŠK H€	PK H€
	Ùœzt^ÁrÁŐ^[{^dā&ÁT^æa}ÁŐ[¸ÁŐsā[ādK	NM	ÌΗ	Ã	ŠK ÌH	PK ÌH
	Ùœet^ÁrÁŐ^[{^dā&ÁT^æ),Árāt@éőã;ãnK	ŁM	J€	Ã	ŠK J€	PK J€
С	Ùœet^ÁrÁŐ^[{^dā&ÁT^æa}ÁPāt@ÁŠāĮādK	ŁM	JF	Ã		
	Ùœt^ÁFÁÔ[^~=888}}ơÁ;-ÁXætáænaā[}ÁŠā[ãnK	ŁM	HÈ	Ã	ŠK HĒ	PK HÈ
С	Ùœt^ÁFÁÔ[^~&&?\}ơÁ,~ÁXætáææá]}ÁŠāįãtK	ŁM	HÈH	Ã		
	Ùœt^ÁFÁÙœa)åæbåÁÖã-^\^}&^ÁŠāĮãtK	ŁM	Œ	Ã	šK GÈ€	PK GÈ€
	Ùœzt^ÁGÁŐ^[{^dā&ÁT^aa)ÁS[¸ÁSā[ādK	NM	ÌG	Ã	ŠK ÌG	PK ÌG
С	Ùcæ*^ÁGÁŐ^[{^dā&ÁT^æ)ÁS[¸ÁSā[ādK	NM	ÌF	Ã		
	Ùœz*^ÁGÁŐ^[{^dā&ÁT^aa)ÁPā*@ÁSã;ãnK	ŁM	JG	Ã	ŠK JG	PK JG
С	Ùœz*^ÁGÁŐ^[{^dā&ÁT^aa)ÁPā*@ÁSã;ãnK	ŁM	JI	Ã		
	Ùœt^ÁGÁÔ[^~=3821\}oÁ;-ÁXætāænaā[}ÁŠā[ānK	ŁM	ΙÈΗ	Ã	šKIÈH	PK I 🗎
С	Ùœ * ^ÁGÁÔ[^~ = 8821^} oÁ; -ÁX æ + ãæ e ā; } ÁŠā; ãt K	ŁM	ΙÈG	Ã		
	Ùœet^ÁGÁÙœa) åædåÁÖã^\^}&^AŠãĮ ãdK	ŁM	Œ	Ã	šK GÈ€	PK GÈE
	V^{] ^ æcë ^ ÆS[, ÆSã[ãdK	NM	ΗÎĚ	»Ô	ŠK HÎĒ	PK HÎĚ
	V^{]^¦æc°¦^ÁPâ°@ÑSãĮãnK	ŁM	Η̈́Ē	»Ô	ŠK HÏĒ	PK HÏĚ
	Ùæ[] ā]*Á028&*¦æ&?ÁŠā[ãnK	ŁM	G	Ã	ŠK G	PK G
ł	ÁŒ[]ælæĕ•kÁCÁÞ~{à^\Á,Áç^••^ •Ác^•c^åkÃ,ÁN•^\ÁÖ^	-ą̃, ^åÁWÙl	ÚÁŠĄ̃ã			
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HOW AGILENT CROSSLAB COMPLIANCE SERVICES INTEGRATE WITH QUALITY SYSTEMS AND REGULATIONS



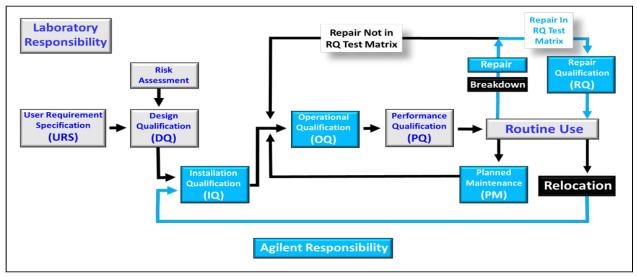


Agilent CrossLab Compliance Services

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.



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.
- 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 (0Q)

The main function of the 00 stage is to evaluate and document instrument performance at the intended operational range of use. 00 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 0Q 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. Requalifying 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	00 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

Information, descriptions and specifications in this publication are subject to change without notice.

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DISSOLUTION PERFORMANCE VERIFICATION STANDARD - PREDNISONE

(10 mg nominal prednisone content per tablet)

USP Catalog No.: 1222818 USP Lot No.: R182R0

Valid Use Date	15-DEC-2025
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- μ m-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-type or equivalent).

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

Analysis: UV at 242 nm

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Dissolution <711>

Procedure: Determine the quantity of prednisone, C₂₁H₂₆O₅, dissolved at 30 minutes in each vessel

expressed as percent of the labeled amount.

Single-Stage Test Instructions and Acceptance Criteria

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.
- 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	81-94	4.4
	7	81-94	4.3
	8	81-94	4.2
	12	81-94	4.3
	14	81-94	4.3
2 (Paddle)	6	45-57	5.4
	7	45-57	5.3
	8	45-56	5.2
	12	45-57	5.4
	14	45-57	5.3

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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	First Stage of Two-Stage Test		Second Stage of Two-Stage Test	
	vessels per run	Geometric Mean, % Prednisone Dissolved	%CV	Geometric Mean, % Prednisone Dissolved	%CV
1 (Basket)	6	83-91	3.3	81-94	4.4
	7	83-91	3.3	81-94	4.3
	8	83-91	3.3	81-94	4.2
2 (Paddle)	6	47-54	4.1	45-57	5.4
	7	47-54	4.1	45-57	5.3
	8	47-54	4.1	45-56	5.2

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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	7.6	7.5	7.4

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_0)), (average (Ln x_{n+1} :Ln x_2 n)))) = exp(average (Ln x_1 :Ln x_2 n))

%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



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Label



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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. 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.

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

Cat. No. 1222818 Material mfd. in Spain



Danielle A. Vattimo

Quality Assurance

Certificate Version History

Version Number	Date	Reasons for Change
00	14-MAR-2024	First issue
01 (Current)	10-MAR-2025	 Change Valid Use Date from "31-JUL-2025" to "15-DEC-2025". Change "alcohol" to "methanol or ethanol" under Standard solution. Add the filter type information in Note 1 under Sample solution. Change "UV at maximum absorbance of about 242 nm" to "UV at 242 nm" under Analysis.

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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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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 \geq 99.0% and \leq 101.0% for working and control standards (calculations are performed <u>only</u> if the control standard is used)
Filter Validation	N/A	Recovery \geq 98% and \leq 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

Information, descriptions and specifications in this publication are subject to change without notice.

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