



Study Name: Valid_OQMVM Study
Study ID: 3470
Project Name: Valid_OQMVM
User Name: Sandra O'Halloran (Sandra)
Processing Node: Rmcsweeneythkpa



OQMVM Summary Report RS

Study Name:	Valid_OQMVM Study	Validation Protocol:	Valid_OQMVM Study
Study Description:	Validation Study for Software	Validation Protocol ID:	4862
Study ID:	3470	Analytical Method Type:	Assay
Study Start Date:	7/14/2006 4:06:05 PM EDT	Compound Type:	Drug Product
Study Finish Date:	10/29/2010 10:30:27 AM EDT	Development Phase:	Development
Study Status:	Study Complete	Validation Protocol Comment:	LinAccRepeatCompReprodLOD

Linearity Results

Linearity Results

	Validation Result Id	Component	Test Description	R Squared	Relative Response Factor Mean	Faults
1	5643	Arg	AAA - LinearityLow	0.994180	0.931698	No
2	5645	Cys	AAA - LinearityLow	0.991503	0.975821	No
3	5644	Gly	AAA - LinearityLow	0.995843	1.030339	No
4	5640	Arg	AAA - LinearityNormal	0.998948	0.995683	No
5	5642	Cys	AAA - LinearityNormal	0.999355	1.007813	No
6	5641	Gly	AAA - LinearityNormal	0.999506	1.000895	No

Linearity Regression ANOVA Table

Test: AAA - LinearityNormal Component: Arg Assessed Field: Area ValRes Id: 5640

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	3.039776e+004	8	3.799719e+003				No
2	Error	3.198053e+001	7	4.568647e+000				No
3	Model	3.036577e+004	1	3.036577e+004	6646.557348	12.246383	0.000000	No

Linearity Regression ANOVA Table

Test: AAA - LinearityNormal Component: Gly Assessed Field: Area ValRes Id: 5641

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	3.172326e+004	8	3.965408e+003				No
2	Error	1.567600e+001	7	2.239428e+000				No
3	Model	3.170759e+004	1	3.170759e+004	14158.786223	12.246383	0.000000	No

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Linearity Regression ANOVA Table

Test: AAA - Linearity Normal Component: Cys Assessed Field: Area ValRes Id: 5642

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	2.549274e+004	8	3.186593e+003				No
2	Error	1.645093e+001	7	2.350133e+000				No
3	Model	2.547629e+004	1	2.547629e+004	10840.359242	12.246383	0.000000	No

Linearity Regression ANOVA Table

Test: AAA - Linearity Low Component: Arg Assessed Field: Area ValRes Id: 5643

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	4.678172e+001	8	5.847714e+000				No
2	Error	2.722737e-001	7	3.889624e-002				No
3	Model	4.650944e+001	1	4.650944e+001	1195.730966	12.246383	0.000000	No

Linearity Regression ANOVA Table

Test: AAA - Linearity Low Component: Gly Assessed Field: Area ValRes Id: 5644

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	5.183369e+001	8	6.479211e+000				No
2	Error	2.154889e-001	7	3.078413e-002				No
3	Model	5.161820e+001	1	5.161820e+001	1676.779632	12.246383	0.000000	No

Linearity Regression ANOVA Table

Test: AAA - Linearity Low Component: Cys Assessed Field: Area ValRes Id: 5645

	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Faults
1	Total	3.874205e+001	8	4.842756e+000				No
2	Error	3.291769e-001	7	4.702527e-002				No
3	Model	3.841287e+001	1	3.841287e+001	816.855871	12.246383	0.000000	No

Linearity Comparison Results

Linearity Comparison Results

	Validation Result Id	Component Type	Linearity Test 1 Description	Linearity Test 2 Description	Intercept Comparison p-Value	Slope Comparison p-Value	Faults
1	5646	Arg	AAA - Linearity Low	AAA - Linearity Normal	0.807582	0.000000	No
2	5648	Cys	AAA - Linearity Low	AAA - Linearity Normal	0.811448	0.000001	No
3	5647	Gly	AAA - Linearity Low	AAA - Linearity Normal	0.940636	0.000000	No

LOD/LOQ Results

LOD LOQ Results

	Validation Result Id	Component	Component Type	Linearity Test Id	Linearity Test Description	Method to Determine LOD/LOQ	LOD	LOQ	Units	Faults
1	5659	Arg	Arg	5643	AAA - Linearity Low	Linearity Curve Intercept SD	0.276878	0.839025	pmol	No
2	5661	Cys	Cys	5645	AAA - Linearity Low	Linearity Curve Intercept SD	0.167495	0.507562	pmol	No
3	5660	Gly	Gly	5644	AAA - Linearity Low	Linearity Curve Intercept SD	0.233812	0.708522	pmol	No

Study Name: Valid_OQMVM Study

Study ID: 3470

Processing Node: Rmcsweeneythkpa

Project Name

User Name:

Valid_OQMVM

Sandra O'Halloran (Sandra)

Specificity Results

Specificity Results

	Validation Result Id	Component	Test Description	Area Mean Std Error	Retention Time Mean (min)	Retention Time Mean CI	Retention Time Mean Std Error	Faults
1	5672	Arg	AAA - Specificity	1257.164820	3.571633	0.007709	0.000607	No
2	5674	Cys	AAA - Specificity	1112.791895	6.612208	0.004641	0.000365	No
3	5673	Gly	AAA - Specificity	863.142274	3.687791	0.004877	0.000384	No

Accuracy Results

Accuracy Overall Results

	Validation Result Id	Component	Test Description	Overall Mean % Recovery	% RSD	Calculated Validation Target	Faults
1	5649	EtP	Parabens - Acc 3 Preps 3 Injs	100.386495	1.107765	30.115948	No
2	5650	MeP	Parabens - Acc 3 Preps 3 Injs	100.222303	2.487046	25.055576	No

Per Level Accuracy Results

Component: EtP Validation Result Id: 5649

	Level	# Points	Mean % Recovery at Level	Standard Deviation	Summary Faults
1	Level 1	3	100.973593	0.033857	No
2	Level 2	3	101.268875	0.089926	No
3	Level 3	3	98.917017	0.115734	No

Per Level Accuracy Results

Component: MeP Validation Result Id: 5650

	Level	# Points	Mean % Recovery at Level	Standard Deviation	Summary Faults
1	Level 1	3	100.525683	0.072390	No
2	Level 2	3	102.935880	0.039037	No
3	Level 3	3	97.205346	0.092758	No

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Repeatability Results

Repeatability Results

Assessed Field: Area

	Validation Result Id	Component	Test Description	Assessed Field	Assessed Field Mean	Assessed Field Mean Std Error	Faults
1	5653	MeP	Parabens - Repeatability	Area	1759608.975447	249118.797478	No

Repeatability Results

Assessed Field: Retention Time

	Validation Result Id	Component	Test Description	Assessed Field	Assessed Field Mean	Assessed Field Mean Std Error	Faults
1	5654	MeP	Parabens - Repeatability	Retention Time	2.325611	0.001422	No

Reproducibility Results

Reproducibility Overall Results

Assessed Field: % Recovery

	Validation Result Id	Component	Test Description	Assessed Field	Variance Cochran Test p-Value	Variance R^2	Retention Time Mean CI	Faults
1	5655	EtP	Parabens - Reprod. Labs B & D	% Recovery	0.757123	0.552628	0.046829	No
2	5656	MeP	Parabens - Reprod. Labs B & D	% Recovery	0.741910	0.002776	0.022672	No

Reproducibility Overall Results

Assessed Field: Retention Time

	Validation Result Id	Component	Test Description	Assessed Field	Variance Cochran Test p-Value	Variance R^2	Retention Time Mean CI	Faults
1	5657	EtP	Parabens - Reprod. Labs B & D	Retention Time	0.020465	0.936777	0.046829	No
2	5658	MeP	Parabens - Reprod. Labs B & D	Retention Time	0.039875	0.938012	0.022672	No

Intermediate Precision Results

Intermediate Precision Results

Assessed Field: Area

	Validation Result Id	Component	Assessed Field	Assessed Field Mean	Assessed Field Mean LCL	Assessed Field Mean UCL	Faults
1	5662	EtP	Area	3719580.384032	3707905.131278	3731255.636787	No
2	5663	MeP	Area	3537357.115048	3525286.591164	3549427.638933	No

Intermediate Precision Results

Assessed Field: Retention Time

	Validation Result Id	Component	Assessed Field	Assessed Field Mean	Assessed Field Mean LCL	Assessed Field Mean UCL	Faults
1	5664	EtP	Retention Time	3.950286	3.929850	3.970723	No
2	5665	MeP	Retention Time	2.370925	2.358342	2.383508	No

Study Name: Valid_OQMVM Study
 Study ID: 3470
 Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
 User Name: Sandra O'Halloran (Sandra)

Intermediate Precision DOE Results

Intermediate Precision DOE Overall Results Assessed Field: Area

	Validation Result Id	Component	Assessed Field	Assessed Field Mean	Assessed Field Mean CI	Assessed Field Skew	Faults
1	5666	Arg	Area	40635.125164	242.766184	-1.162699	No
2	5668	Cys	Area	36479.157964	195.642403	-0.555751	No
3	5667	Gly	Area	42714.626652	343.404487	-1.093267	No

Intermediate Precision DOE Overall Results Assessed Field: Retention Time

	Validation Result Id	Component	Assessed Field	Assessed Field Mean	Assessed Field Mean CI	Assessed Field Skew	Faults
1	5669	Arg	Retention Time	3.625984	0.005508	0.668623	No
2	5671	Cys	Retention Time	6.629033	0.004074	-0.070175	No
3	5670	Gly	Retention Time	3.746035	0.005692	0.616130	No

DOE ANOVA Table

Test: AAA - IP DOE Component: Arg Assessed Field: Area ValRes Id: 5666

	Factor	Source	SS	DF	MS	F-Ratio	F-Ratio Reference	p-Value	Variance Component	% Variance Component
1		Total	1.801809e+007	35	5.148025e+005				545938.916546	100.000000
2		Error (Intra)	1.388041e+007	32	4.337627e+005				433762.656393	79.452599
3		Model (Inter)	4.137682e+006	3	1.379227e+006	3.179682	2.901120	0.037156	112176.260153	20.547401
4	A	DOE Analyst	3.493256e+005	1	3.493256e+005	0.805338	4.149097	0.376205	-7036.420326	-1.288866
5	B	DOE Instrument	2.506545e+005	1	2.506545e+005	0.577861	4.149097	0.452717	-15259.010238	-2.795003
6	C	DOE Column	2.047423e+006	1	2.047423e+006	4.720146	4.149097	0.037327	134471.690717	24.631270

DOE ANOVA Table

Test: AAA - IP DOE Component: Arg Assessed Field: Area ValRes Id: 5666

	Variance Component SD	Variance Component % RSD	Faults
1	738.876794	1.818320	No
2	658.606602	1.620782	No
3	334.927246	0.824231	No
4	0.000000	0.000000	No
5	0.000000	0.000000	No
6	366.703819	0.902431	No

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Robustness Results

Robustness Overall Results

Assessed Field: Area

	Validation Result Id	Component	Test Description	Experiments	Assessed Field	Assessed Field Mean	Assessed Field Mean CI	Assessed Field Mean Std Error	Faults
1	5696	Arg	AAA - Robustness	16	Area	43283.185774	6024.311306	2826.391701	No
2	5698	Cys	AAA - Robustness	16	Area	38351.993732	5309.509877	2491.032400	No
3	5697	Gly	AAA - Robustness	16	Area	45269.916019	6234.025852	2924.782276	No

Robustness Overall Results

Assessed Field: Retention Time

	Validation Result Id	Component	Test Description	Experiments	Assessed Field	Assessed Field Mean	Assessed Field Mean CI	Assessed Field Mean Std Error	Faults
1	5693	Arg	AAA - Robustness	16	Retention Time	3.615181	0.059656	0.027988	No
2	5695	Cys	AAA - Robustness	16	Retention Time	6.620963	0.023496	0.011024	No
3	5694	Gly	AAA - Robustness	16	Retention Time	3.737056	0.066101	0.031012	No

Robustness Overall Results

Assessed Field: USP Resolution

	Validation Result Id	Component	Test Description	Experiments	Assessed Field	Assessed Field Mean	Assessed Field Mean CI	Assessed Field Mean Std Error	Faults
1	5699	Arg	AAA - Robustness	16	USP Resolution	3.208636	0.232392	0.109030	No
2	5701	Cys	AAA - Robustness	16	USP Resolution	3.520080	0.162322	0.076156	No
3	5700	Gly	AAA - Robustness	16	USP Resolution	2.222253	0.184624	0.086619	No

Stability Results

Stability Overall Results

	Validation Result Id	Component	Test Description	Assessed Field	Assessed Field Skew	Retention Time Skew	Faults
1	5675	Arg	AAA - Stability	Area	1.491708	-0.013640	No
2	5677	Cys	AAA - Stability	Area	0.959880	-0.088517	No
3	5676	Gly	AAA - Stability	Area	1.870764	-0.018262	No

Study Name: Valid_OQMVM Study
Study ID: 3470
Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
User Name: Sandra O'Halloran (Sandra)

Filter Validation Results

Filter Validation Filtrate Volume Summary
Component: EtP Validation Result Id: 5688

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	EtP	Filter 1	10.000	Area	2407340.744275	2.278249	No

Filter Validation Filtrate Volume Summary
Component: EtP Validation Result Id: 5690

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	EtP	Filter 1	20.000	Area	2126791.804659	2.365679	No

Filter Validation Filtrate Volume Summary
Component: EtP Validation Result Id: 5692

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	EtP	Filter 1	30.000	Area	1944988.309018	9.231972	No

Filter Validation Filtrate Volume Summary
Component: MeP Validation Result Id: 5687

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	MeP	Filter 1	10.000	Area	2293383.577146	2.393264	No

Filter Validation Filtrate Volume Summary
Component: MeP Validation Result Id: 5689

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	MeP	Filter 1	20.000	Area	2023843.581357	2.188116	No

Filter Validation Filtrate Volume Summary
Component: MeP Validation Result Id: 5691

	Component	Filter Type	Filtrate Volume	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Summary Faults
1	MeP	Filter 1	30.000	Area	1849610.570899	9.155486	No

System Precision Results

System Precision Overall Results
Assessed Field: Area

	Validation Result Id	Component	Test Description	Points	Assessed Field	Assessed Field Mean	Assessed Field % RSD	Faults
1	5651	EtP	Parabens - Repeatability	6	Area	1692822.382115	0.272239	No
2	5652	MeP	Parabens - Repeatability	6	Area	1612052.325924	0.418658	No

Study Name: Valid_OQMVM Study
Study ID: 3470
Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
User Name: Sandra O'Halloran (Sandra)

Protocol Method: Valid_OQMVM Study

Stored: 8/9/2006 4:57:05 PM EDT

System Precision Test - Acquisition Parameters

Require System Precision in each sample set No
Injections/ Vial 6
Vials/ SampleSet 1
Criteria Exact
Injections 6
Allow Both Multiple Preparations and Multiple Injections No

System Precision Test - Component Types

	Component Type	Assessed Field	Significance Level
1	EtP	Area	0.01
2	MeP	Area	0.01

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	System Precision Result	Assessed Field Mean	1692822.38211457				Yes
2	System Precision Result	Assessed Field % RSD	0.27223906403909				Yes

'Level Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	System Precision Result	Assessed Field Mean	1612052.32592364				Yes
2	System Precision Result	Assessed Field % RSD	0.41865785534532				Yes

'Level Acceptance Criteria for Component Type Table Row 2' table contains no data.

AAA - Linearity Normal Test - Acquisition Parameters

Levels 3
Preparations/Level 3
Criteria Exact
Injections/Preparation 1
Injections 9
Allow Both Multiple Preparations and Multiple Injections No

	Levels
1	10%
2	100%
3	1000%

AAA - Linearity Normal Test - Processing Parameters and Acceptance Criteria

Linearity of the Method No
Validation Target Response Factor RF of Closest Point to Validation Target

Study Name: Valid_OQMVM Study

Study ID: 3470

Processing Node: Rmcsweeneythkpa

Project Name

Valid_OQMVM

User Name:

Sandra O'Halloran (Sandra)

AAA - Linearity Normal Test - Component Types

	Component Type	Significance Level	Fit	Weighting	Average By
1	Arg	0.01			
2	Gly	0.01			
3	Cys	0.01			

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99894793121424				Yes
2	Linearity Result	Relative Response Factor Mean	0.99568335583094				Yes
3	Regression ANOVA	Regression Total SS	30397.7553973153				Yes
4	Regression ANOVA	Regression Total MS	3799.71942466442				Yes
5	Regression ANOVA	Regression Error SS	31.9805296107644				Yes
6	Regression ANOVA	Regression Error MS	4.56864708725205				Yes
7	Regression ANOVA	Regression Model SS	30365.7748677046				Yes
8	Regression ANOVA	Regression Model MS	30365.7748677046				Yes
9	Regression ANOVA	Regression F-Ratio	6646.55734789289				Yes
10	Regression ANOVA	Regression p-Value	0.0000000001100				Yes

'Level Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99950585164214				Yes
2	Linearity Result	Relative Response Factor Mean	1.00089495518639				Yes
3	Regression ANOVA	Regression Total SS	31723.2647708352				Yes
4	Regression ANOVA	Regression Total MS	3965.40809635440				Yes
5	Regression ANOVA	Regression Error SS	15.6759991924745				Yes
6	Regression ANOVA	Regression Error MS	2.23942845606778				Yes
7	Regression ANOVA	Regression Model SS	31707.5887716428				Yes
8	Regression ANOVA	Regression Model MS	31707.5887716428				Yes
9	Regression ANOVA	Regression F-Ratio	14158.7862232126				Yes
10	Regression ANOVA	Regression p-Value	0.00000000000078				Yes

'Level Acceptance Criteria for Component Type Table Row 2' table contains no data.

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99935468164707				Yes
2	Linearity Result	Relative Response Factor Mean	1.00781349046173				Yes
3	Regression ANOVA	Regression Total SS	25492.7413376940				Yes
4	Regression ANOVA	Regression Total MS	3186.59266721175				Yes
5	Regression ANOVA	Regression Error SS	16.4509338517122				Yes
6	Regression ANOVA	Regression Error MS	2.35013340738746				Yes
7	Regression ANOVA	Regression Model SS	25476.2904038423				Yes
8	Regression ANOVA	Regression Model MS	25476.2904038423				Yes
9	Regression ANOVA	Regression F-Ratio	10840.3592424837				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
10	Regression ANOVA	Regression p-Value	0.0000000000199				Yes

'Level Acceptance Criteria for Component Type Table Row 3' table contains no data.

AAA - Linearity Low Test - Acquisition Parameters

Levels 3
 Preparations/Level 3
 Criteria Exact
 Injections/Preparation 1
 Injections 9
 Allow Both Multiple Preparations and Multiple Injections No

	Levels
1	10% Low
2	100% Low
3	1000% Low

AAA - Linearity Low Test - Processing Parameters and Acceptance Criteria

Linearity of the Method No
 Validation Target Response Factor RF of Closest Point to Validation Target

AAA - Linearity Low Test - Component Types

	Component Type	Significance Level	Fit	Weighting	Average By
1	Arg	0.01			
2	Gly	0.01			
3	Cys	0.01			

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99417991205253				Yes
2	Linearity Result	Relative Response Factor Mean	0.93169812379276				Yes
3	Regression ANOVA	Regression Total SS	46.7817158284606				Yes
4	Regression ANOVA	Regression Total MS	5.84771447855757				Yes
5	Regression ANOVA	Regression Error SS	0.27227370045525				Yes
6	Regression ANOVA	Regression Error MS	0.03889624292218				Yes
7	Regression ANOVA	Regression Model SS	46.5094421280053				Yes
8	Regression ANOVA	Regression Model MS	46.5094421280053				Yes
9	Regression ANOVA	Regression F-Ratio	1195.73096612593				Yes
10	Regression ANOVA	Regression p-Value	0.00000000438703				Yes

'Level Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99584268637758				Yes
2	Linearity Result	Relative Response Factor Mean	1.03033918962679				Yes
3	Regression ANOVA	Regression Total SS	51.8336886353886				Yes

Study Name: Valid_OQMVM Study
 Study ID: 3470
 Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
 User Name: Sandra O'Halloran (Sandra)

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
4	Regression ANOVA	Regression Total MS	6.47921107942358				Yes
5	Regression ANOVA	Regression Error SS	0.21548889986441				Yes
6	Regression ANOVA	Regression Error MS	0.03078412855206				Yes
7	Regression ANOVA	Regression Model SS	51.6181997355242				Yes
8	Regression ANOVA	Regression Model MS	51.6181997355242				Yes
9	Regression ANOVA	Regression F-Ratio	1676.77963169343				Yes
10	Regression ANOVA	Regression p-Value	0.0000000135046				Yes

'Level Acceptance Criteria for Component Type Table Row 2' table contains no data.

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Result	R^2	0.99150336819112				Yes
2	Linearity Result	Relative Response Factor Mean	0.97582105591193				Yes
3	Regression ANOVA	Regression Total SS	38.7420488049330				Yes
4	Regression ANOVA	Regression Total MS	4.84275610061663				Yes
5	Regression ANOVA	Regression Error SS	0.32917692421734				Yes
6	Regression ANOVA	Regression Error MS	0.04702527488819				Yes
7	Regression ANOVA	Regression Model SS	38.4128718807157				Yes
8	Regression ANOVA	Regression Model MS	38.4128718807157				Yes
9	Regression ANOVA	Regression F-Ratio	816.855871061823				Yes
10	Regression ANOVA	Regression p-Value	0.00000001650958				Yes

'Level Acceptance Criteria for Component Type Table Row 3' table contains no data.

AAA - Linearity Comparison Test - Processing Parameters and Acceptance Criteria

Linearity of the Method No

Linearity Test 1 AAA - Linearity Low

Linearity Test 2 AAA - Linearity Normal

AAA - Linearity Comparison Test -
 Component Types

	Component Type	Significance Level
1	Arg	0.01
2	Gly	0.01
3	Cys	0.01

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Comparison Result	Intercept p-Value	0.80758172310898				Yes
2	Linearity Comparison Result	Slope p-Value	0.00000027522529				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Comparison Result	Intercept p-Value	0.94063573852365				Yes
2	Linearity Comparison Result	Slope p-Value	0.00000011464997				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Linearity Comparison Result	Intercept p-Value	0.81144783021830				Yes
2	Linearity Comparison Result	Slope p-Value	0.0000083316987				Yes

Parabens - Acc 3 Preps 3 Injs Test - Acquisition Parameters

Levels 3
 Preparations/Level 3
 Criteria Exact
 Injections/Preparation 1
 Injections 9
 Allow Both Multiple Preparations and Multiple Injections No
 Calculate Accuracy Profile No
 Experiments
 Experiment Group By

'Levels' table contains no data.

Parabens - Acc 3 Preps 3 Injs Test - Component Types

	Component Type	Assessed Field	Significance Level	Acceptance Limit (%)
1	EtP	% Recovery	0.01	
2	MeP	% Recovery	0.01	

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Accuracy Result	% Recovery Mean	100.386494648855				Yes
2	Accuracy Result	% Recovery % RSD	1.10776541883188				Yes
3	Accuracy Result	Calculated Validation Target	30.1159483946565				Yes

Level Acceptance Criteria for Component Type Table Row 1

	Level	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Level 1	Level Summary	% Recovery Mean	100.973592638337				Yes
2	Level 2	Level Summary	% Recovery Mean	101.268874571586				Yes
3	Level 3	Level Summary	% Recovery Mean	98.9170167366416				Yes
4	Level 1	Level Summary	% Recovery SD	0.03385720837164				Yes
5	Level 2	Level Summary	% Recovery SD	0.08992642709358				Yes
6	Level 3	Level Summary	% Recovery SD	0.11573396032426				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Accuracy Result	% Recovery Mean	100.222302789567				Yes
2	Accuracy Result	% Recovery % RSD	2.48704639768032				Yes
3	Accuracy Result	Calculated Validation Target	25.0555756973919				Yes

Level Acceptance Criteria for Component Type Table Row 2

	Level	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Level 1	Level Summary	% Recovery Mean	100.525682764277				Yes
2	Level 2	Level Summary	% Recovery Mean	102.935879923248				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Level Acceptance Criteria for Component Type Table Row 2

	Level	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
3	Level 3	Level Summary	% Recovery Mean	97.2053456811778				Yes
4	Level 1	Level Summary	% Recovery SD	0.07238971642226				Yes
5	Level 2	Level Summary	% Recovery SD	0.03903713297929				Yes
6	Level 3	Level Summary	% Recovery SD	0.09275813988861				Yes

Parabens - Repeatability Test - Acquisition Parameters

Levels 3
 Preparations/Level 3
 Criteria Exact
 Injections/Preparation 1
 Injections 9
 Allow Both Multiple Preparations and Multiple Injections No

'Levels' table contains no data.

Parabens - Repeatability Test - Component Types

	Component Type	Assessed Field	Significance Level
1	MeP	Area	0.01
2	MeP	Retention Time	0.01

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Repeatability Result	Assessed Field Mean	1759608.97544651				Yes
2	Repeatability Result	Assessed Field Mean Std Error	249118.797477560				Yes

'Level Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Repeatability Result	Assessed Field Mean	2.32561060094947				Yes
2	Repeatability Result	Assessed Field Mean Std Error	0.00142189808514				Yes

'Level Acceptance Criteria for Component Type Table Row 2' table contains no data.

Parabens - Reprod. Labs B & D Test - Acquisition Parameters

Laboratories 2
 Preparations/Laboratory 3
 Levels 1
 Level
 Group By Laboratory Name
 Criteria Minimum
 Injections/Preparation 1
 Injections 6
 Allow Both Multiple Preparations and Multiple Injections No

Parabens - Reprod. Labs B & D Test - Component Types

	Component Type	Assessed Field	Significance Level
1	EtP	% Recovery	0.05
2	MeP	% Recovery	0.05

	Component Type	Assessed Field	Significance Level
3	EtP	Retention Time	0.05
4	MeP	Retention Time	0.05

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Reproducibility Result	Variance Cochran Test p-Value	0.75712264753392				Yes
2	Reproducibility Result	Variance R^2	0.55262844127681				Yes
3	Reproducibility Result	Retention Time Mean CI	0.04682907319947				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Reproducibility Result	Variance Cochran Test p-Value	0.74191029195967				Yes
2	Reproducibility Result	Variance R^2	0.00277553789805				Yes
3	Reproducibility Result	Retention Time Mean CI	0.02267200790395				Yes

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Reproducibility Result	Variance Cochran Test p-Value	0.02046492966131				Yes
2	Reproducibility Result	Variance R^2	0.93677709782798				Yes

Acceptance Criteria for Component Type Table Row 4

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Reproducibility Result	Variance Cochran Test p-Value	0.03987489719869				Yes
2	Reproducibility Result	Variance R^2	0.93801244854327				Yes

AAA - LOD/LOQ Determination Test - Acquisition Parameters

Method to Determine LOD/LOQ

Linearity Curve Intercept SD

Linearity Test

AAA - Linearity Low

S/N Field

Levels

Preparations/Level

Criteria

Exact

Injections/Preparation

Injections

Allow Both Multiple Preparations and Multiple Injections No

'Levels' table contains no data.

AAA - LOD/LOQ Determination Test - Component Types

	Component Type	Significance Level
1	Arg	0.01
2	Gly	0.01
3	Cys	0.01

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	LOD/LOQ Result	LOD	0.27687820081359				Yes
2	LOD/LOQ Result	LOQ	0.83902485095028				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	LOD/LOQ Result	LOD	0.23381238260534				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
2	LOD/LOQ Result	LOQ	0.70852237153133				Yes

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	LOD/LOQ Result	LOD	0.16749536336465				Yes
2	LOD/LOQ Result	LOQ	0.50756170716562				Yes

Parabens -Varying Column Test - Acquisition Parameters

Levels 1

Level

Experiment Group By Experiment Name

Criteria Exact

Injections/Preparation 1

Injections 20

Allow Both Multiple Preparations and Multiple Injections No

Experiments 4

Preparations/Experiment 5

Parabens -Varying Column Test - Component Types

	Component Type	Assessed Field	Significance Level	Supportable Spec Limits Points/Experiment
1	EtP	Area	0.05	6
2	MeP	Area	0.05	6
3	EtP	Retention Time	0.05	6
4	MeP	Retention Time	0.05	6

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision Result	Assessed Field Mean	3719580.38403242				Yes
2	Intermediate Precision Result	Assessed Field Mean LCL	3707905.13127832				Yes
3	Intermediate Precision Result	Assessed Field Mean UCL	3731255.63678652				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision Result	Assessed Field Mean	3537357.11504823				Yes
2	Intermediate Precision Result	Assessed Field Mean LCL	3525286.59116381				Yes
3	Intermediate Precision Result	Assessed Field Mean UCL	3549427.63893266				Yes

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision Result	Assessed Field Mean	3.95028636156771				Yes
2	Intermediate Precision Result	Assessed Field Mean LCL	3.92984957144182				Yes
3	Intermediate Precision Result	Assessed Field Mean UCL	3.97072315169359				Yes

Acceptance Criteria for Component Type Table Row 4

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision Result	Assessed Field Mean	2.37092494402178				Yes
2	Intermediate Precision Result	Assessed Field Mean LCL	2.35834211186102				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 4

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
3	Intermediate Precision Result	Assessed Field Mean UCL	2.38350777618253				Yes

AAA - IP DOE Test - Acquisition Parameters

Factors	4
Levels	1
Level	100%
Criteria	Exact
Injections/Preparation	1
Injections	36
Allow Both Multiple Preparations and Multiple Injections	No
Experiments	6
Preparations/Experiment	6

AAA - IP DOE Test - Component Types

	Component Type	Assessed Field	Significance Level
1	Arg	Area	0.05
2	Gly	Area	0.05
3	Cys	Area	0.05
4	Arg	Retention Time	0.05
5	Gly	Retention Time	0.05
6	Cys	Retention Time	0.05

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)
1	Intermediate Precision DOE Result	Assessed Field Mean	40635.1251641041			
2	Intermediate Precision DOE Result	Assessed Field Mean CI	242.766184216973			
3	Intermediate Precision DOE Result	Assessed Field Skew	-1.16269854540401			
4	ANOVA	Variance Total SS	18018086.8060872			
5	ANOVA	Variance Total MS	514802.480173920			
6	ANOVA	Variance Total Component	545938.916546191			
7	ANOVA	Variance Error SS	13880405.0045704			
8	ANOVA	Variance Error MS	433762.656392825			
9	ANOVA	Variance Error Component	433762.656393034			
10	ANOVA	Variance Model SS	4137681.80151681			
11	ANOVA	Variance Model MS	1379227.26717227			
12	ANOVA	Variance F-Ratio	3.17968189941001			
13	ANOVA	Variance p-Value	0.03715556645279			
14	ANOVA	Variance Model Component	112176.260153157			
15	ANOVA	% Variance Total Component	100.000000000000			
16	ANOVA	Variance Total Component SD	738.876793887987			
17	ANOVA	Variance Total Component % RSD	1.81832045774204			
18	ANOVA	% Variance Error Component	79.4525986784702			
19	ANOVA	Variance Error Component SD	658.606602148076			
20	ANOVA	Variance Error Component % RSD	1.62078152703678			

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)
21	ANOVA	% Variance Model Component	20.5474013215298			
22	ANOVA	Variance Model Component SD	334.927246059734			
23	ANOVA	Variance Model Component % RSD	0.82423087096973			

Acceptance Criteria
for Component Type
Table Row 1

	Fault on Target
1	Yes
2	Yes
3	Yes
4	Yes
5	Yes
6	Yes
7	Yes
8	Yes
9	Yes
10	Yes
11	Yes
12	Yes
13	Yes
14	Yes
15	Yes
16	Yes
17	Yes
18	Yes
19	Yes
20	Yes
21	Yes
22	Yes
23	Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision DOE Result	Assessed Field Mean	42714.6266516215				Yes
2	Intermediate Precision DOE Result	Assessed Field Mean CI	343.404486652129				Yes
3	Intermediate Precision DOE Result	Assessed Field Skew	-1.09326726783849				Yes

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision DOE Result	Assessed Field Mean	36479.1579637712				Yes
2	Intermediate Precision DOE Result	Assessed Field Mean CI	195.642402737320				Yes
3	Intermediate Precision DOE Result	Assessed Field Skew	-0.55575058671746				Yes

Study Name: Valid_OQMVM Study
 Study ID: 3470
 Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
 User Name: Sandra O'Halloran (Sandra)

Acceptance Criteria for Component Type Table Row 4

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision DOE Result	Assessed Field Mean	3.62598409991269				Yes
2	Intermediate Precision DOE Result	Assessed Field Mean CI	0.00550767109133				Yes
3	Intermediate Precision DOE Result	Assessed Field Skew	0.66862325435503				Yes

Acceptance Criteria for Component Type Table Row 5

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision DOE Result	Assessed Field Mean	3.74603539422693				Yes
2	Intermediate Precision DOE Result	Assessed Field Mean CI	0.00569236142515				Yes
3	Intermediate Precision DOE Result	Assessed Field Skew	0.61613020850826				Yes

Acceptance Criteria for Component Type Table Row 6

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Intermediate Precision DOE Result	Assessed Field Mean	6.62903286894678				Yes
2	Intermediate Precision DOE Result	Assessed Field Mean CI	0.00407411103876				Yes
3	Intermediate Precision DOE Result	Assessed Field Skew	-0.07017457964169				Yes

AAA - Specificity Test - Acquisition Parameters

Preparations 2
 Levels 1
 Level 100%
 Criteria Exact
 Injections/Preparation 1
 Injections 2
 Allow Both Multiple Preparations and Multiple Injections No

AAA - Specificity Test - Component Types

	Component Type	Relative Area % Threshold	Relative Resolution
1	Arg	0.05	USP
2	Gly	0.05	USP
3	Cys	0.05	USP

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Specificity Result	Area Mean Std Error	1257.16481956710				Yes
2	Specificity Result	Retention Time Mean	3.57163298875629				Yes
3	Specificity Result	Retention Time Mean CI	0.00770932763469				Yes
4	Specificity Result	Retention Time Mean Std Error	0.00060673724332				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Specificity Result	Area Mean Std Error	863.142273684400				Yes
2	Specificity Result	Retention Time Mean	3.68779089415307				Yes
3	Specificity Result	Retention Time Mean CI	0.00487684167194				Yes
4	Specificity Result	Retention Time Mean Std Error	0.00038381576349				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

'Relative Peak Acceptance Criteria for Component Type Table Row 2' table contains no data.

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Specificity Result	Area Mean Std Error	1112.79189867595				Yes
2	Specificity Result	Retention Time Mean	6.61220775506009				Yes
3	Specificity Result	Retention Time Mean CI	0.00464105180246				Yes
4	Specificity Result	Retention Time Mean Std Error	0.00036525869832				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 3' table contains no data.

AAA - Stability Test - Acquisition Parameters

Group By	Storage Condition
Reference Storage Condition	Reference
Storage Conditions	4
Storage Times	4
Preparations	2
Reference Preparations	1
Injections/ Reference Preparation	1
Levels	1
Level	100%
Criteria	Exact
Injections/Preparation	1
Injections	33
Allow Both Multiple Preparations and Multiple Injections	No

	Storage Conditions
1	Condition 1
2	Condition 2
3	Condition 3
4	Condition 4

AAA - Stability Test - Component Types

	Component Type	Assessed Field	Significance Level	Relative Area % Threshold	Relative Resolution
1	Arg	Area	0.05	0.05	USP
2	Gly	Area	0.05	0.05	USP
3	Cys	Area	0.05	0.05	USP

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Stability Result	Assessed Field Skew	1.49170762417106				Yes
2	Stability Result	Retention Time Skew	-0.01364018786879				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Stability Result	Assessed Field Skew	1.87076367428031				Yes
2	Stability Result	Retention Time Skew	-0.01826212996838				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 2' table contains no data.

Study Name: Valid_OQMVM Study

Study ID: 3470

Processing Node: Rmcsweeneythkpa

Project Name

User Name:

Valid_OQMVM

Sandra O'Halloran (Sandra)

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Stability Result	Assessed Field Skew	0.95988007870397				Yes
2	Stability Result	Retention Time Skew	-0.08851742826769				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 3' table contains no data.

AAA - Repeat Ref for Robustness Test - Acquisition Parameters

Levels 1
Preparations/Level 4
Criteria Exact
Injections/Preparation 1
Injections 4
Allow Both Multiple Preparations and Multiple Injections No

	Levels
1	100%

AAA - Repeat Ref for Robustness Test - Component Types

	Component Type	Assessed Field	Significance Level
1	Arg	Area	0.05
2	Cys	Area	0.05
3	Gly	Area	0.05
4	Arg	Retention Time	0.05
5	Cys	Retention Time	0.05
6	Gly	Retention Time	0.05
7	Arg	USP Resolution	0.05
8	Cys	USP Resolution	0.05
9	Gly	USP Resolution	0.05

'Acceptance Criteria for Component Type Table Row 1' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 1' table contains no data.

'Acceptance Criteria for Component Type Table Row 2' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 2' table contains no data.

'Acceptance Criteria for Component Type Table Row 3' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 3' table contains no data.

'Acceptance Criteria for Component Type Table Row 4' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 4' table contains no data.

'Acceptance Criteria for Component Type Table Row 5' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 5' table contains no data.

'Acceptance Criteria for Component Type Table Row 6' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 6' table contains no data.

'Acceptance Criteria for Component Type Table Row 7' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 7' table contains no data.

'Acceptance Criteria for Component Type Table Row 8' table contains no data.

Study Name: Valid_OQMVM Study
Study ID: 3470
Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
User Name: Sandra O'Halloran (Sandra)

'Level Acceptance Criteria for Component Type Table Row 8' table contains no data.

'Acceptance Criteria for Component Type Table Row 9' table contains no data.

'Level Acceptance Criteria for Component Type Table Row 9' table contains no data.

Parabens - Filter Type 1 vol 10 Test - Acquisition Parameters

Reference Filter
Filters 1
Filtrate Volumes/ Filter 1
Preparations 2
Reference Preparations 0
Injections/ Reference Preparation 0
Levels 1
Level
Criteria Exact
Injections/Preparation 1
Injections 2
Allow Both Multiple Preparations and Multiple Injections No

	Filter Types
1	Filter 1

Parabens - Filter Type 1 vol 10 Test - Component Types

	Component Type	Assessed Field	Significance Level	Relative Area % Threshold	Relative Resolution
1	MeP	Area	0.05	0.05	USP
2	EtP	Area	0.05	0.05	USP

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Filtrate Volume Summary	Assessed Field Mean	2293383.57714590				Yes
2	Filtrate Volume Summary	Assessed Field % RSD	2.39326425682754				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Filtrate Volume Summary	Assessed Field Mean	2407340.74427454				Yes
2	Filtrate Volume Summary	Assessed Field % RSD	2.27824928248943				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 2' table contains no data.

Parabens - Filter Type 1 vol 20 Test - Acquisition Parameters

Reference Filter
Filters 1
Filtrate Volumes/ Filter 1
Preparations 2
Reference Preparations 0
Injections/ Reference Preparation 0
Levels 1
Level
Criteria Exact
Injections/Preparation 1

Study Name: Valid_OQMVM Study
Study ID: 3470
Processing Node: Rmcsweeneythkpa

Project Name Valid_OQMVM
User Name: Sandra O'Halloran (Sandra)

Injections 2
Allow Both Multiple Preparations and Multiple Injections No

Filter Types
1 Filter 1

Parabens - Filter Type 1 vol 20 Test - Component Types

Component Type	Assessed Field	Significance Level	Relative Area % Threshold	Relative Resolution
1 MeP	Area	0.05	0.05	USP
2 EtP	Area	0.05	0.05	USP

Acceptance Criteria for Component Type Table Row 1

Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1 Filtrate Volume Summary	Assessed Field Mean	2023843.58135732				Yes
2 Filtrate Volume Summary	Assessed Field % RSD	2.18811629301948				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1 Filtrate Volume Summary	Assessed Field Mean	2126791.80465872				Yes
2 Filtrate Volume Summary	Assessed Field % RSD	2.36567938429035				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 2' table contains no data.

Parabens - Filter Type 1 vol 30 Test - Acquisition Parameters

Reference Filter

Filters 1
Filtrate Volumes/ Filter 1
Preparations 2
Reference Preparations 0
Injections/ Reference Preparation 0
Levels 1
Level
Criteria Exact
Injections/Preparation 1
Injections 2
Allow Both Multiple Preparations and Multiple Injections No

Filter Types
1 Filter 1

Parabens - Filter Type 1 vol 30 Test - Component Types

Component Type	Assessed Field	Significance Level	Relative Area % Threshold	Relative Resolution
1 MeP	Area	0.05	0.05	USP
2 EtP	Area	0.05	0.05	USP

Acceptance Criteria for Component Type Table Row 1

Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1 Filtrate Volume Summary	Assessed Field Mean	1849610.57089869				Yes

Study Name: Valid_OQMVM Study

Project Name

Valid_OQMVM

Study ID: 3470

User Name:

Sandra O'Halloran (Sandra)

Processing Node: Rmcsweeneythkpa

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
2	Filtrate Volume Summary	Assessed Field % RSD	9.15548556595725				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 1' table contains no data.

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Filtrate Volume Summary	Assessed Field Mean	1944988.30901766				Yes
2	Filtrate Volume Summary	Assessed Field % RSD	9.23197223133296				Yes

'Relative Peak Acceptance Criteria for Component Type Table Row 2' table contains no data.

AAA - Robustness Test - Acquisition Parameters

Experimental Design Type	1/2 Fractional
Factors	5
Factor Levels	2
Center Point Preparations	0
Repeatability Reference	AAA - Repeat Ref for Robustness
Experiments	16
Preparations/Experiment	1
Resolution	RES V
Levels	1
Level	100%
Criteria	Exact
Injections/Preparation	1
Injections	16
Allow Both Multiple Preparations and Multiple Injections	No

Robustness Factors

	Factor Label	Factor Name	Lower Value (-1)	Upper Value (+1)	Nominal Value (0)
1	A	Volume_of_EluentA_mL	47.5	52.5	50.0
2	B	Column_Temperature	53 Degrees C	57 Degrees C	55 Degrees C
3	C	Flow_Rate_mLPerMin	0.665	0.735	0.7
4	D	Injection_Volume_uL	0.8	1.3	1.0
5	E	Derivitization_Volume_uL	15	25	20

AAA - Robustness Test - Component Types

	Component Type	Assessed Field	Significance Level
1	Arg	Retention Time	0.05
2	Gly	Retention Time	0.05
3	Cys	Retention Time	0.05
4	Arg	Area	0.05
5	Gly	Area	0.05
6	Cys	Area	0.05
7	Arg	USP Resolution	0.05
8	Gly	USP Resolution	0.05
9	Cys	USP Resolution	0.05

Study Name: Valid_OQMVM Study

Study ID: 3470

Processing Node: Rmcsweeneythkpa

Project Name

User Name:

Valid_OQMVM

Sandra O'Halloran (Sandra)

Acceptance Criteria for Component Type Table Row 1

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	3.61518113911818				Yes
2	Robustness Result	Assessed Field Mean CI	0.05965573471522				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.02798834006627				Yes

Acceptance Criteria for Component Type Table Row 2

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	3.73705613340794				Yes
2	Robustness Result	Assessed Field Mean CI	0.06610069881478				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.03101208703367				Yes

Acceptance Criteria for Component Type Table Row 3

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	6.62096265171163				Yes
2	Robustness Result	Assessed Field Mean CI	0.02349604988796				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.01102350742334				Yes

Acceptance Criteria for Component Type Table Row 4

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	43283.1857740746				Yes
2	Robustness Result	Assessed Field Mean CI	6024.31130623924				Yes
3	Robustness Result	Assessed Field Mean Std Error	2826.39170079772				Yes

Acceptance Criteria for Component Type Table Row 5

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	45269.9160189147				Yes
2	Robustness Result	Assessed Field Mean CI	6234.02585214637				Yes
3	Robustness Result	Assessed Field Mean Std Error	2924.78227558004				Yes

Acceptance Criteria for Component Type Table Row 6

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	38351.9937321263				Yes
2	Robustness Result	Assessed Field Mean CI	5309.50987661250				Yes
3	Robustness Result	Assessed Field Mean Std Error	2491.03239983946				Yes

Acceptance Criteria for Component Type Table Row 7

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	3.20863615581320				Yes
2	Robustness Result	Assessed Field Mean CI	0.23239244382689				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.10903023452327				Yes

Acceptance Criteria for Component Type Table Row 8

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	2.22225312536525				Yes
2	Robustness Result	Assessed Field Mean CI	0.18462411783352				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.08661904205902				Yes

Study Name: Valid_OQMVM Study

Study ID: 3470

Processing Node: Rmcsweeneythkpa

Project Name

User Name:

Valid_OQMVM

Sandra O'Halloran (Sandra)

Acceptance Criteria for Component Type Table Row 9

	Field Type	Field Name	Target	% Range	Lower Limit (LL)	Upper Limit (UL)	Fault on Target
1	Robustness Result	Assessed Field Mean	3.52008039526487				Yes
2	Robustness Result	Assessed Field Mean CI	0.16232195296818				Yes
3	Robustness Result	Assessed Field Mean Std Error	0.07615566284753				Yes

Revision History

This method contains 24 items in the revision history.

Empower SQT Sign Table

	Sign Off Validation Result ID	Sign Off Full Name	Sign Off Date	Sign Off ID	Sign Off Method Name
1	5651	Daniel McSweeney (Daniel)	1/20/2012 10:33:44 AM EST	5720	OQMVM Summary Report RS
2	5652	Daniel McSweeney (Daniel)	1/20/2012 10:33:44 AM EST	5720	OQMVM Summary Report RS
3	5651	Sandra O'Halloran (Sandra)	1/20/2012 10:35:11 AM EST	5721	OQMVM Summary Report RS
4	5652	Sandra O'Halloran (Sandra)	1/20/2012 10:35:11 AM EST	5721	OQMVM Summary Report RS

Empower SQT Sign Table

	Sign Off Method Id	Sign Off Method Version	Sign Off Type	Sign Off Reason
1	5621	4	Validation Result	Sign Off Level 1, Reason: Review
2	5621	4	Validation Result	Sign Off Level 1, Reason: Review
3	5621	4	Validation Result	Sign Off Level 2, Reason: Approval
4	5621	4	Validation Result	Sign Off Level 2, Reason: Approval