

Linearity report b

Data Files: **Date:** **Time:**
Linearity.jmp Thursday, December 18, 2025 16:36:38

Data Integrity

Study descriptives		Note
Analyst	a	
Analytical method	b	
Instrument	c	
Purpose	d	
Standard Expiry	e	
Standard ID	f	
Study date(s)	g	
Unit	h	

Limit	Specification
USL	130
LSL	70

Method Attribute	Criteria (% of tolerance)
Accuracy	20
Repeatability	60
IP	70
Upper Linearity Limit	120
Lower Linearity Limit	80

User Information

User Name: paule
Computer Name: PADC-SURFACE
Logon Server: \PADC-SURFACE
User Domain: PADC-SURFACE
Addin version: 2512181633
JMP Version: 19.0.1

Analyst Signature/Date

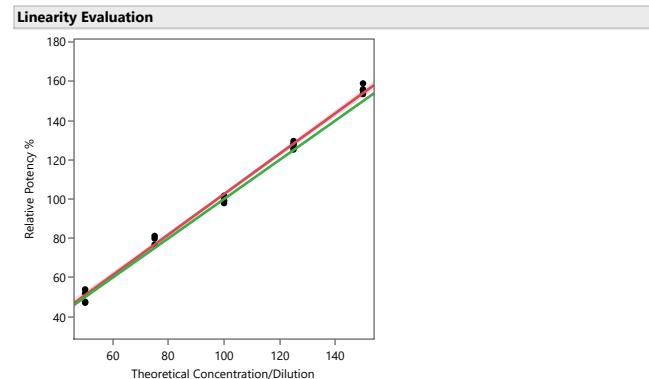
Reviewer Signature/Date

Linearity - Data table

Theoretical Concentration/Dilution	Day	Analyst	Instrument	Relative Potency %	Jackknife Distances By Theoretical Concentration/Dilution	Include/Exclude	Accuracy/Bias
150 D1	A1	I2		153.6	0.83 Ok	Included	3.60
50 D1	A2	I2		47.1	0.45 Ok	Included	-2.90
150 D2	A2	I1		156	0.33 Ok	Included	6.00
125 D2	A1	I2		128.2	0.62 Ok	Included	3.20
50 D1	A1	I1		52	0.73 Ok	Included	2.00
50 D1	A1	I1		47.6	0.33 Ok	Included	-2.40
100 D2	A2	I2		97.9	1.89 Ok	Included	-2.10
75 D2	A2	I1		76.7	0.76 Ok	Included	1.70
75 D1	A1	I2		79.9	0.39 Ok	Included	4.90
100 D1	A1	I1		99.5	0.21 Ok	Included	-0.50
100 D1	A1	I1		99.4	0.28 Ok	Included	-0.60
150 D1	A1	I2		153.7	0.81 Ok	Included	3.70
50 D2	A1	I2		41.3	3.06 Outlier	Excluded	-8.70
100 D2	A2	I2		99	0.61 Ok	Included	-1.00
150 D1	A2	I1		168.9	6.07 Outlier	Excluded	18.90
125 D2	A1	I1		129.6	1.03 Ok	Included	4.60
125 D2	A1	I1		127.8	0.51 Ok	Included	2.80
150 D2	A1	I2		155.5	0.43 Ok	Included	5.50
75 D1	A2	I2		80.1	0.46 Ok	Included	5.10
50 D2	A2	I1		53.9	1.31 Ok	Included	3.90
100 D2	A2	I2		101.7	2.01 Ok	Included	1.70
75 D2	A1	I2		73.4	3.43 Outlier	Excluded	-1.60
150 D2	A2	I1		159	0.23 Ok	Included	9.00
125 D1	A2	I1		117.1	6.17 Outlier	Excluded	-7.90
75 D2	A1	I1		81.2	0.90 Ok	Included	6.20
75 D1	A2	I1		81.4	0.98 Ok	Included	6.40
50 D2	A2	I2		52.2	0.78 Ok	Included	2.20
125 D1	A2	I2		126.3	0.14 Ok	Included	1.30
100 D1	A1	I1		101.1	1.16 Ok	Included	1.10
125 D1	A2	I2		125.3	0.10 Ok	Included	0.30

K Sigma: 3

Linearity - Linearity Evaluation



Linear Fit

Relative Potency % = $-0.505077 + 1.03032 \times \text{Theoretical Concentration/Dilution}$

Summary of Fit

RSquare	0.993983
RSquare Adj	0.993732
Root Mean Square Error	2.892684
Mean of Response	102.5269
Observations (or Sum Wgts)	26

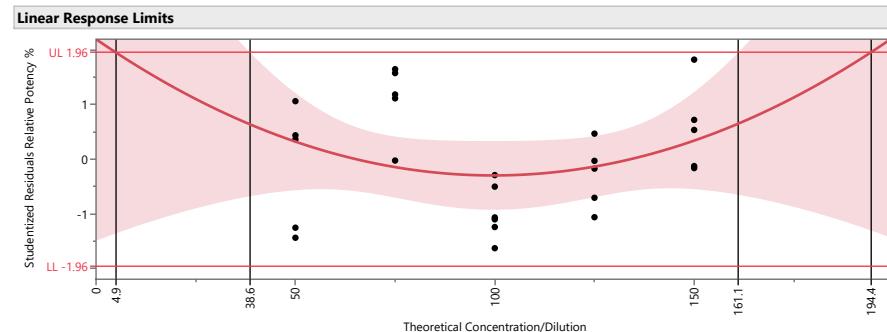
Analysis of Variance

Source	DF	Sum of Squares		F Ratio
		Model	Error	
Model	1	33173.728	33173.7	3964.534
Error	24	200.823	8.4	Prob > F
C. Total	25	33374.551		<.0001*

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob> t	Lower 95%	Upper 95%
Intercept	-0.505077	1.731898	-0.29	0.7731	-4.079539	3.0693851
Theoretical Concentration/Dilution	1.03032	0.016363	62.96	<.0001*	0.9965474	1.0640926

Linearity - Range of Linearity



Polynomial Fit Degree=2

Studentized Residuals Relative Potency % = $-0.316337 + 0.0001877 \times \text{Theoretical Concentration/Dilution} + 0.0002516 \times (\text{Theoretical Concentration/Dilution}-100)^2$

Summary of Fit

RSquare	0.07044
RSquare Adj	-0.01039
Root Mean Square Error	1.023805
Mean of Response	0.004817
Observations (or Sum Wgts)	26

Parameter Estimates

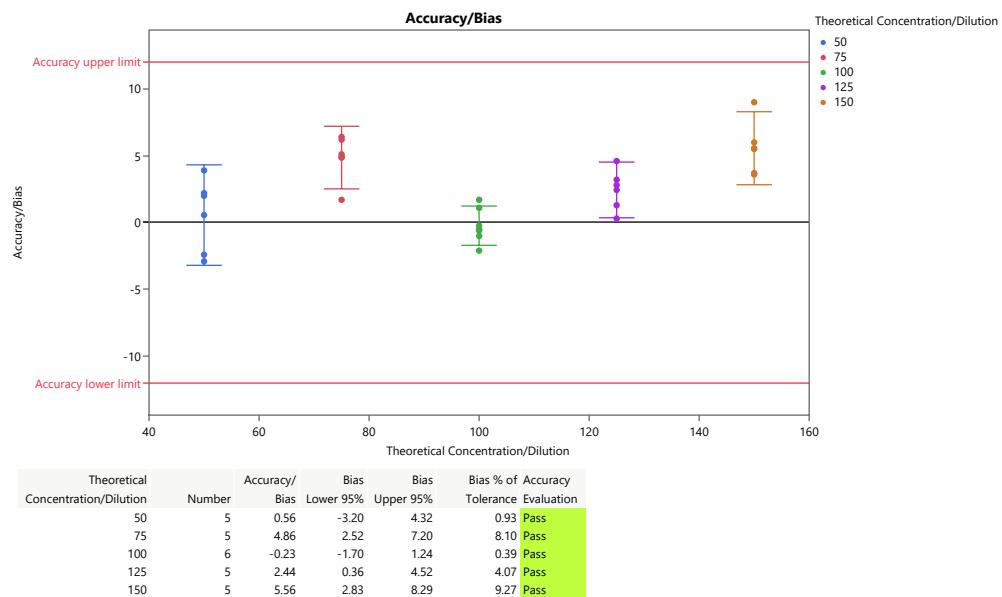
Term	Estimate	Std Error	t Ratio	Prob> t	Lower 95%	Upper 95%
Intercept	-0.316337	0.654388	-0.48	0.6334	-1.670041	1.0373683
Theoretical Concentration/Dilution	0.0001877	0.005792	0.03	0.9744	-0.0111793	0.0121684
(Theoretical Concentration/Dilution-100)^2	0.0002516	0.000191	1.32	0.1999	-0.000143	0.0006459

Linearity Limits

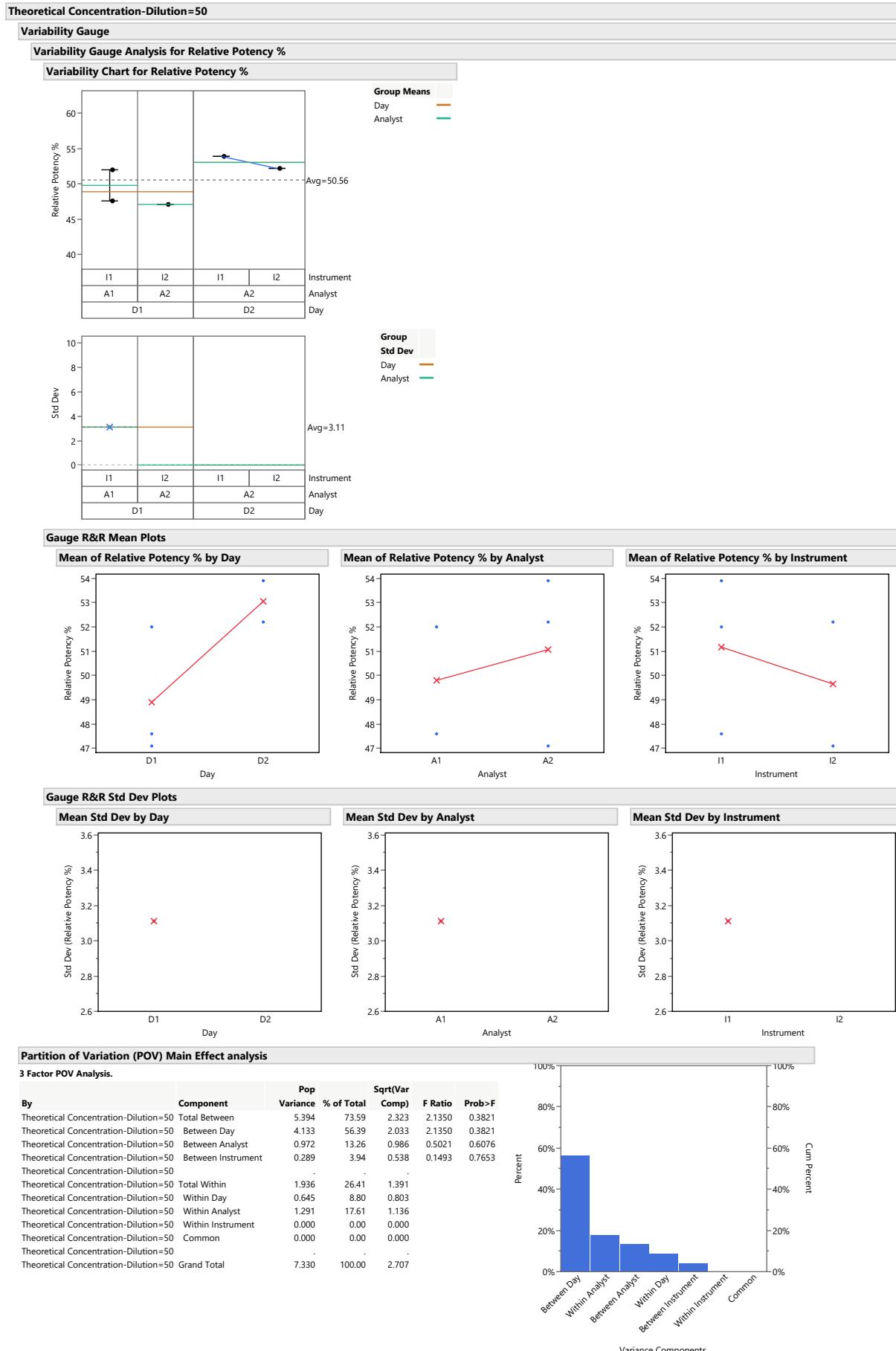
Curve	Lower Acceptance Limit	Lower Spec Limit	Lower Concentration	Upper Concentration	Upper Spec Limit	Upper Acceptance Limit	Results
Quadratic	56.0	70	4.9	194.4	130	156.0	Pass Linearity Criterion
95% Confidence Interval	56.0	70	38.6	161.1	130	156.0	Pass Linearity Criterion

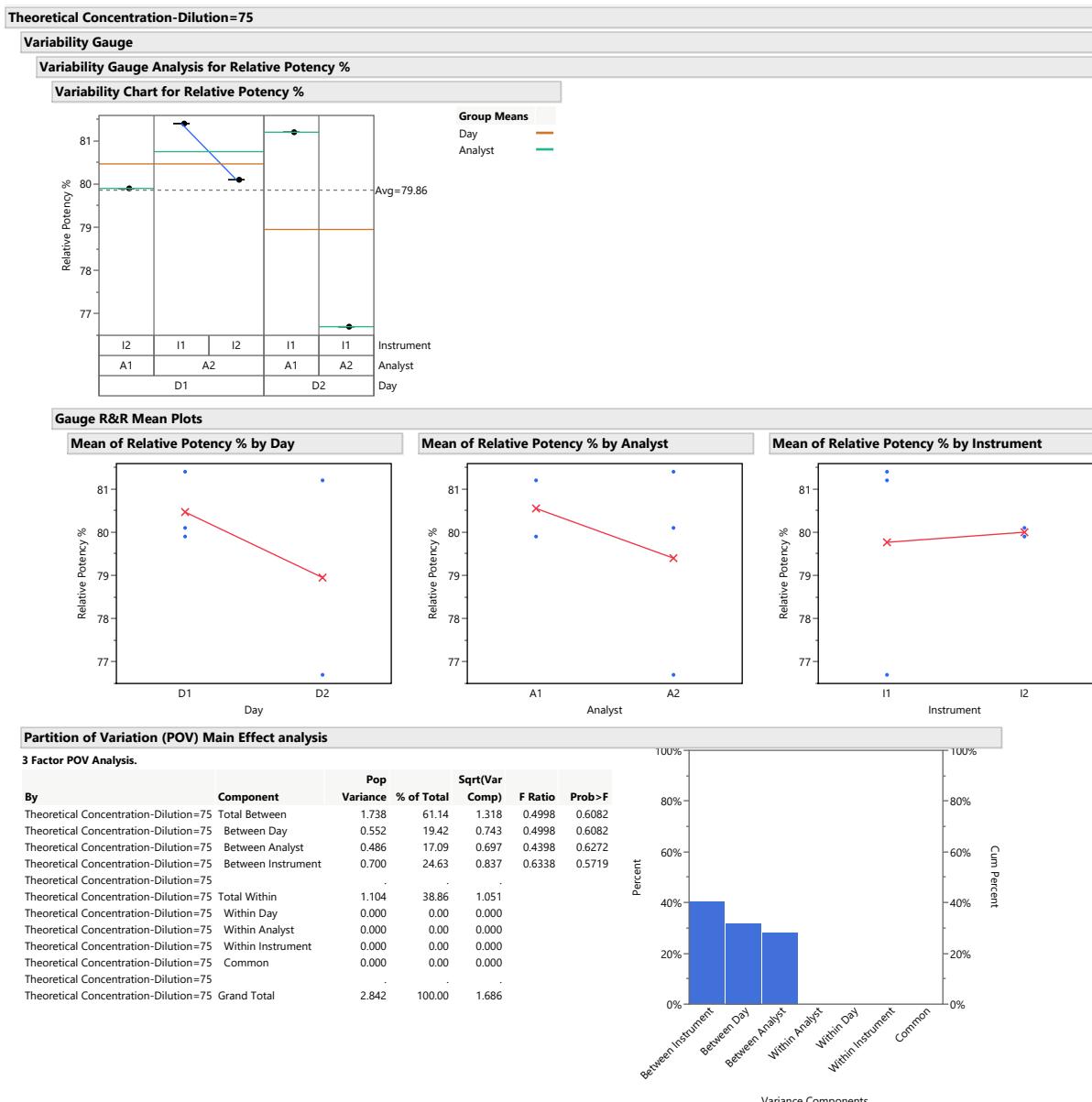
If concentration is calculated as below 0, report shows 0.

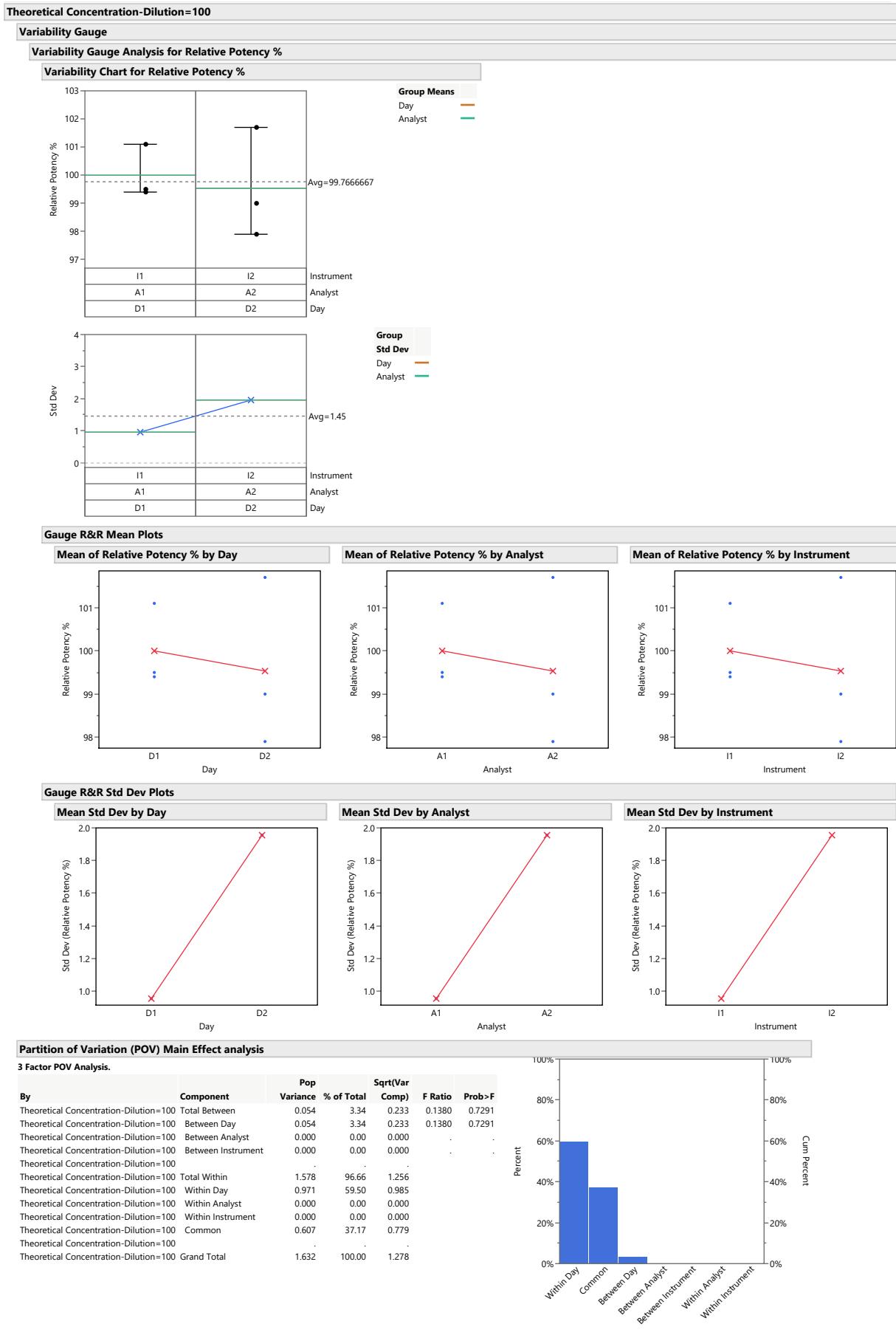
LSL = 70, USL = 130, Lower Linearity Limit = 80, Upper Linearity Limit = 120, Lower Acceptance Limit = 56, Upper Acceptance Limit = 156

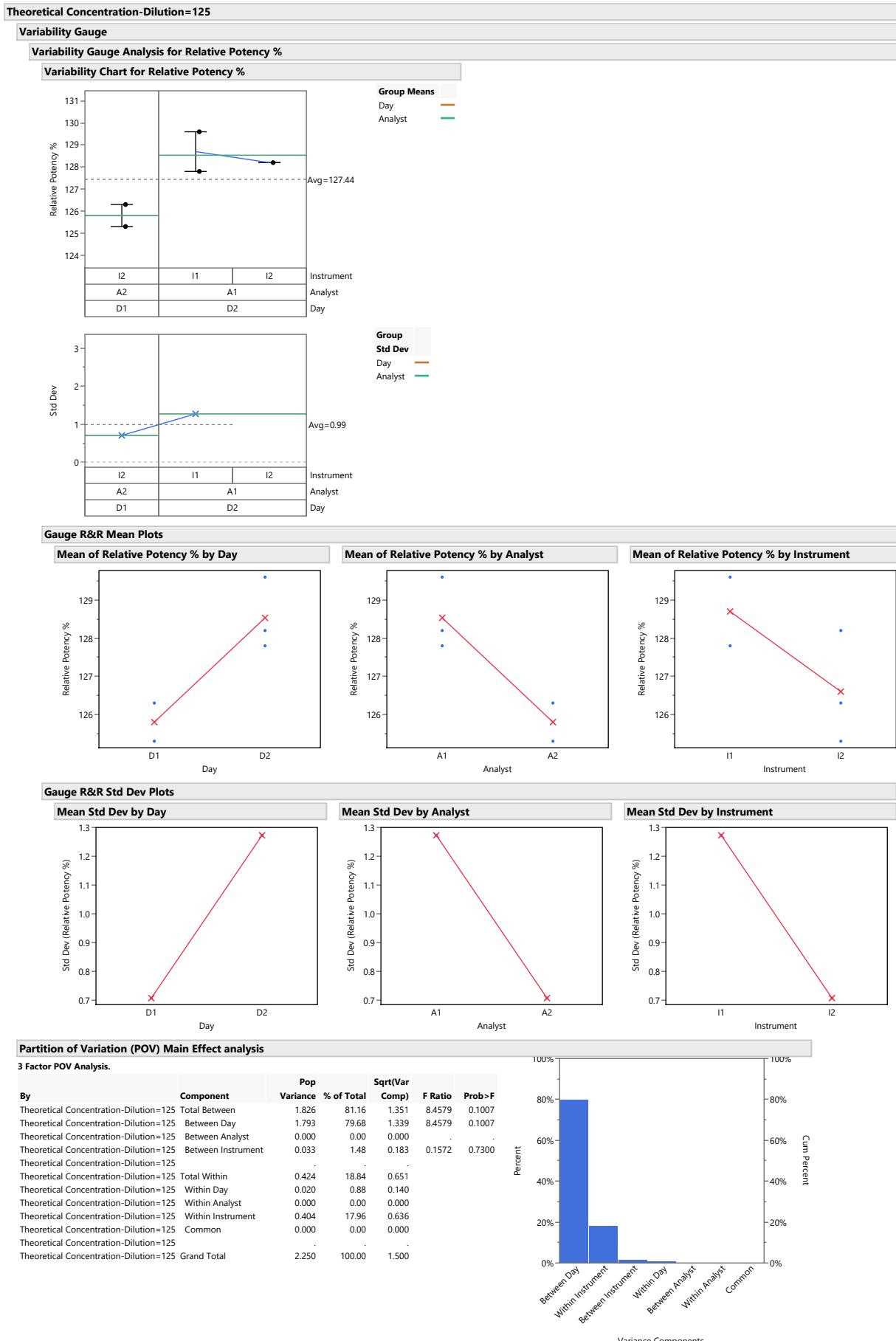
Linearity - Bias/Accuracy

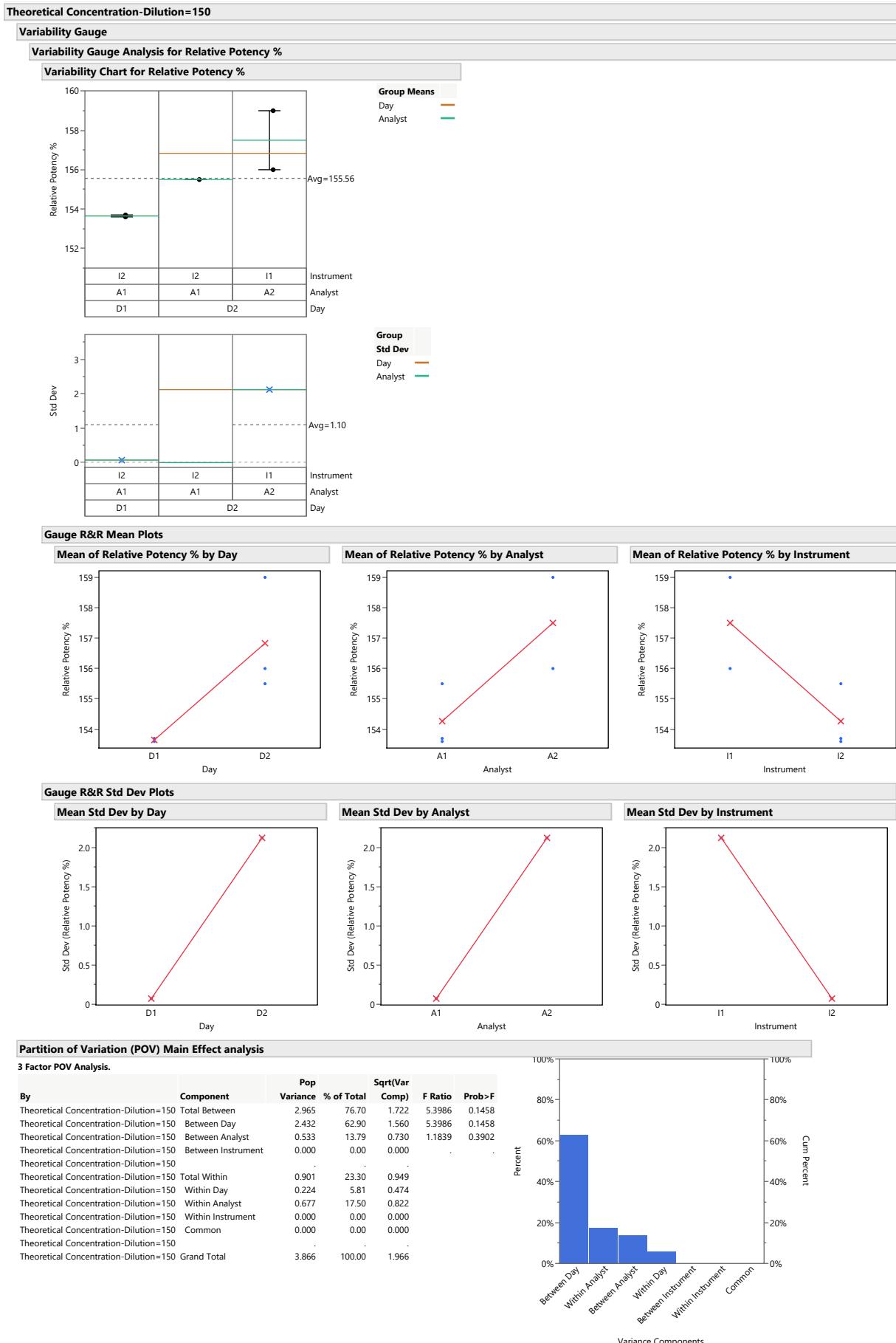
Partition of Variation, Intermediate Precision











Linearity - Repeatability and Intermediate Precision

Theoretical Concentration/Dilution	Number	Between Day	Between Analyst	Between Instrument	Repeatability (%)	Repeatability Upper 95% CL	Repeatability Lower 95% CL	Repeatability % of Tolerance (n=1)	Repeatability % of Tolerance (n=3)	Repeatability Pass/Fail (n=1)	Repeatability Pass/Fail (n=3)
50	5	2.033	0.986	0.538	1.391	3.998	0.834	11.9	6.9	Pass	Pass
75	5	0.743	0.697	0.837	1.051	3.020	0.630	9	5.2	Pass	Pass
100	6	0.233	0.000	0.000	1.256	3.081	0.784	10.8	6.2	Pass	Pass
125	5	1.339	0.000	0.183	0.651	1.871	0.390	5.6	3.2	Pass	Pass
150	5	1.560	0.730	0.000	0.949	2.728	0.569	8.1	4.7	Pass	Pass

Theoretical Concentration/Dilution	Number	Between Day	Between Analyst	Between Instrument	Intermediate Precision (%)	IP Upper 95% CL	IP Lower 95% CL	IP % of Tolerance (n=1)	IP % of Tolerance (n=3)	Intermediate Precision Pass/Fail (n=1)	Intermediate Precision Pass/Fail (n=3)
50	5	2.033	0.986	0.538	2.707	7.780	1.622	23.2	13.4	Pass	Pass
75	5	0.743	0.697	0.837	1.686	4.845	1.010	14.5	8.4	Pass	Pass
100	6	0.233	0.000	0.000	1.278	3.133	0.797	11	6.3	Pass	Pass
125	5	1.339	0.000	0.183	1.500	4.311	0.899	12.9	7.4	Pass	Pass
150	5	1.560	0.730	0.000	1.966	5.650	1.178	16.9	9.7	Pass	Pass

Repeatability acceptance criterion: 60

Report Summary

Range of linearity		
Curve	Lower Concentration	Upper Concentration
Quadratic	4.9	194.4
95% Confidence Interval	38.6	161.1

Bias/Accuracy		
Theoretical Concentration/Dilution	Bias % of Accuracy	Evaluation
50	0.93	Pass
75	8.10	Pass
100	0.39	Pass
125	4.07	Pass
150	9.27	Pass

Repeatability and Intermediate Precision								
Theoretical Concentration/Dilution	Repeatability % of Tolerance (n=1)	IP % of Tolerance (n=1)	Repeatability % of Tolerance (n=3)	IP % of Tolerance (n=3)	Repeatability Pass/Fail (n=1)	IP Pass/Fail (n=1)	Intermediate Precision Pass/Fail (n=1)	Intermediate Precision Pass/Fail (n=3)
50	11.9	23.2	6.9	13.4	Pass	Pass	Pass	Pass
75	9	14.5	5.2	8.4	Pass	Pass	Pass	Pass
100	10.8	11	6.2	6.3	Pass	Pass	Pass	Pass
125	5.6	12.9	3.2	7.4	Pass	Pass	Pass	Pass
150	8.1	16.9	4.7	9.7	Pass	Pass	Pass	Pass

Assay Range

Curve	Sample Size (n)	Reported Range
Quadratic	1	50 - 150
Quadratic	3	50 - 150
95% Confidence Interval	1	50 - 150
95% Confidence Interval	3	50 - 150

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