Linearity report q

Data Files:	Date:	Time:
Linearity.jmp	Friday, January 19, 2024	17:07:09

Data Integrity

Study descriptives	Note
Analyst	ujk
Analytical method	q
Instrument	ery
Purpose	qre
Standard Expiry	7576
Standard ID	y
Study date(s)	y
Unit	

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: 2306131702
JMP Version: 17.2.0

- -
Analyst Signature/Date

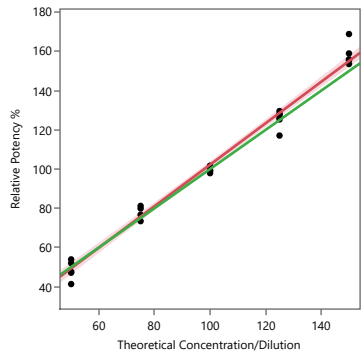
- -
Reviewer Signature/Date

Linearity - Data table

Theoretical Concentration/Dilution	Day	Analyst	Instrument	Relative Potency %	Accuracy/ Bias
150	D1	A1	I2	153.6	3.60
50	D1	A2	I2	47.1	-2.90
150	D2	A2	I1	156	6.00
125	D2	A1	I2	128.2	3.20
50	D1	A1	I1	52	2.00
50	D1	A1	I1	47.6	-2.40
100	D2	A2	I2	97.9	-2.10
75	D2	A2	I1	76.7	1.70
75	D1	A1	I2	79.9	4.90
100	D1	A1	I1	99.5	-0.50
100	D1	A1	I1	99.4	-0.60
150	D1	A1	I2	153.7	3.70
50	D2	A1	I2	41.3	-8.70
100	D2	A2	I2	99	-1.00
150	D1	A2	I1	168.9	18.90
125	D2	A1	I1	129.6	4.60
125	D2	A1	I1	127.8	2.80
150	D2	A1	I2	155.5	5.50
75	D1	A2	I2	80.1	5.10
50	D2	A2	I1	53.9	3.90
100	D2	A2	I2	101.7	1.70
75	D2	A1	I2	73.4	-1.60
150	D2	A2	I1	159	9.00
125	D1	A2	I1	117.1	-7.90
75	D2	A1	I1	81.2	6.20
75	D1	A2	I1	81.4	6.40
50	D2	A2	I2	52.2	2.20
125	D1	A2	I2	126.3	1.30
100	D1	A1	I1	101.1	1.10
125	D1	A2	I2	125.3	0.30

Linearity - Linearity Evaluation

Linearity Evaluation



Linear Fit

Relative Potency % = -3.573333 + 1.0578667*Theoretical Concentration/Dilution

Summary of Fit

RSquare	0.98542
RSquare Adj	0.984899
Root Mean Square Error	4.709049
Mean of Response	102.2133
Observations (or Sum Wgts)	30

Analysis of Variance

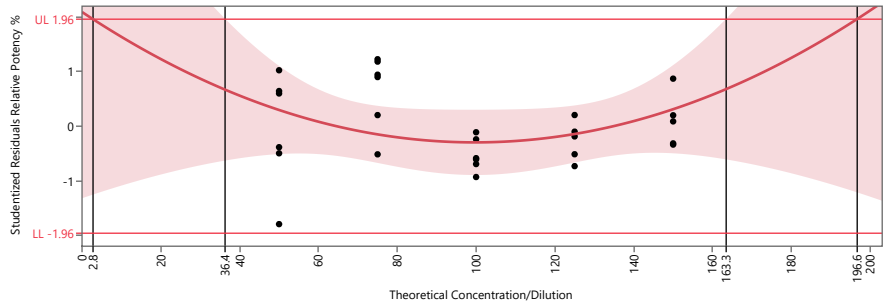
Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	41965.571	41965.6	1892.460
Error	28	620.904	22.2	Prob > F
C. Total	29	42586.475		<.0001*

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	-3.573333	2.579252	-1.39	0.1769	-8.856692	1.7100257
Theoretical Concentration/Dilution	1.0578667	0.024317	43.50	<.0001*	1.0080547	1.1076787

Linearity - Range of Linearity

Linear Response Limits



Polynomial Fit Degree=2

Studentized Residuals Relative Potency % = -0.310967 + 0.0001423*Theoretical Concentration/Dilution + 0.0002404*(Theoretical Concentration/Dilution-100)^2

Summary of Fit

RSquare	0.062651
RSquare Adj	-0.00678
Root Mean Square Error	1.025253
Mean of Response	0.003757
Observations (or Sum Wgts)	30

Parameter Estimates

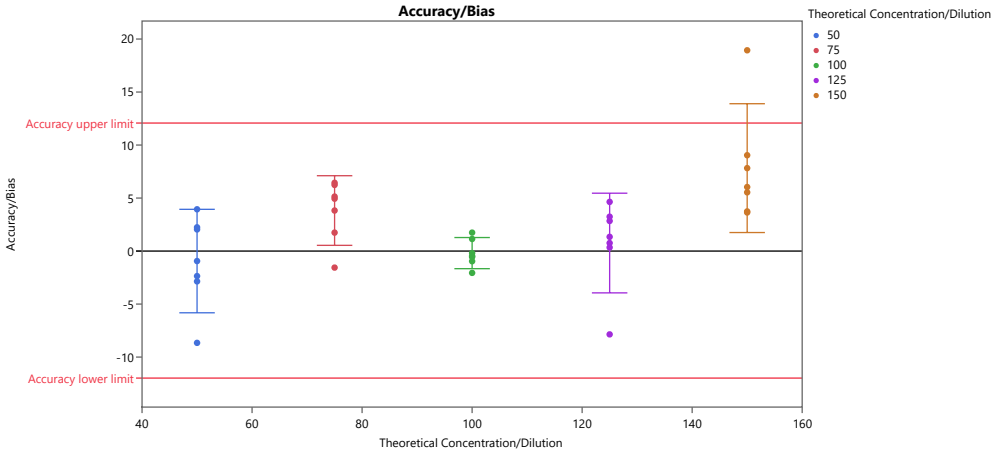
Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	-0.310967	0.604481	-0.51	0.6111	-1.55126	0.9293265
Theoretical Concentration/Dilution	0.0001423	0.005294	0.03	0.9788	-0.010721	0.0110055
(Theoretical Concentration/Dilution-100)^2	0.0002404	0.000179	1.34	0.1904	-0.000127	0.0006076

Linearity Limits

Curve	Lower Acceptance Limit	Lower Spec Limit	Lower Concentration	Upper Concentration	Upper Spec Limit	Upper Acceptance Limit	Results
Quadratic	56.0	70	2.8	196.6	130	156.0	Pass Linearity Criterion
95% Confidence Interval	56.0	70	36.4	163.3	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



Theoretical Concentration/Dilution	Number	Accuracy/ Bias	Bias Lower 95%	Bias Upper 95%	Bias % of Tolerance	Accuracy Evaluation
50	6	-0.98	-5.86	3.90	1.64	Pass
75	6	3.78	0.50	7.07	6.31	Pass
100	6	-0.23	-1.70	1.24	0.39	Pass
125	6	0.72	-3.98	5.42	1.19	Pass
150	6	7.78	1.71	13.86	12.97	Pass

Bias Acceptance Criterion: 20

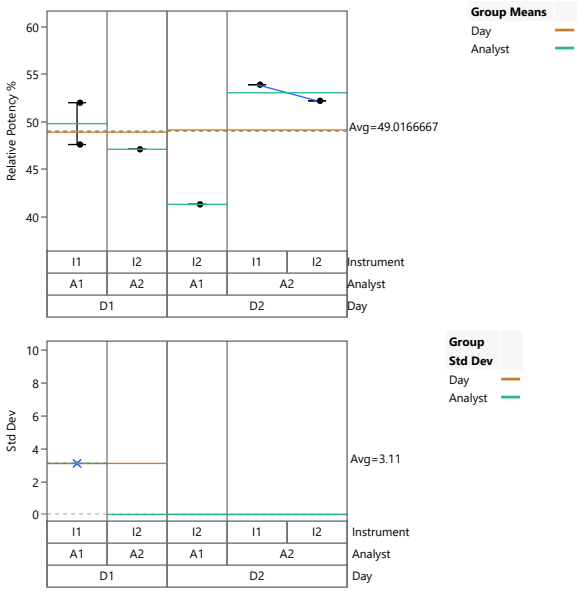
Partition of Variation, Intermediate Precision

Theoretical Concentration-Dilution=50

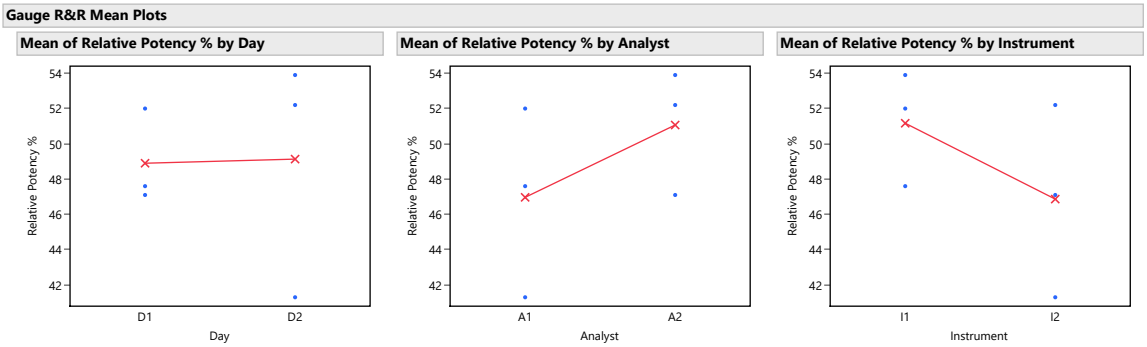
Variability Gauge

Variability Gauge Analysis for Relative Potency %

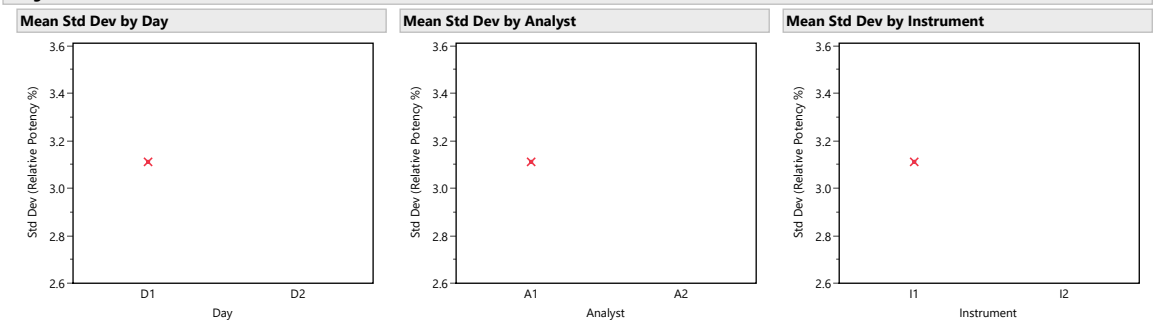
Variability Chart for Relative Potency %



Gauge R&R Mean Plots



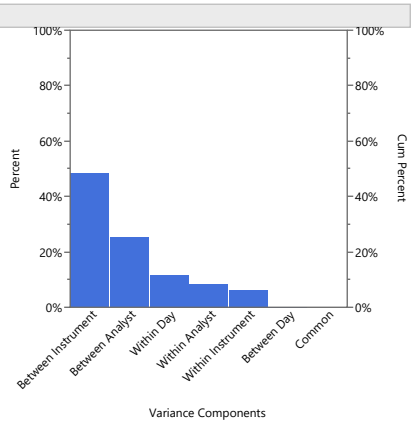
Gauge R&R Std Dev Plots



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=50	Total Between	13.258	73.58	3.641	0.0057	0.9466
Theoretical Concentration-Dilution=50	Between Day	0.014	0.08	0.117	0.0057	0.9466
Theoretical Concentration-Dilution=50	Between Analyst	4.550	25.25	2.133	1.9117	0.3009
Theoretical Concentration-Dilution=50	Between Instrument	8.694	48.25	2.949	3.6528	0.1961
Theoretical Concentration-Dilution=50		.	.	.		
Theoretical Concentration-Dilution=50	Total Within	4.760	26.42	2.182		
Theoretical Concentration-Dilution=50	Within Day	2.116	11.74	1.455		
Theoretical Concentration-Dilution=50	Within Analyst	1.511	8.39	1.229		
Theoretical Concentration-Dilution=50	Within Instrument	1.133	6.29	1.065		
Theoretical Concentration-Dilution=50	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=50		.	.	.		
Theoretical Concentration-Dilution=50	Grand Total	18.018	100.00	4.245		

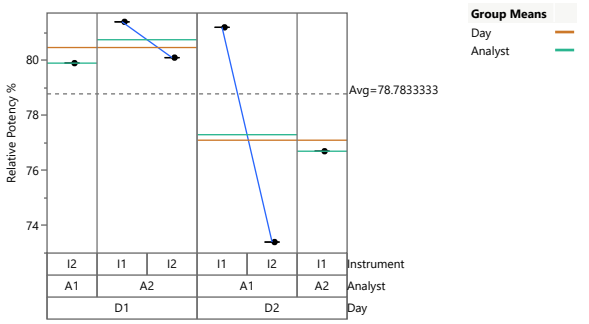


Theoretical Concentration-Dilution=75

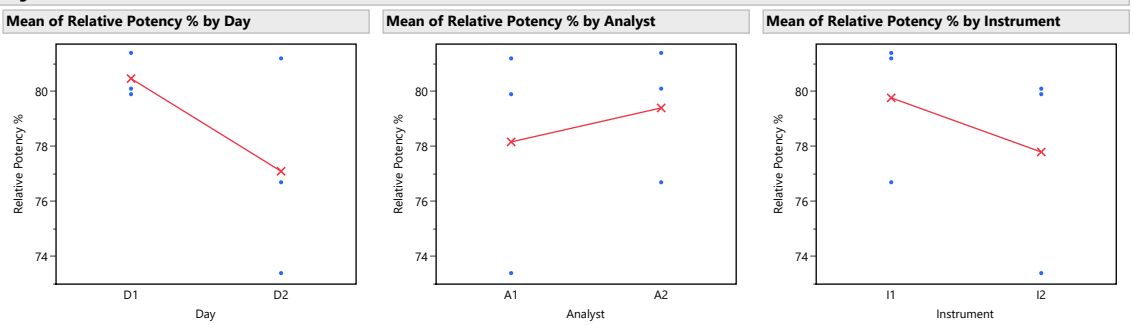
Variability Gauge

Variability Gauge Analysis for Relative Potency %

Variability Chart for Relative Potency %



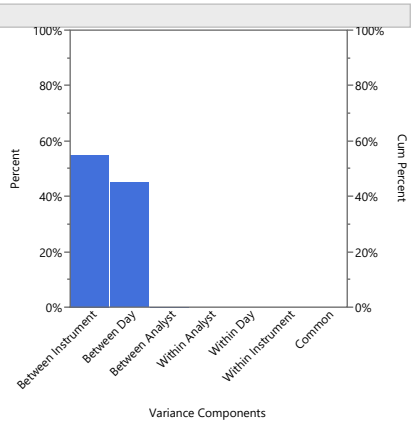
Gauge R&R Mean Plots



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=75	Total Between	6.288	77.01	2.507	3.0189	0.2244
Theoretical Concentration-Dilution=75	Between Day	2.834	34.71	1.683	3.0189	0.2244
Theoretical Concentration-Dilution=75	Between Analyst	0.003	0.04	0.059	0.0037	0.9570
Theoretical Concentration-Dilution=75	Between Instrument	3.450	42.26	1.858	3.6761	0.1952
Theoretical Concentration-Dilution=75		.	.	.		
Theoretical Concentration-Dilution=75	Total Within	1.877	22.99	1.370		
Theoretical Concentration-Dilution=75	Within Day	0.000	0.00	0.000		
Theoretical Concentration-Dilution=75	Within Analyst	0.000	0.00	0.000		
Theoretical Concentration-Dilution=75	Within Instrument	0.000	0.00	0.000		
Theoretical Concentration-Dilution=75	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=75		.	.	.		
Theoretical Concentration-Dilution=75	Grand Total	8.165	100.00	2.857		

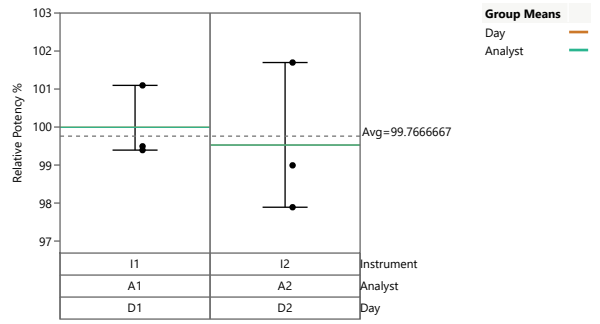


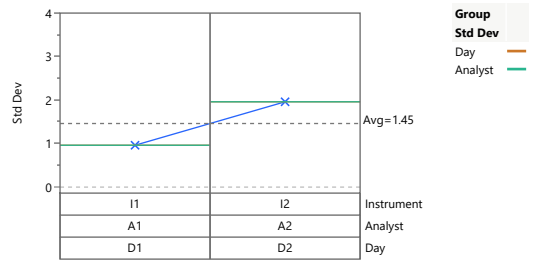
Theoretical Concentration-Dilution=100

Variability Gauge

Variability Gauge Analysis for Relative Potency %

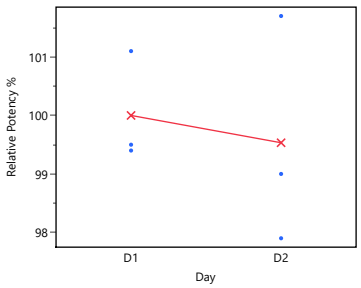
Variability Chart for Relative Potency %



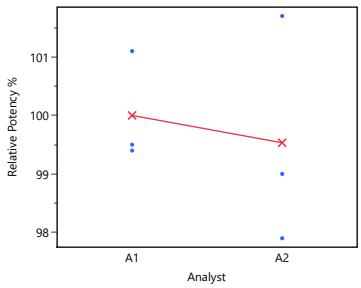


Gauge R&R Mean Plots

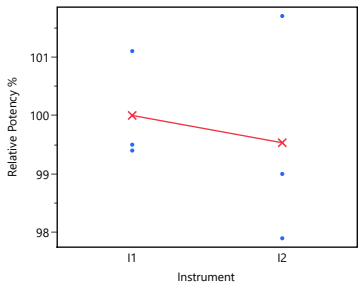
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

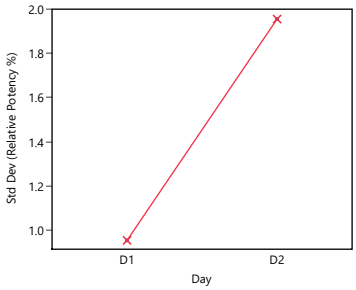


Mean of Relative Potency % by Instrument

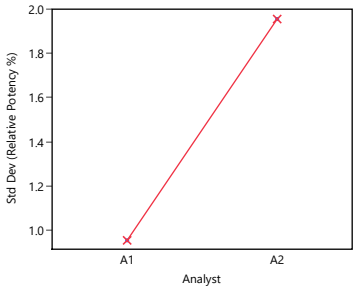


Gauge R&R Std Dev Plots

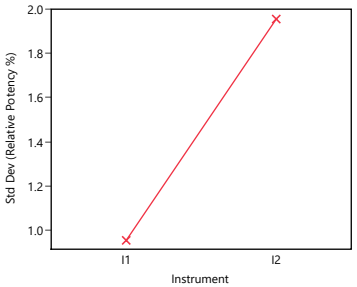
Mean Std Dev by Day



Mean Std Dev by Analyst



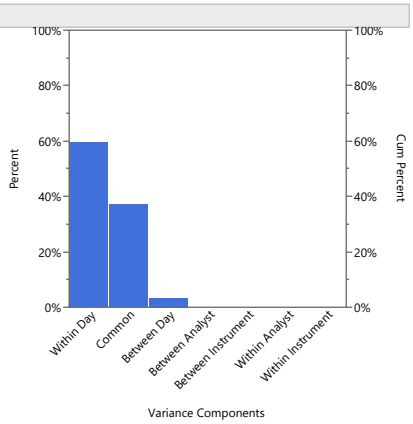
Mean Std Dev by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=100	Total Between	0.054	3.34	0.233	0.1380	0.7291
Theoretical Concentration-Dilution=100	Between Day	0.054	3.34	0.233	0.1380	0.7291
Theoretical Concentration-Dilution=100	Between Analyst	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=100	Between Instrument	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=100		.	.	.		
Theoretical Concentration-Dilution=100	Total Within	1.578	96.66	1.256		
Theoretical Concentration-Dilution=100	Within Day	0.971	59.50	0.985		
Theoretical Concentration-Dilution=100	Within Analyst	0.000	0.00	0.000		
Theoretical Concentration-Dilution=100	Within Instrument	0.000	0.00	0.000		
Theoretical Concentration-Dilution=100	Common	0.607	37.17	0.779		
Theoretical Concentration-Dilution=100		.	.	.		
Theoretical Concentration-Dilution=100	Grand Total	1.632	100.00	1.278		

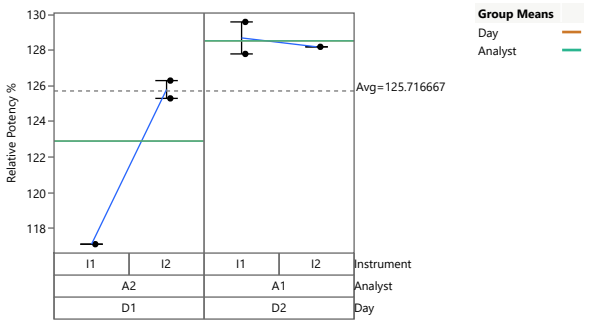


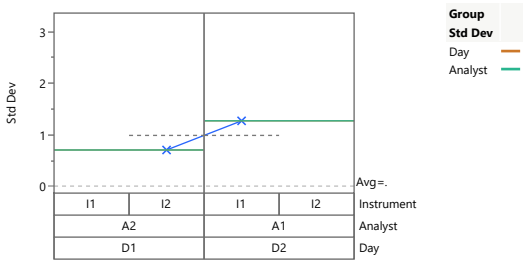
Theoretical Concentration-Dilution=125

Variability Gauge

Variability Gauge Analysis for Relative Potency %

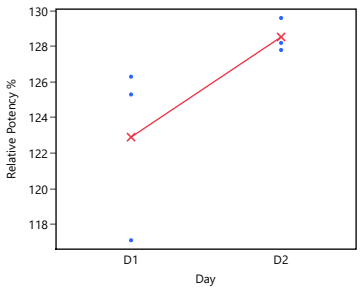
Variability Chart for Relative Potency %



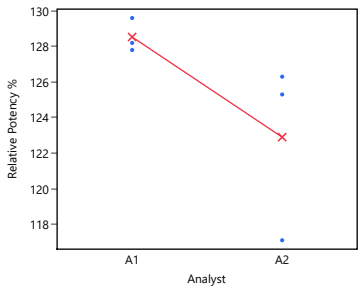


Gauge R&R Mean Plots

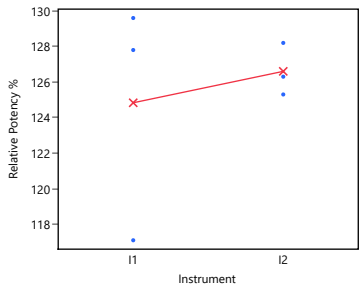
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

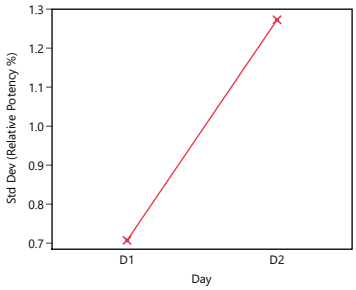


Mean of Relative Potency % by Instrument

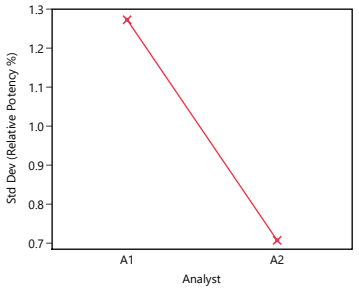


Gauge R&R Std Dev Plots

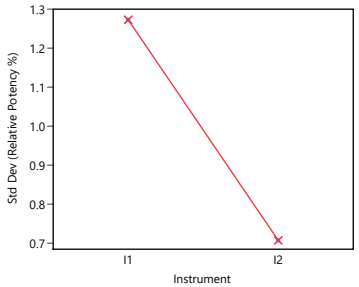
Mean Std Dev by Day



Mean Std Dev by Analyst



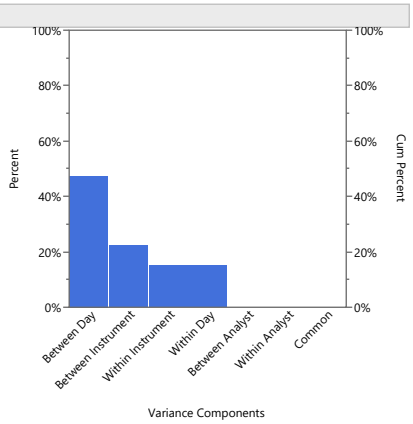
Mean Std Dev by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=125	Total Between	11.669	69.77	3.416	4.7079	0.1185
Theoretical Concentration-Dilution=125	Between Day	7.934	47.44	2.817	4.7079	0.1185
Theoretical Concentration-Dilution=125	Between Analyst	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=125	Between Instrument	3.736	22.34	1.933	2.2167	0.2333
Theoretical Concentration-Dilution=125		.	.	.		
Theoretical Concentration-Dilution=125	Total Within	5.056	30.23	2.248		
Theoretical Concentration-Dilution=125	Within Day	2.528	15.11	1.590		
Theoretical Concentration-Dilution=125	Within Analyst	0.000	0.00	0.000		
Theoretical Concentration-Dilution=125	Within Instrument	2.528	15.11	1.590		
Theoretical Concentration-Dilution=125	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=125		.	.	.		
Theoretical Concentration-Dilution=125	Grand Total	16.725	100.00	4.090		

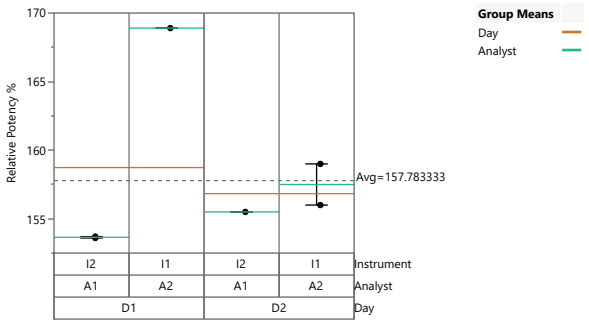


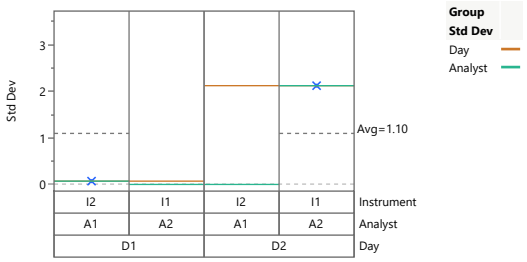
Theoretical Concentration-Dilution=150

Variability Gauge

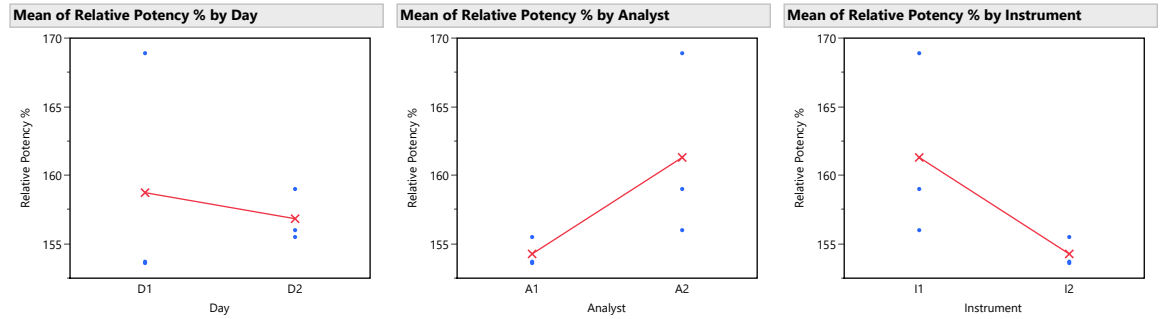
Variability Gauge Analysis for Relative Potency %

Variability Chart for Relative Potency %

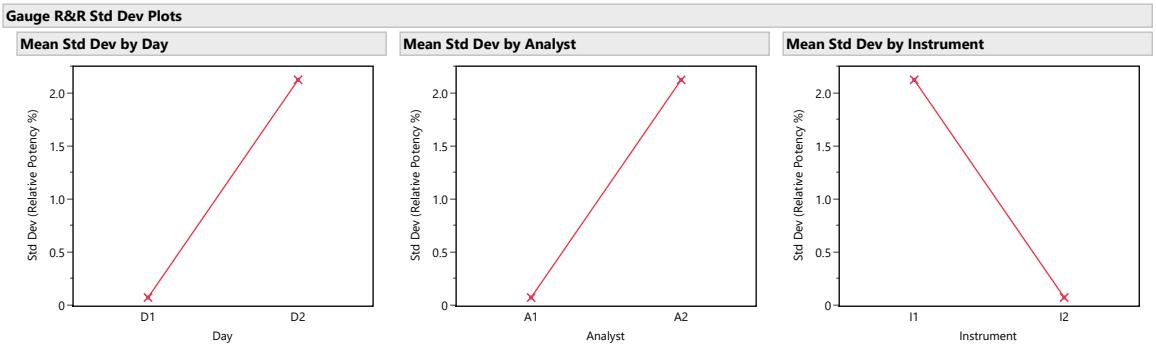




Gauge R&R Mean Plots



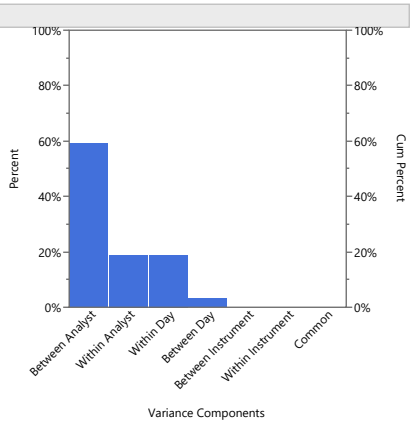
Gauge R&R Std Dev Plots



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=150	Total Between	17.434	62.40	4.175	0.2578	0.6466
Theoretical Concentration-Dilution=150	Between Day	0.902	3.23	0.950	0.2578	0.6466
Theoretical Concentration-Dilution=150	Between Analyst	16.531	59.17	4.066	4.7213	0.1181
Theoretical Concentration-Dilution=150	Between Instrument	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=150		.	.	.		
Theoretical Concentration-Dilution=150	Total Within	10.504	37.60	3.241		
Theoretical Concentration-Dilution=150	Within Day	5.252	18.80	2.292		
Theoretical Concentration-Dilution=150	Within Analyst	5.252	18.80	2.292		
Theoretical Concentration-Dilution=150	Within Instrument	0.000	0.00	0.000		
Theoretical Concentration-Dilution=150	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=150		.	.	.		
Theoretical Concentration-Dilution=150	Grand Total	27.938	100.00	5.286		



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	6	0.117	2.133	2.949	2.182	5.351	1.362	18.7	10.8	Pass	Pass
75	6	1.683	0.059	1.858	1.370	3.360	0.855	11.8	6.8	Pass	Pass
100	6	0.233	0.000	0.000	1.256	3.081	0.784	10.8	6.2	Pass	Pass
125	6	2.817	0.000	1.933	2.248	5.515	1.404	19.3	11.1	Pass	Pass
150	6	0.950	4.066	0.000	3.241	7.949	2.023	27.8	16.1	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	6	0.117	2.133	2.949	4.245	10.411	2.650	36.4	21	Pass	Pass
75	6	1.683	0.059	1.858	2.857	7.008	1.784	24.5	14.2	Pass	Pass
100	6	0.233	0.000	0.000	1.278	3.133	0.797	11	6.3	Pass	Pass
125	6	2.817	0.000	1.933	4.090	10.030	2.553	35.1	20.3	Pass	Pass
150	6	0.950	4.066	0.000	5.286	12.964	3.299	45.4	26.2	Pass	Pass

Repeatability acceptance criterion: 60

Report Summary

Range of linearity

Curve	Lower Concentration	Upper Concentration	Results
Quadratic	2.8	196.6	Pass Linearity Criterion
95% Confidence Interval	36.4	163.3	Pass Linearity Criterion

Bias/Accuracy

Theoretical Concentration/Dilution	Bias % of Tolerance	Accuracy Evaluation
50	1.64	Pass
75	6.31	Pass
100	0.39	Pass
125	1.19	Pass
150	12.97	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)	Repeatability Pass/Fail (n=3)	Intermediate Precision Pass/Fail (n=1)	Intermediate Precision Pass/Fail (n=3)
50	18.7	36.4	10.8	21	Pass	Pass	Pass	Pass
75	11.8	24.5	6.8	14.2	Pass	Pass	Pass	Pass
100	10.8	11	6.2	6.3	Pass	Pass	Pass	Pass
125	19.3	35.1	11.1	20.3	Pass	Pass	Pass	Pass
150	27.8	45.4	16.1	26.2	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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