Linearity report

Data Integrity

Study descriptives	Note
Analyst	
Analytical method	
Instrument	
Standard Expiry	
Standard ID	
Study date(s)	

Limit	Specification
USL	130
LSL	70

Method Attribute	Criteria (% of tolerance)
Accuracy	10
Repeatability	25
IP	30
Upper Linearity Limit	120
Lower Linearity Limit	80

Data Files:	Date:	Time:
Linearity.jmp	Wednesday, June 7, 2023	10:59:08

User Information
User Name: paule
Computer Name: PADC-SURFACE
Logon Server: \\PADC-SURFACE
User Domain: PADC-SURFACE
Addin version: 2306071058
JMP Version: 16.2.0

Analyst Signature/Date

Reviewer Signature/Date

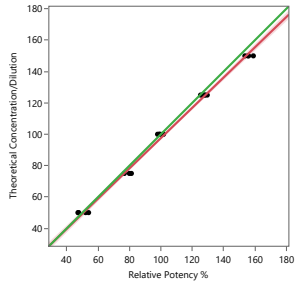
Data table

Theoretical Concentration/Dilution	Day	Analyst	Instrument	Relative Potency %	Jackknife Distances By Theoretical Concentration/Dilution	Outlier	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
Linear Fit

Linear Fit

Theoretical Concentration/Dilution = 1.0889887 + 0.9647321*Relative Potency %

Summary of Fit

RSquare	0.993983
RSquare Adj	0.993732
Root Mean Square Error	2.7991
Mean of Response	100
Observations (or Sum Wgts)	26

Analysis of Variance

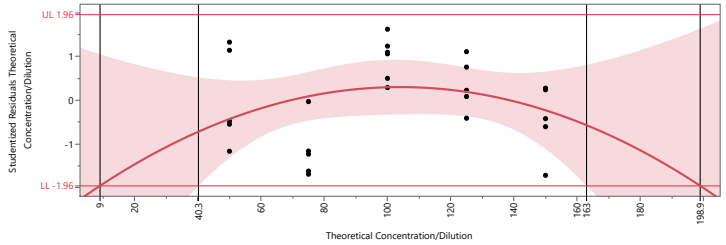
Source	DF	Sum of Squares	Mean Square	F Ratio
Model	1	31061.961	31062.0	3964.534
Error	24	188.039	7.8	Prob > F
C. Total	25	31250.000		<.0001*

Parameter Estimates

Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	1.0889887	1.664053	0.65	0.5191	-2.345447	4.5234248
Relative Potency %	0.9647321	0.015322	62.96	<.0001*	0.9331094	0.9963548

Range of Linearity

Linear Response Limits



Polynomial Fit Degree=2

Polynomial Fit Degree=2

Studentized Residuals Theoretical Concentration/Dilution =
0.0973533 + 0.0020015*Theoretical Concentration/Dilution -
0.0002509*(Theoretical Concentration/Dilution-100)^2

Summary of Fit

RSquare	0.074909
RSquare Adj	-0.00553
Root Mean Square Error	1.020835
Mean of Response	-0.00404
Observations (or Sum Wgts)	26

Parameter Estimates

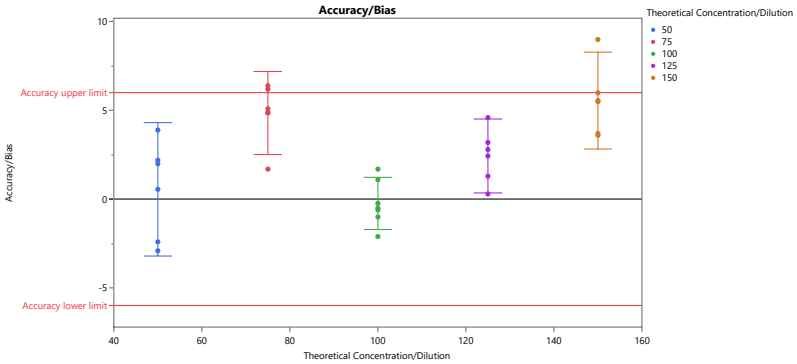
Term	Estimate	Std Error	t Ratio	Prob>|t|	Lower 95%	Upper 95%
Intercept	0.0973533	0.65249	0.15	0.8827	-1.252425	1.4471312
Theoretical Concentration/Dilution	0.0020015	0.005775	0.35	0.7320	-0.009944	0.0139474
(Theoretical Concentration/Dilution-100)^2	-0.000251	0.00019	-1.32	0.1998	-0.000644	0.0001423

Linearity Limits

Curve and 95% CI Limits	Limit	Pass/Fail Linearity
Lower Curve	9.05	Pass Linearity Criterion
Upper Curve	198.93	Pass Linearity Criterion
Lower 95% CL	40.26	Pass Linearity Criterion
Upper 95% CL	163.02	Pass Linearity Criterion

Concentrations below 0 show as '.'

Bias/Accuracy



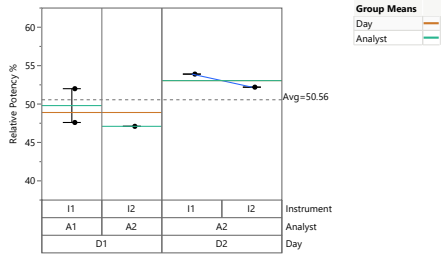
Theoretical Concentration/Dilution	Number	Accuracy/ Bias	Bias Lower 95%	Bias Upper 95%	Bias % of Tolerance	Accuracy Evaluation
50	5	0.56	-3.20	4.32	0.93	Pass
75	5	4.86	2.52	7.20	8.10	Pass
100	6	-0.23	-1.70	1.24	0.39	Pass
125	5	2.44	0.36	4.52	4.07	Pass
150	5	5.56	2.83	8.29	9.27	Pass

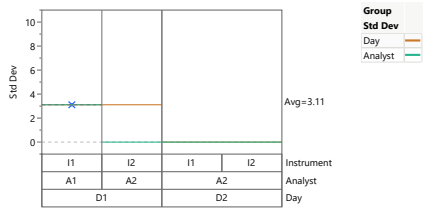
Partition of Variation, Intermediate Precision

Theoretical Concentration-Dilution=50

Variability Gauge

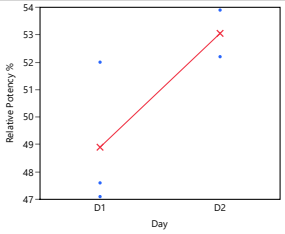
Variability Chart for Relative Potency %



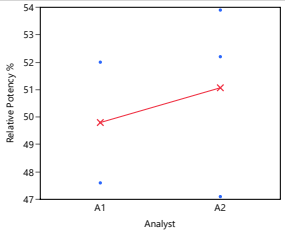


Gauge R&R Mean Plots

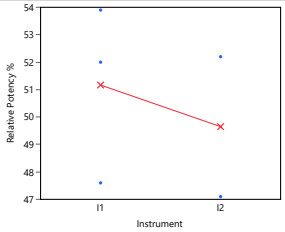
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

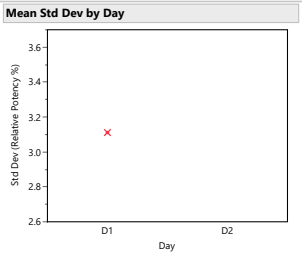


Mean of Relative Potency % by Instrument

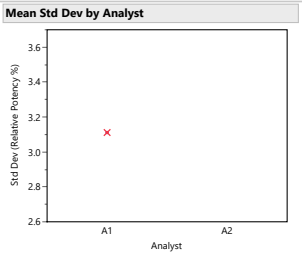


Gauge R&R Std Dev Plots

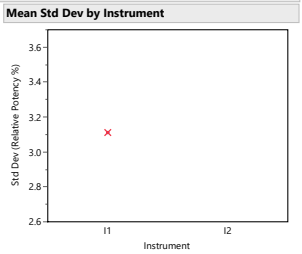
Mean Std Dev by Day



Mean Std Dev by Analyst



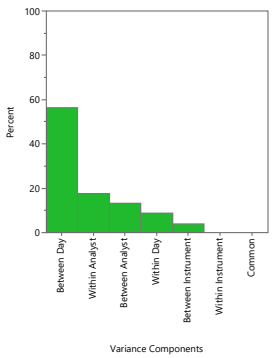
Mean Std Dev by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

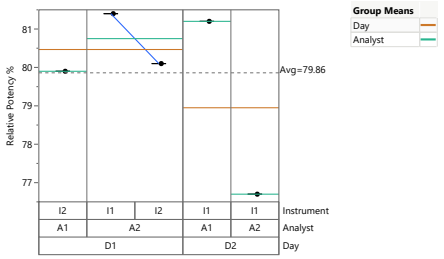
By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=50	Total Between	5.394	73.59	2.323	2.1350	0.3821
Theoretical Concentration-Dilution=50	Between Day	4.133	56.39	2.033	2.1350	0.3821
Theoretical Concentration-Dilution=50	Between Analyst	0.972	13.26	0.986	0.5021	0.6076
Theoretical Concentration-Dilution=50	Between Instrument	0.289	3.94	0.538	0.1493	0.7653
Theoretical Concentration-Dilution=50		.	.	.		
Theoretical Concentration-Dilution=50	Total Within	1.936	26.41	1.391		
Theoretical Concentration-Dilution=50	Within Day	0.645	8.80	0.803		
Theoretical Concentration-Dilution=50	Within Analyst	1.291	17.61	1.136		
Theoretical Concentration-Dilution=50	Within Instrument	0.000	0.00	0.000		
Theoretical Concentration-Dilution=50	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=50		.	.	.		
Theoretical Concentration-Dilution=50	Grand Total	7.330	100.00	2.707		



Theoretical Concentration-Dilution=75

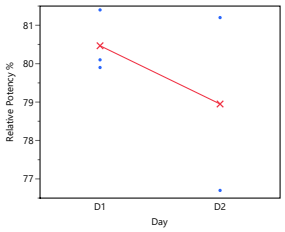
Variability Gauge

Variability Chart for Relative Potency %

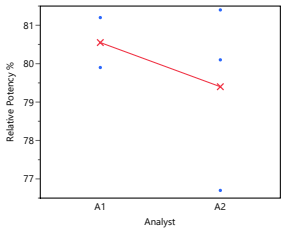


Gauge R&R Mean Plots

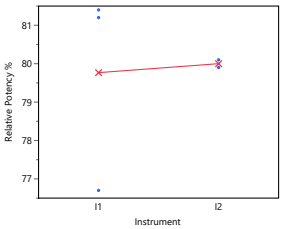
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst



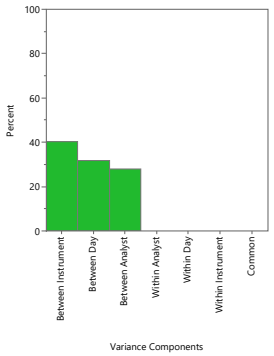
Mean of Relative Potency % by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

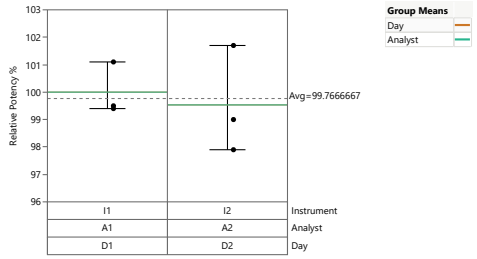
By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=75	Total Between	1.738	61.14	1.318	0.4998	0.6082
Theoretical Concentration-Dilution=75	Between Day	0.552	19.42	0.743	0.4998	0.6082
Theoretical Concentration-Dilution=75	Between Analyst	0.486	17.09	0.697	0.4398	0.6272
Theoretical Concentration-Dilution=75	Between Instrument	0.700	24.63	0.837	0.6338	0.5719
Theoretical Concentration-Dilution=75		.	.	.		
Theoretical Concentration-Dilution=75	Total Within	1.104	38.86	1.051		
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	2.842	100.00	1.686		

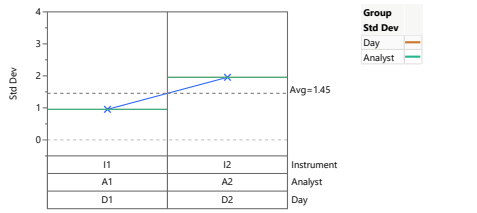


Theoretical Concentration-Dilution=100

Variability Gauge

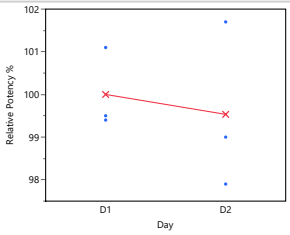
Variability Chart for Relative Potency %



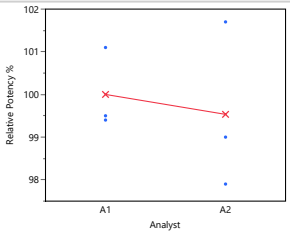


Gauge R&R Mean Plots

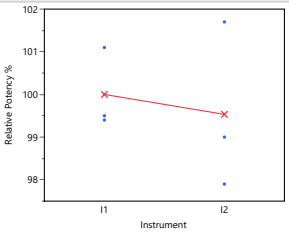
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

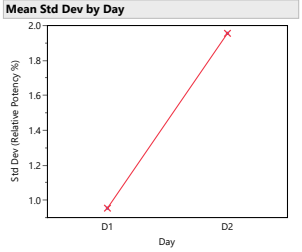


Mean of Relative Potency % by Instrument

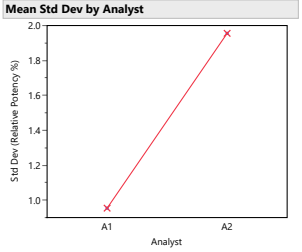


Gauge R&R Std Dev Plots

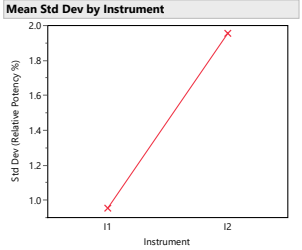
Mean Std Dev by Day



Mean Std Dev by Analyst



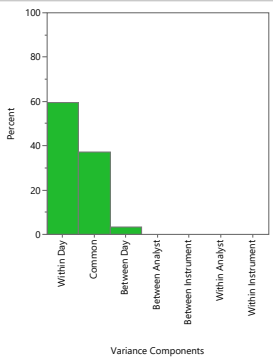
Mean Std Dev by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

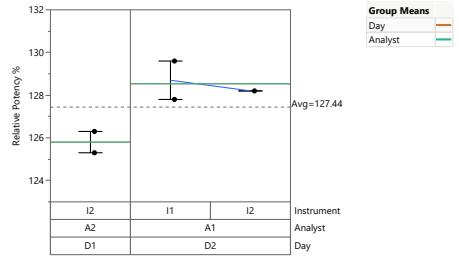
By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=100	Total Between	0.054	3.34	0.233	0.1380	0.7291
Theoretical Concentration-Dilution=100	Between Day	0.054	3.34	0.233	0.1380	0.7291
Theoretical Concentration-Dilution=100	Between Analyst	0.000	0.00	0.000	.	.
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		

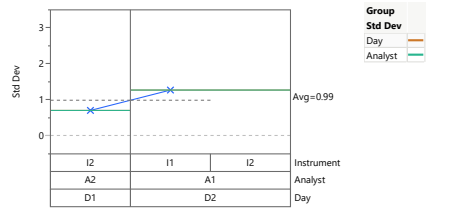


Theoretical Concentration-Dilution=125

Variability Gauge

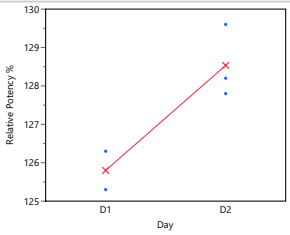
Variability Chart for Relative Potency %



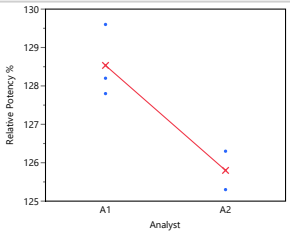


Gauge R&R Mean Plots

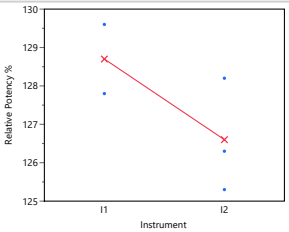
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

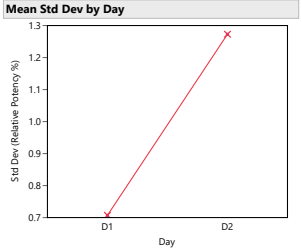


Mean of Relative Potency % by Instrument

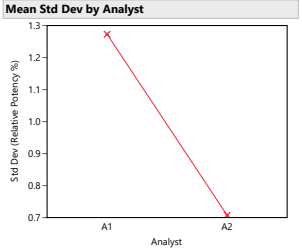


Gauge R&R Std Dev Plots

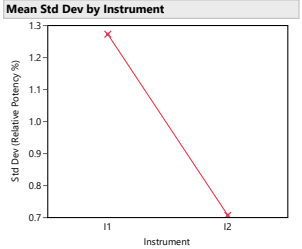
Mean Std Dev by Day



Mean Std Dev by Analyst



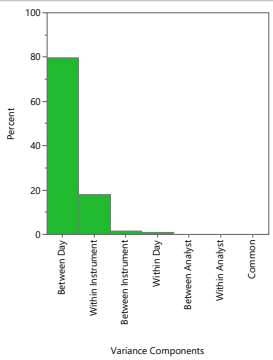
Mean Std Dev by Instrument



Partition of Variation (POV) Main Effect analysis

3 Factor POV Analysis.

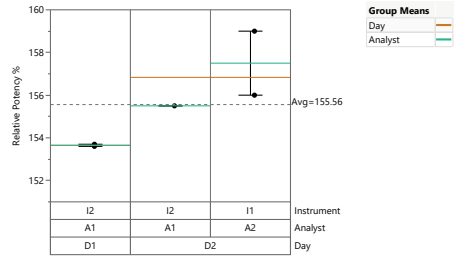
By	Component	Pop Variance	% of Total	Sqrt(Var Comp)	F Ratio	Prob>F
Theoretical Concentration-Dilution=125	Total Between	1.826	81.16	1.351	8.4579	0.1007
Theoretical Concentration-Dilution=125	Between Day	1.793	79.68	1.339	8.4579	0.1007
Theoretical Concentration-Dilution=125	Between Analyst	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=125	Between Instrument	0.033	1.48	0.183	0.1572	0.7300
Theoretical Concentration-Dilution=125		.	.	.		
Theoretical Concentration-Dilution=125	Total Within	0.424	18.84	0.651		
Theoretical Concentration-Dilution=125	Within Day	0.020	0.88	0.140		
Theoretical Concentration-Dilution=125	Within Analyst	0.000	0.00	0.000		
Theoretical Concentration-Dilution=125	Within Instrument	0.404	17.96	0.636		
Theoretical Concentration-Dilution=125	Common	0.000	0.00	0.000		
Theoretical Concentration-Dilution=125		.	.	.		
Theoretical Concentration-Dilution=125	Grand Total	2.250	100.00	1.500		

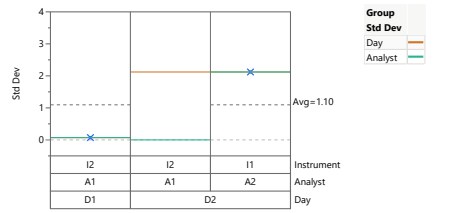


Theoretical Concentration-Dilution=150

Variability Gauge

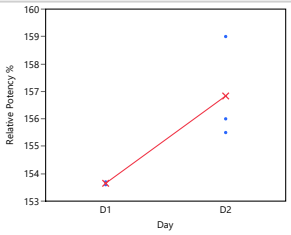
Variability Chart for Relative Potency %



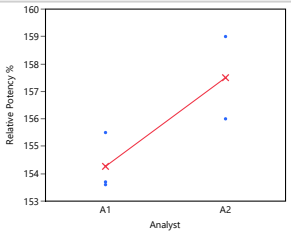


Gauge R&R Mean Plots

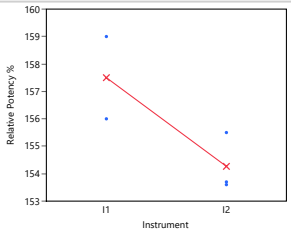
Mean of Relative Potency % by Day



Mean of Relative Potency % by Analyst

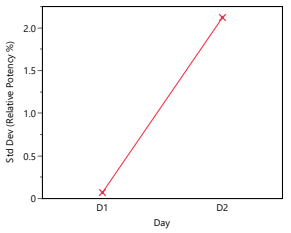


Mean of Relative Potency % by Instrument

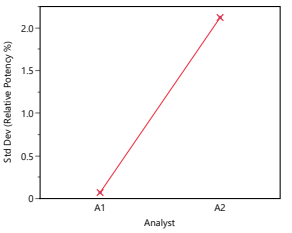


Gauge R&R Std Dev Plots

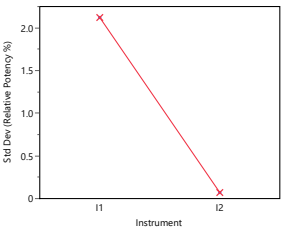
Mean Std Dev by Day



Mean Std Dev by Analyst



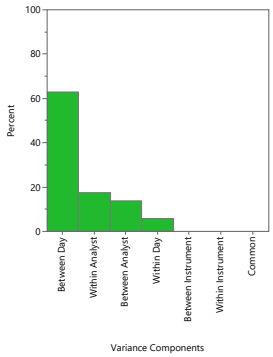
Mean Std Dev by Instrument



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=150	Total Between	2.965	76.70	1.722	5.3986	0.1458
Theoretical Concentration-Dilution=150	Between Day	2.432	62.90	1.560	5.3986	0.1458
Theoretical Concentration-Dilution=150	Between Analyst	0.533	13.79	0.730	1.1839	0.3902
Theoretical Concentration-Dilution=150	Between Instrument	0.000	0.00	0.000	.	.
Theoretical Concentration-Dilution=150		.	.	.		
Theoretical Concentration-Dilution=150	Total Within	0.901	23.30	0.949		
Theoretical Concentration-Dilution=150	Within Day	0.224	5.81	0.474		
Theoretical Concentration-Dilution=150	Within Analyst	0.677	17.50	0.822		
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	3.866	100.00	1.966		



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

Linearity Report Summary Table

Attribute	Reported Value (% of Tolerance)	Specification Limit	Pass/Fail	Reported Range
Lower Curve	9.05	56	Pass	
Upper Curve	198.93	156	Pass	
Lower 95% CL	40.26	56	Pass	
Upper 95% CL	163.02	156	Pass	
Accuracy/Bias 50	0.93	10	Pass	
Accuracy/Bias 75	8.10	10	Pass	
Accuracy/Bias 100	0.39	10	Pass	
Accuracy/Bias 125	4.07	10	Pass	
Accuracy/Bias 150	9.27	10	Pass	
Repeatability (n=1) 50	11.90	25	Pass	
Repeatability (n=1) 75	9.00	25	Pass	
Repeatability (n=1) 100	10.80	25	Pass	
Repeatability (n=1) 125	5.60	25	Pass	
Repeatability (n=1) 150	8.10	25	Pass	
Repeatability (n=3) 50	6.90	25	Pass	
Repeatability (n=3) 75	5.20	25	Pass	
Repeatability (n=3) 100	6.20	25	Pass	
Repeatability (n=3) 125	3.20	25	Pass	
Repeatability (n=3) 150	4.70	25	Pass	
Intermediate Precision (n=1) 50	23.20	30	Pass	
Intermediate Precision (n=1) 75	14.50	30	Pass	
Intermediate Precision (n=1) 100	11.00	30	Pass	
Intermediate Precision (n=1) 125	12.90	30	Pass	
Intermediate Precision (n=1) 150	16.90	30	Pass	
Intermediate Precision (n=3) 50	13.40	30	Pass	
Intermediate Precision (n=3) 75	8.40	30	Pass	
Intermediate Precision (n=3) 100	6.30	30	Pass	
Intermediate Precision (n=3) 125	7.40	30	Pass	
Intermediate Precision (n=3) 150	9.70	30	Pass	
Assay Range Curve (n=1)	.	.	Pass	50 - 150
Assay Range Curve (n=3)	.	.	Pass	50 - 150
Assay Range CI (n=1)	.	.	Pass	50 - 150
Assay Range CI (n=3)	.	.	Pass	50 - 150

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