

Linearity report b

Data Files:      Date:      Time:  
Linearity.jmp   Friday, October 25, 2024   10:50:14

Data Integrity

Study	
descriptives	Note
Analyst	a
Analytical method	b
Instrument	c
Purpose	d
Standard Expiry	ef
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: 2410251042  
JMP Version: 18.1.0

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Analyst Signature/Date

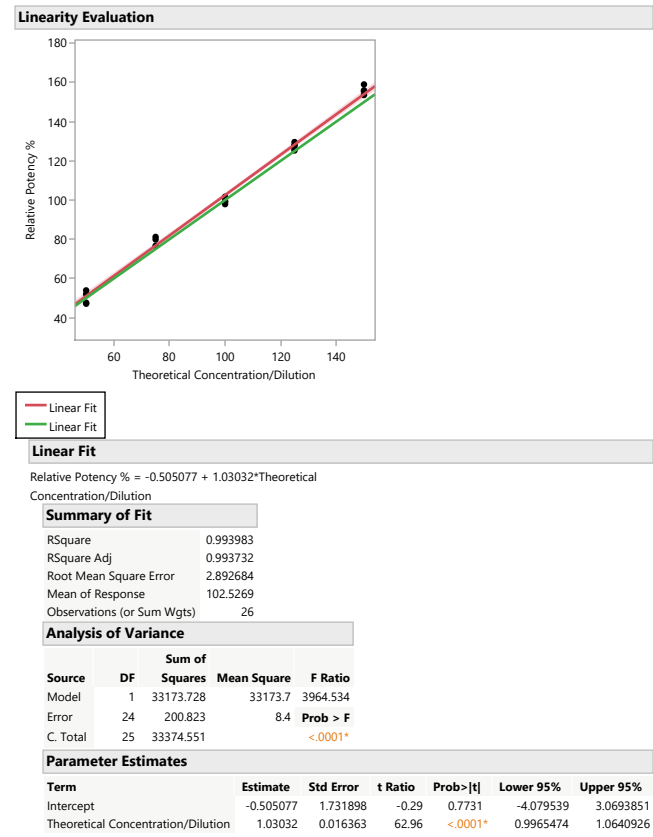
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Reviewer Signature/Date

Linearity - Data table

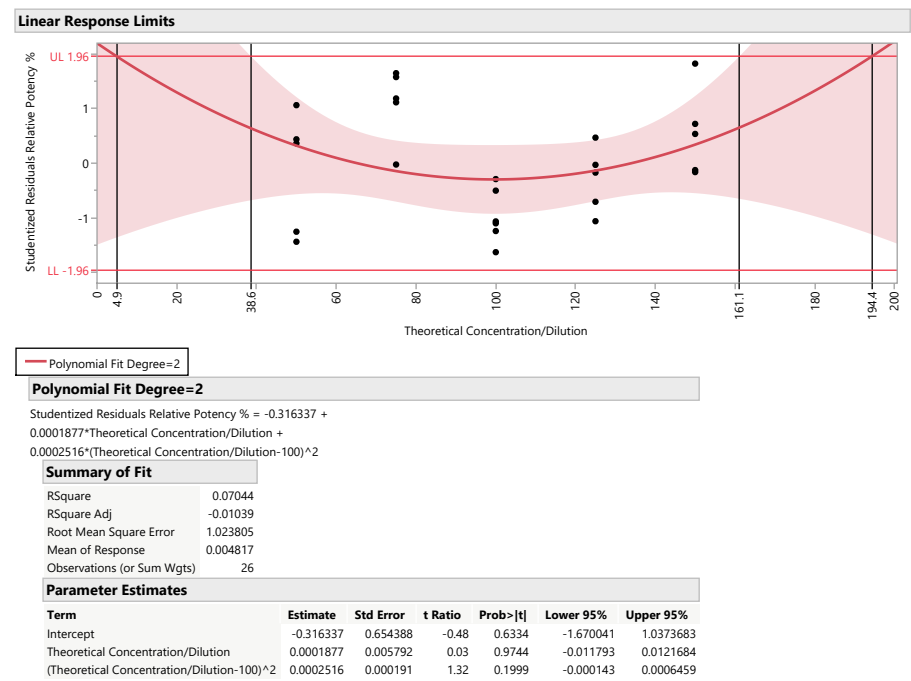
Theoretical				Relative Potency %	Jackknife Distances By			Include/ Exclude	Accuracy/Bias
Concentration/Dilution	Day	Analyst	Instrument		Theoretical	Concentration/Dilution	Outlier		
150 D1	A1	I2		153.6		0.83	Ok	Included	3.60
50 D1	A2	I2		47.1		0.45	Ok	Included	-2.90
150 D2	A2	I1		156		0.33	Ok	Included	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



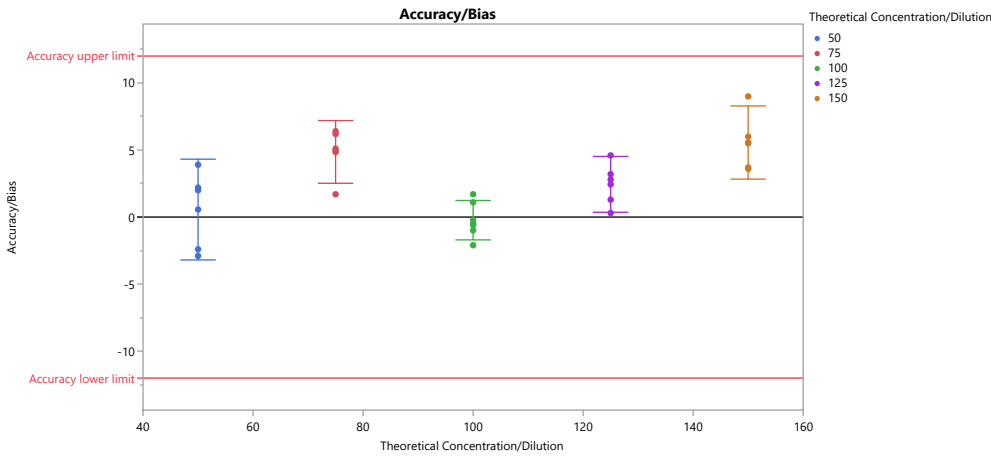
Linearity - Range of Linearity



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

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 Accuracy 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

Bias Acceptance Criterion: 20

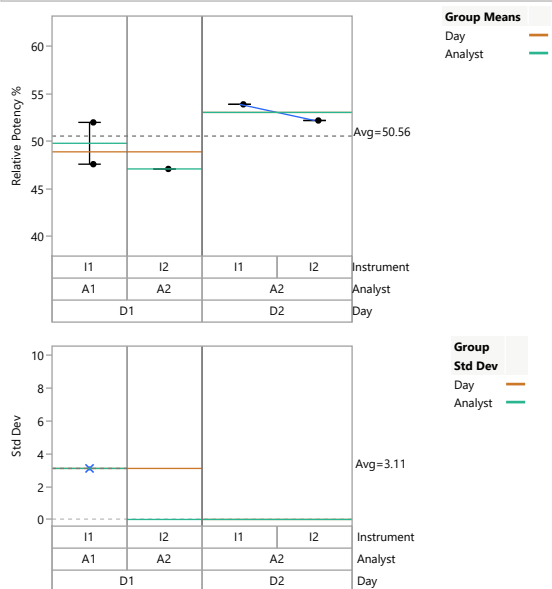
## Partition of Variation, Intermediate Precision

## Theoretical Concentration-Dilution=50

## Variability Gauge

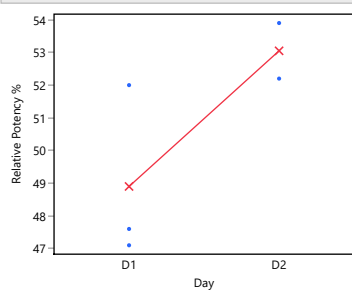
## Variability Gauge Analysis for Relative Potency %

## Variability Chart for Relative Potency %

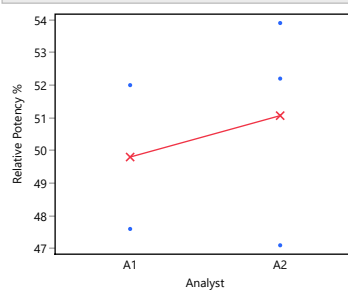


## Gauge R&amp;R Mean Plots

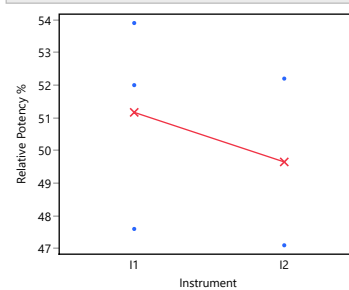
## Mean of Relative Potency % by Day



## Mean of Relative Potency % by Analyst

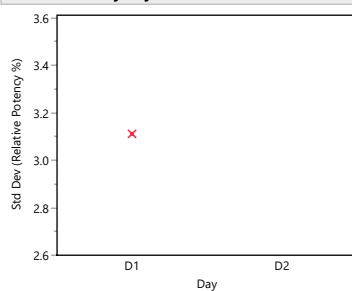


## Mean of Relative Potency % by Instrument

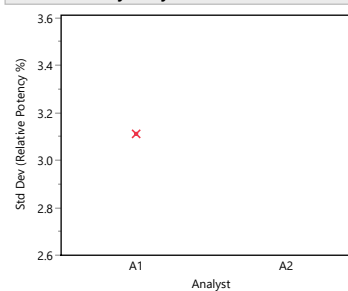


## Gauge R&amp;R Std Dev Plots

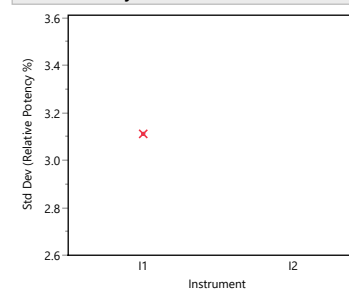
## Mean Std Dev by Day



## Mean Std Dev by Analyst



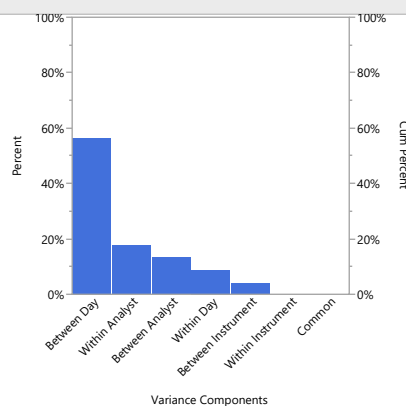
## Mean Std Dev by Instrument



## 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	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	Grand Total	7.330	100.00	2.707		

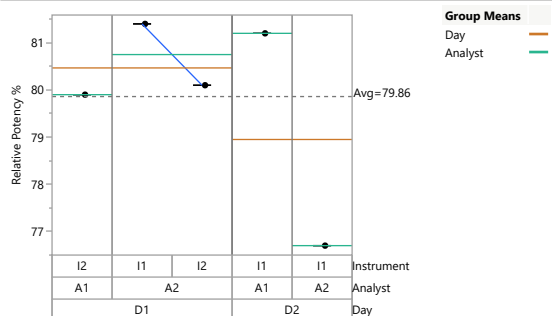


Theoretical Concentration-Dilution=75

## Variability Gauge

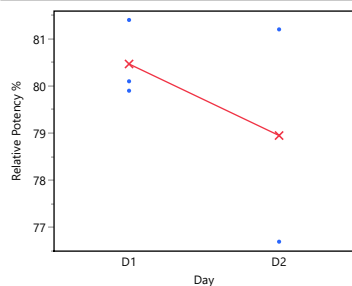
## Variability Gauge Analysis for Relative Potency %

## Variability Chart for Relative Potency %

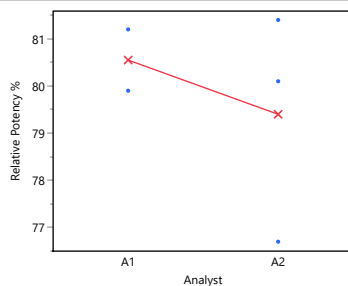


## Gauge R&amp;R Mean Plots

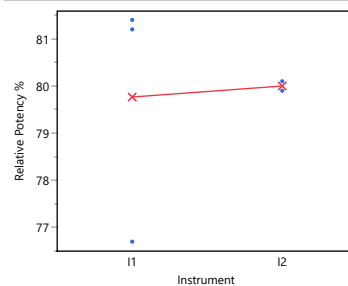
## Mean of Relative Potency % by Day



## Mean of Relative Potency % by Analyst



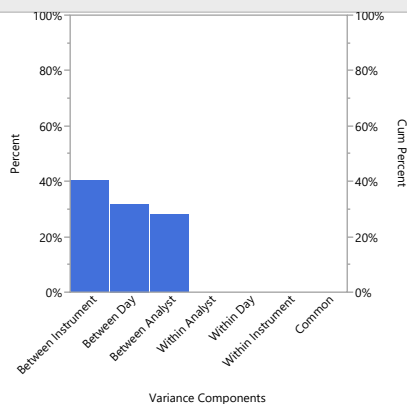
## Mean of Relative Potency % by Instrument



## 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	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	Grand Total	2.842	100.00	1.686		

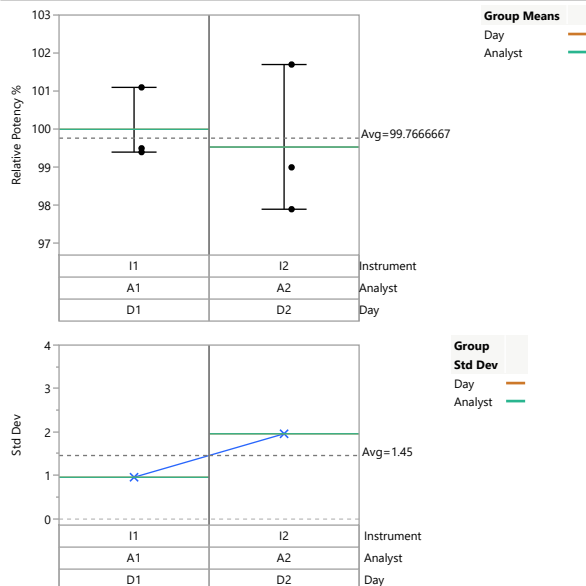


## Theoretical Concentration-Dilution=100

## Variability Gauge

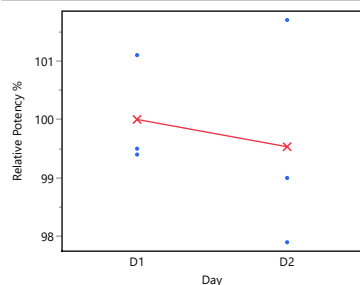
## Variability Gauge Analysis for Relative Potency %

## Variability Chart for Relative Potency %

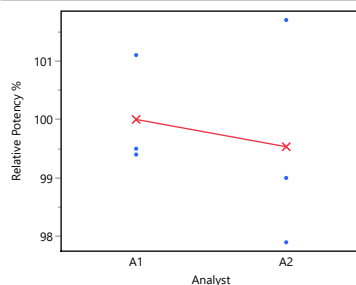


## Gauge R&amp;R Mean Plots

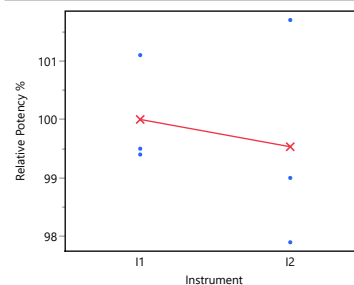
## Mean of Relative Potency % by Day



## Mean of Relative Potency % by Analyst

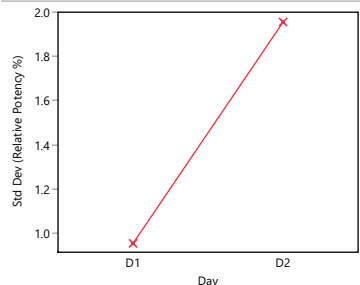


## Mean of Relative Potency % by Instrument

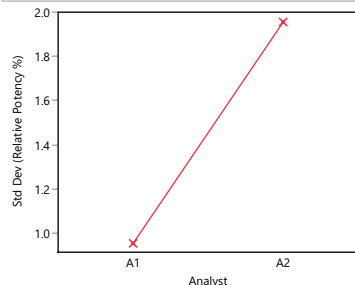


## Gauge R&amp;R Std Dev Plots

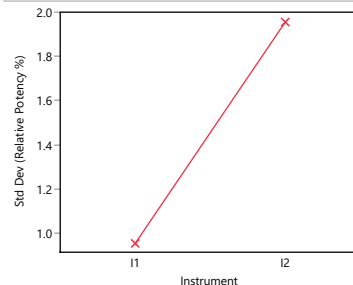
## Mean Std Dev by Day



## Mean Std Dev by Analyst



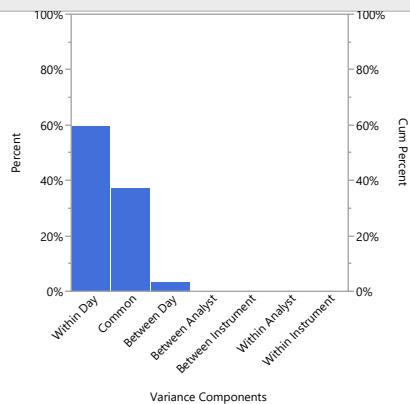
## Mean Std Dev by Instrument



## 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	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	Grand Total	1.632	100.00	1.278	.	.

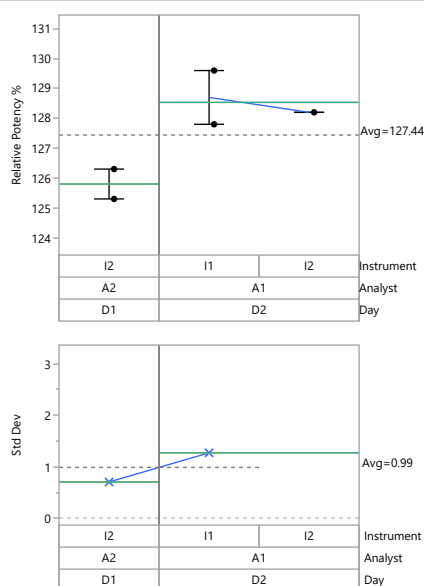


Theoretical Concentration-Dilution=125

## Variability Gauge

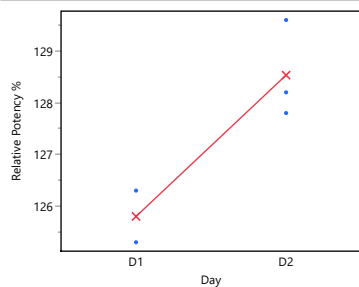
## Variability Gauge Analysis for Relative Potency %

## Variability Chart for Relative Potency %

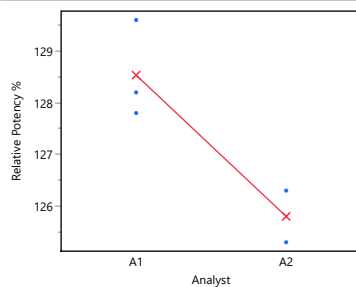


## Gauge R&amp;R Mean Plots

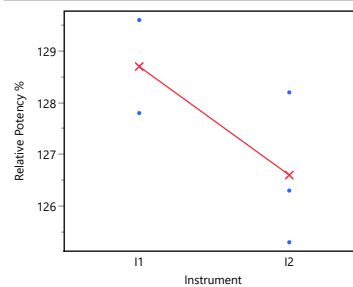
## Mean of Relative Potency % by Day



## Mean of Relative Potency % by Analyst

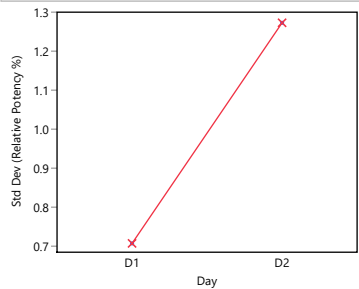


## Mean of Relative Potency % by Instrument

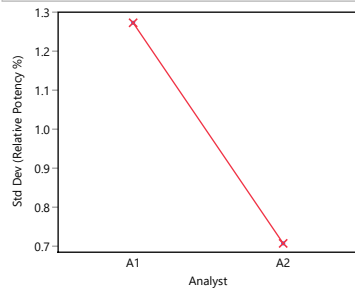


## Gauge R&amp;R Std Dev Plots

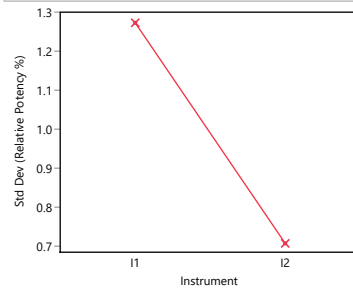
## Mean Std Dev by Day



## Mean Std Dev by Analyst



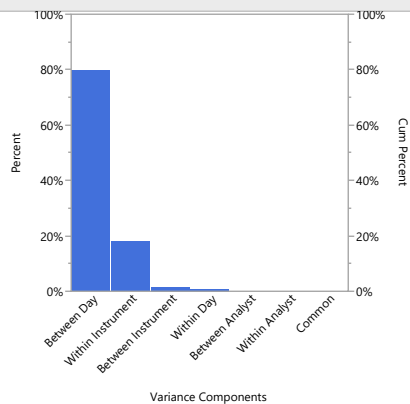
## Mean Std Dev by Instrument



## 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	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	Grand Total	2.250	100.00	1.500		



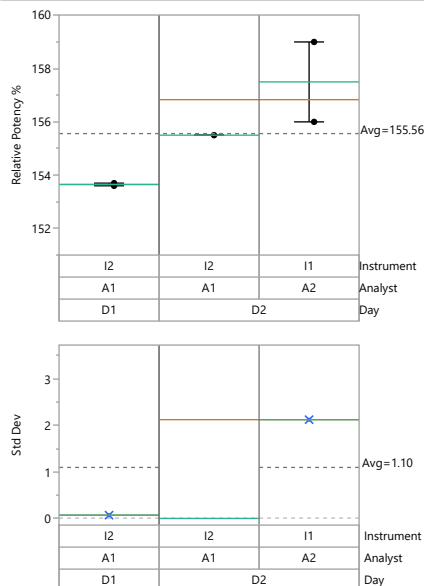


## Theoretical Concentration-Dilution=150

## Variability Gauge

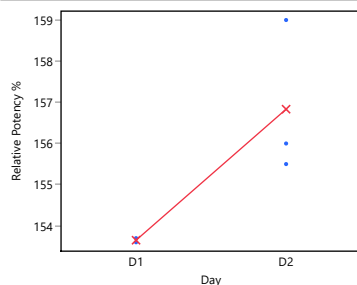
## Variability Gauge Analysis for Relative Potency %

## Variability Chart for Relative Potency %

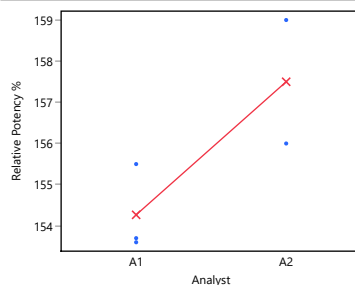


## Gauge R&amp;R Mean Plots

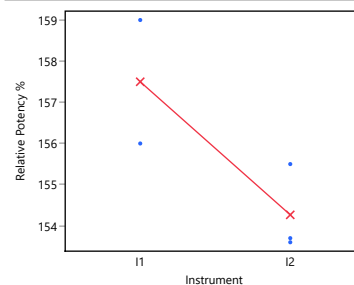
## Mean of Relative Potency % by Day



## Mean of Relative Potency % by Analyst

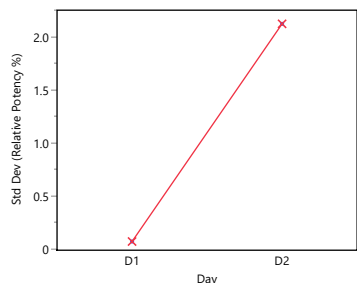


## Mean of Relative Potency % by Instrument

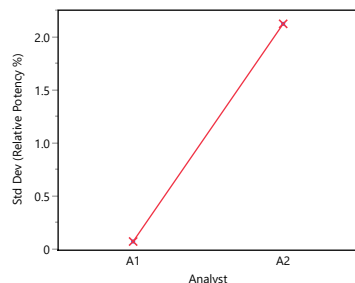


## Gauge R&amp;R Std Dev Plots

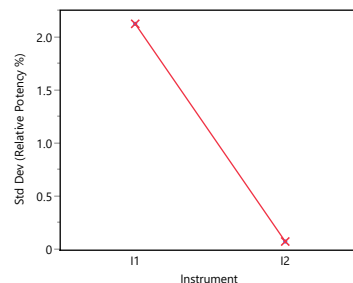
## Mean Std Dev by Day



## Mean Std Dev by Analyst



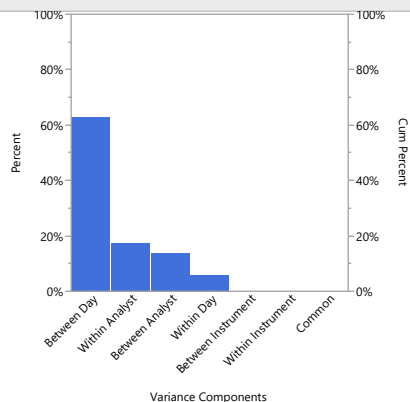
## Mean Std Dev by Instrument



## 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	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	Grand Total	3.866	100.00	1.966		



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	Results
Quadratic	4.9	194.4	Pass Linearity Criterion
95% Confidence Interval	38.6	161.1	Pass Linearity Criterion

Bias/Accuracy		
Theoretical Concentration/Dilution	Bias % of Tolerance	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)	Repeatability Pass/Fail (n=3)	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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