

Specificity Interference report b

Data Files:

Date:

Time:

Specificity interference.jmp

Thursday, December 18, 2025

16:43:21

Data Integrity

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

Specification	Value
Accuracy (%)	10
Tolerance (USL-LSL)	50

User Information

User Name: paule

User Domain: PADC-SURFACE

Logon Server: \\PADC-SURFACE

User Domain: PADC-SURFACE

Addin version: 2512181633

JMP Version: 19.0.1

Analyst Signature/Date

Reviewer Signature/Date

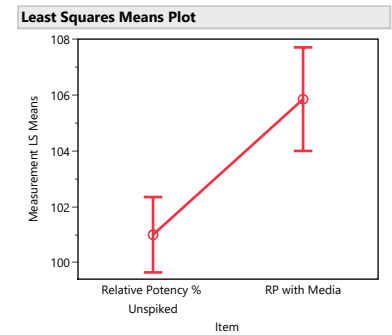
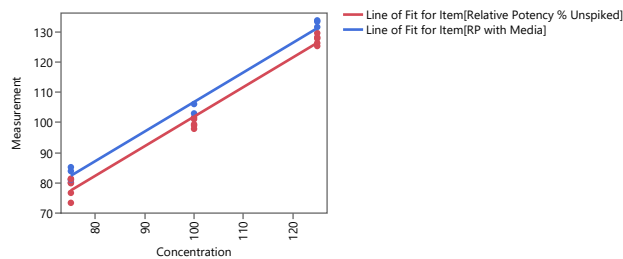
Specificity interference - Data table

Theoretical Concentration/Dilution	Relative Potency % Unspiked		RP with Forced Deg	RP with interaction
		RP with Media		
125	128.2	131.6	133	160.25
125	129.6	133.4	135.1	162
125	127.8	133.8	131.3	159.75
125	117.1	.	.	146.375
125	126.3	.	.	157.875
125	125.3	.	.	156.625
100	97.9	103	100	97.9
100	99.5	106.1	104.4	99.5
100	99.4	103.1	101.9	99.4
100	99	.	.	99
100	101.7	.	.	101.7
100	101.1	.	.	101.1
75	76.7	81	79	57.525
75	79.9	85.2	83.1	59.925
75	80.1	83.9	82.6	60.075
75	73.4	.	.	55.05
75	81.2	.	.	60.9
75	81.4	.	.	61.05

Specificity interference - Specificity RP with Media

Effect Tests					
Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	137.7629	18.3803	0.0003*
Concentration	1	1	9305.3042	1241.510	<.0001*
Item*Concentration	1	1	1.2278	0.1638	0.6896

Interaction not significant



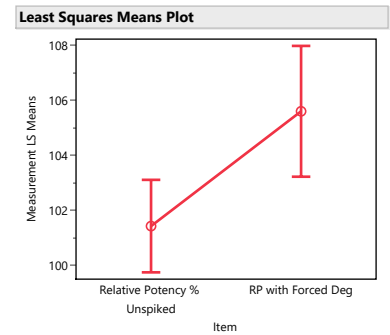
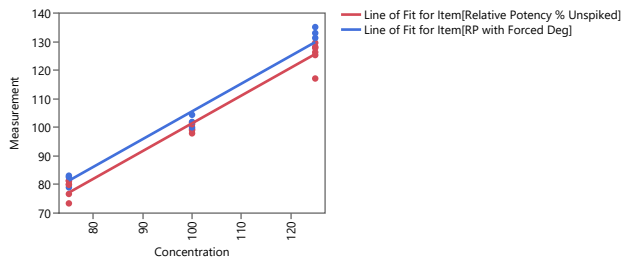
LSMeans Differences Student's t						
$\alpha = 0.050$ $t = 2.06866$						
Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with Media	Relative Potency % Unspiked	4.852431	1.108537	2.559247	7.145614	0.0002*

Result						
Level	- Level	Difference (h)	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL)	Result
RP with Media	Relative Potency % Unspiked	4.852431	2.559247	7.145614	9.7	Pass

Specificity interference - Specificity RP with Forced Deg

Effect Tests					
Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	104.7230	9.0578	0.0062*
Concentration	1	1	9702.2500	839.1810	<.0001*
Item*Concentration	1	1	21.4678	1.8568	0.1862

Interaction not significant



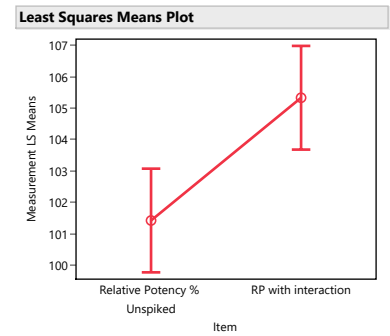
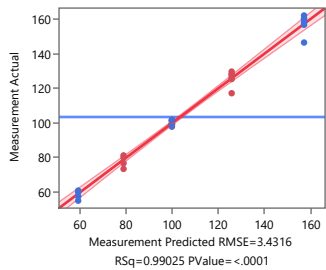
LSMeans Differences Student's t						
$\alpha = 0.050$ $t = 2.0639$						
Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with Forced Deg	Relative Potency % Unspiked	4.177778	1.412700	1.262108	7.093447	0.0069*

Result					
Level	- Level	Difference (h)	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL) Result
RP with Forced Deg	Relative Potency % Unspiked	4.177778	1.262108	7.093447	8.4 Pass

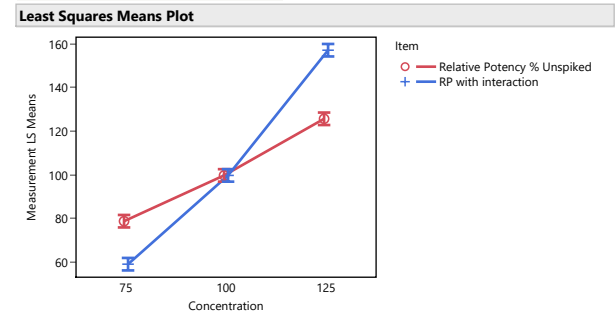
Specificity interference - Specificity RP with interaction

Effect Tests					
Source	Nparm	DF	Sum of Squares	F Ratio	Prob > F
Item	1	1	137.671	6.7072	0.0143*
Concentration	1	1	31533.875	1536.291	<.0001*
Item*Concentration	1	1	3920.648	191.0091	<.0001*

Significant interaction



LSMeans Differences Student's t						
$\alpha = 0.050$ $t = 2.04227$						
Level	- Level	Difference	Std Err Dif	Lower CL	Upper CL	p-Value
RP with interaction	Relative Potency % Unspiked	3.911111	1.143862	1.575033	6.247189	0.0018*



Result						
Level	- Level	Difference (h)	Lower CL	Upper CL	Specificity % of Tolerance (USL-LSL)	Result
RP with interaction,125	Relative Potency % Unspiked,125	31.42917	25.4031	37.4553	62.9	Fail
Relative Potency % Unspiked,75	RP with interaction,75	19.69583	13.6697	25.7219	39.4	Fail
RP with interaction,100	Relative Potency % Unspiked,100	0.00000	-6.0261	6.0261	0.0	Pass

Specificity interference - Data table with outlier test result

Concentration	Item	Measurement	Externally Studentized			Include/ Exclude	Externally Studentized			Include/ Exclude	Externally Studentized			Include/ Exclude
			Residuals	Measurement	Outlier		Residuals	Measurement 2	Outlier 2		Residuals	Measurement 3	Outlier 3	
125	Relative Potency % Unspiked	128.2		1.122	Ok	Included		1.052	Ok	Included		0.783	Ok	Included
125	RP with Media	131.6		0.010	Ok	Included				Included				Included
125	RP with Forced Deg	133				Included		0.551	Ok	Included				Included
125	RP with interaction	160.25				Included				Included		1.423	Ok	Included
125	Relative Potency % Unspiked	129.6		1.645	Ok	Included		1.537	Ok	Included		1.125	Ok	Included
125	RP with Media	133.4		0.664	Ok	Included				Included				Included
125	RP with Forced Deg	135.1				Included		1.306	Ok	Included				Included
125	RP with interaction	162				Included				Included		1.888	Ok	Included
125	Relative Potency % Unspiked	127.8		0.980	Ok	Included		0.920	Ok	Included		0.687	Ok	Included
125	RP with Media	133.8		0.813	Ok	Included				Included				Included
125	RP with Forced Deg	131.3				Included		-0.028	Ok	Included				Included
125	RP with interaction	159.75				Included				Included		1.295	Ok	Included
125	Relative Potency % Unspiked	117.1		-3.066	Outlier	Excluded		-2.816	Ok	Included		-1.930	Ok	Included
125	RP with interaction	146.375				Included				Included		-1.985	Ok	Included
125	Relative Potency % Unspiked	126.3		0.467	Ok	Included		0.439	Ok	Included		0.331	Ok	Included
125	RP with interaction	157.875				Included				Included		0.831	Ok	Included
125	Relative Potency % Unspiked	125.3		0.136	Ok	Included		0.127	Ok	Included		0.096	Ok	Included
125	RP with interaction	156.625				Included				Included		0.532	Ok	Included
100	Relative Potency % Unspiked	97.9		-1.140	Ok	Included		-1.069	Ok	Included		-0.795	Ok	Included
100	RP with Media	103		-1.273	Ok	Included				Included				Included
100	RP with Forced Deg	100				Included		-1.834	Ok	Included				Included
100	RP with interaction	97.9				Included				Included		-1.741	Ok	Included
100	Relative Potency % Unspiked	99.5		-0.610	Ok	Included		-0.573	Ok	Included		-0.431	Ok	Included
100	RP with Media	106.1		-0.224	Ok	Included				Included				Included
100	RP with Forced Deg	104.4				Included		-0.367	Ok	Included				Included
100	RP with interaction	99.5				Included				Included		-1.341	Ok	Included
100	Relative Potency % Unspiked	99.4		-0.642	Ok	Included		-0.603	Ok	Included		-0.454	Ok	Included
100	RP with Media	103.1		-1.237	Ok	Included				Included				Included
100	RP with Forced Deg	101.9				Included		-1.163	Ok	Included				Included
100	RP with interaction	99.4				Included				Included		-1.366	Ok	Included
100	Relative Potency % Unspiked	99		-0.772	Ok	Included		-0.725	Ok	Included		-0.544	Ok	Included
100	RP with interaction	99				Included				Included		-1.464	Ok	Included
100	Relative Potency % Unspiked	101.7		0.087	Ok	Included		0.082	Ok	Included		0.062	Ok	Included
100	RP with interaction	101.7				Included				Included		-0.821	Ok	Included
100	Relative Potency % Unspiked	101.1		-0.101	Ok	Included		-0.095	Ok	Included		-0.072	Ok	Included
100	RP with interaction	101.1				Included				Included		-0.960	Ok	Included
75	Relative Potency % Unspiked	76.7		-0.415	Ok	Included		-0.391	Ok	Included		-0.294	Ok	Included
75	RP with Media	81		-0.363	Ok	Included				Included				Included
75	RP with Forced Deg	79				Included		-0.277	Ok	Included				Included
75	RP with interaction	57.525				Included				Included		0.286	Ok	Included
75	Relative Potency % Unspiked	79.9		0.647	Ok	Included		0.608	Ok	Included		0.457	Ok	Included
75	RP with Media	85.2		1.185	Ok	Included				Included				Included
75	RP with Forced Deg	83.1				Included		1.144	Ok	Included				Included
75	RP with interaction	59.925				Included				Included		0.858	Ok	Included
75	Relative Potency % Unspiked	80.1		0.715	Ok	Included		0.671	Ok	Included		0.504	Ok	Included
75	RP with Media	83.9		0.689	Ok	Included				Included				Included
75	RP with Forced Deg	82.6				Included		0.962	Ok	Included				Included
75	RP with interaction	60.075				Included				Included		0.894	Ok	Included
75	Relative Potency % Unspiked	73.4		-1.584	Ok	Included		-1.481	Ok	Included		-1.087	Ok	Included
75	RP with interaction	55.05				Included				Included		-0.294	Ok	Included
75	Relative Potency % Unspiked	81.2		1.098	Ok	Included		1.030	Ok	Included		0.767	Ok	Included
75	RP with interaction	60.9				Included				Included		1.097	Ok	Included
75	Relative Potency % Unspiked	81.4		1.170	Ok	Included		1.096	Ok	Included		0.815	Ok	Included
75	RP with interaction	61.05				Included				Included		1.134	Ok	Included

K Sigma: 3

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