

Specificity Interference report

Data Files: **Date:** **Time:**
Specificity.jmp Wednesday, March 22, 2023 10:25:44

| Specification | Value |
|---------------------|-------|
| Accuracy (%) | 10 |
| Tolerance (USL-LSL) | 60 |

Analytical Method: a

User Information

User Name: paule
User Domain: PADC-SURFACE
Logon Server: \\PADC-SURFACE
User Domain: PADC-SURFACE
Addin version: 2303221011
JMP Version: 17.0.0

Analyst Signature/Date

Reviewer Signature/Date

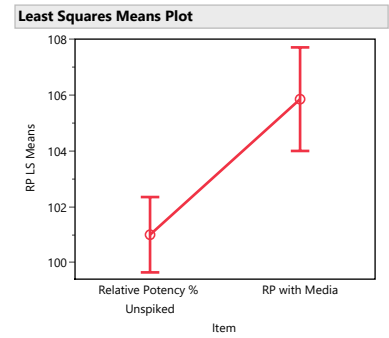
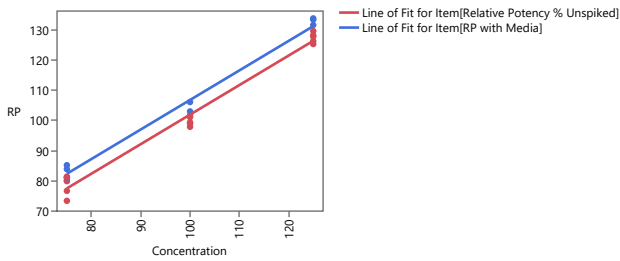
Data table

| Theoretical Concentration/Dilution | Relative Potency % Unspiked | RP with Media | RP with Forced Deg | RP with interaction |
|---------------------------------------|--------------------------------|------------------|-----------------------|------------------------|
| 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 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



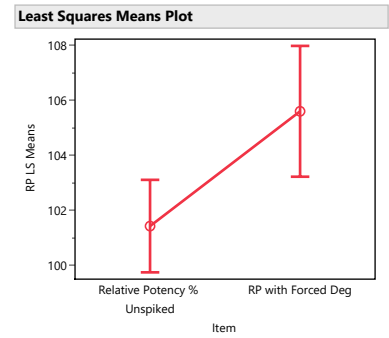
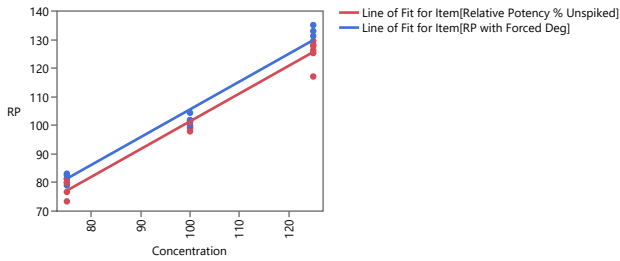
| LSMeans Differences Student's t | | | | | | |
|---------------------------------|-----------------------------|------------|-------------|----------|----------|---------|
| $\alpha = 0.050$ $t = 2.06866$ | | | | | | |
| Level | - Level | Difference | Std Err Dif | Lower CL | Upper CL | p-Value |
|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

| Result | | | | | | |
|---------------|-----------------------------|------------------|----------|----------|--------------------------------------|--------|
| Level | - Level | Difference (%RP) | Lower CL | Upper CL | Specificity % of Tolerance (USL-LSL) | Result |
| RP with Media | Relative Potency % Unspiked | 4.852431 | 2.559247 | 7.145614 | 8.1 | Pass |

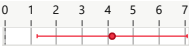
Specificity RP with Forced Deg

| 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* |

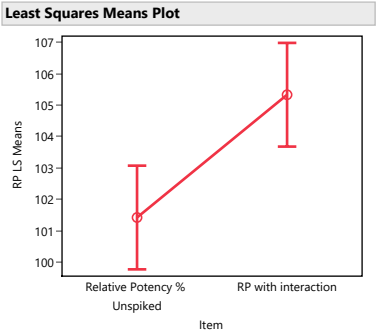
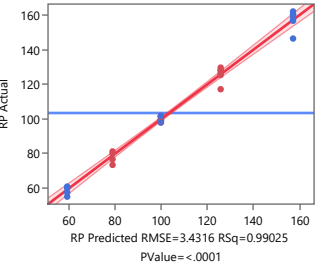


| Result | | | | | | |
|--------------------|-----------------------------|------------------|----------|----------|--------------------------------------|--------|
| Level | - Level | Difference (%RP) | Lower CL | Upper CL | Specificity % of Tolerance (USL-LSL) | Result |
| RP with Forced Deg | Relative Potency % Unspiked | 4.177778 | 1.262108 | 7.093447 | 7.0 | Pass |

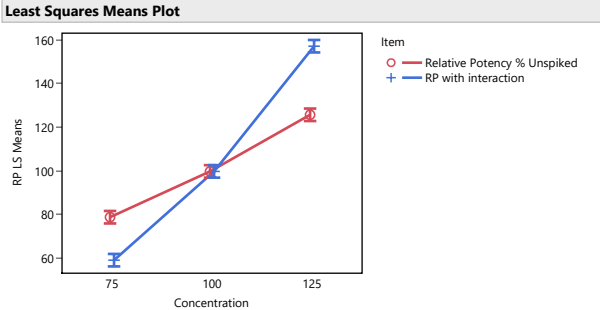
Specificity RP with interaction

| 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 (%RP) | Lower CL | Upper CL | Specificity % of Tolerance (USL-LSL) | Result |
| RP with interaction,125 | Relative Potency % Unspiked,125 | 31.42917 | 25.4031 | 37.4553 | 52.4 | Fail |
| Relative Potency % Unspiked,75 | RP with interaction,75 | 19.69583 | 13.6697 | 25.7219 | 32.8 | Fail |
| RP with interaction,100 | Relative Potency % Unspiked,100 | 0.00000 | -6.0261 | 6.0261 | 0.0 | Pass |

Data table with outlier test result

| Concentration | Item | RP | Externally Studentized | | Include/ | Exclude | Externally Studentized | | Include/ | Exclude | Externally Studentized | | Include/ | Exclude |
|---------------|-----------------------------|---------|------------------------|---------|----------|---------|------------------------|----|----------|---------|------------------------|----|----------|---------|
| | | | Residuals | RP | | | Residuals | RP | | | Residuals | RP | | |
| 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