

STATISTICAL ANALYSIS

CLINICAL STUDY PROTOCOL WHLS - 005

**COMPARISONS OF MEAN PLAQUE SCORES
VERSUS BASELINES AND PLACEBO**

Baseline Comparisons: ANOVA (are baselines significantly different)

LS MINT - MOL WT CLINICAL STUDIES

One-way Analysis of Variance (ANOVA)

The P value is 0.6886, considered not significant.
Variation among column means is not significantly greater than expected by chance.

Tukey-Kramer Multiple Comparisons Test

If the value of q is greater than 3.829 then the P value is less than 0.05.

Comparison	Mean Difference	q	P value	
BASE PLACEBO vs BASE 0.6MM	0.1032	1.420	ns	P>0.05
BASE PLACEBO vs BASE 2.5MM/10%	0.04083	0.6061	ns	P>0.05
BASE PLACEBO vs BASE 2.5MM/5%	-0.01806	0.2680	ns	P>0.05
BASE 0.6MM vs BASE 2.5MM/10%	-0.06238	0.8101	ns	P>0.05
BASE 0.6MM vs BASE 2.5MM/5%	-0.1213	1.575	ns	P>0.05
BASE 2.5MM/10% vs BASE 2.5MM/5%	-0.05889	0.8176	ns	P>0.05

Difference	Mean Difference	95% Confidence Interval	
		From	To
BASE PLACEBO - BASE 0.6MM	0.1032	-0.1750	0.3814
BASE PLACEBO - BASE 2.5MM/10%	0.04083	-0.2171	0.2988
BASE PLACEBO - BASE 2.5MM/5%	-0.01806	-0.2760	0.2399
BASE 0.6MM - BASE 2.5MM/10%	-0.06238	-0.3572	0.2324
BASE 0.6MM - BASE 2.5MM/5%	-0.1213	-0.4161	0.1735
BASE 2.5MM/10% - BASE 2.5MM/5%	-0.05889	-0.3347	0.2169

Assumption test: Are the standard deviations of the groups equal?

ANOVA assumes that the data are sampled from populations with identical SDs. This assumption is tested using the method of Bartlett.

Bartlett statistic (corrected) = 0.3561

The P value is 0.9491.

Bartlett's test suggests that the differences among the SDs is not significant.

Assumption test: Are the data sampled from Gaussian distributions?

ANOVA assumes that the data are sampled from populations that follow Gaussian distributions. This assumption is tested using the method Kolmogorov and Smirnov:

Group	KS	P Value	Passed normality test?
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BASE PLACEBO	0.1540	>0.10	Yes
BASE 0.6MM	0.2311	>0.10	Yes
BASE 2.5MM/10%	0.1404	>0.10	Yes
BASE 2.5MM/5%	0.3096	0.0130	No

At least one column failed the normality test with $P < 0.05$. Consider using a nonparametric test or transforming the data (i.e. converting to logarithms or reciprocals).

Intermediate calculations. ANOVA table

Source of variation	Degrees of freedom	Sum of squares	Mean square
Treatments (between columns)	3	0.06926	0.02309
Residuals (within columns)	33	1.541	0.04669
Total	36	1.610	

$$F = 0.4945 = (MS_{\text{treatment}} / MS_{\text{residual}})$$

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
BASE PLACEBO	12	2.118	0.2007	0.05793	2.105
BASE 0.6MM	7	2.014	0.2356	0.08904	2.010
BASE 2.5MM/10%	9	2.077	0.2026	0.06754	2.040
BASE 2.5MM/5%	9	2.136	0.2336	0.07786	2.040

Group	Minimum	Maximum	95% Confidence Interval	
			From	To
BASE PLACEBO	1.860	2.470	1.990	2.245
BASE 0.6MM	1.720	2.470	1.796	2.232
BASE 2.5MM/10%	1.820	2.450	1.921	2.232
BASE 2.5MM/5%	1.930	2.560	1.956	2.315

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Baseline Comparisons: Nonparametric ANOVA (are baselines significantly different)

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Kruskal-Wallis Test (Nonparametric ANOVA)

The P value is 0.6640, considered not significant.
Variation among column medians is not significantly greater than expected by chance.

The P value is approximate (from chi-square distribution) because at least one column has two or more identical values.

Calculation detail

Group	Number of Points	Sum of Ranks	Mean of Ranks
BASE PLACEBO	12	242.50	20.208
BASE 0.6MM	7	105.00	15.000
BASE 2.5MM/10%	9	163.50	18.167
BASE 2.5MM/5%	9	192.00	21.333

Kruskal-Wallis Statistic KW = 1.580 (corrected for ties)

Dunn's Multiple Comparisons Test

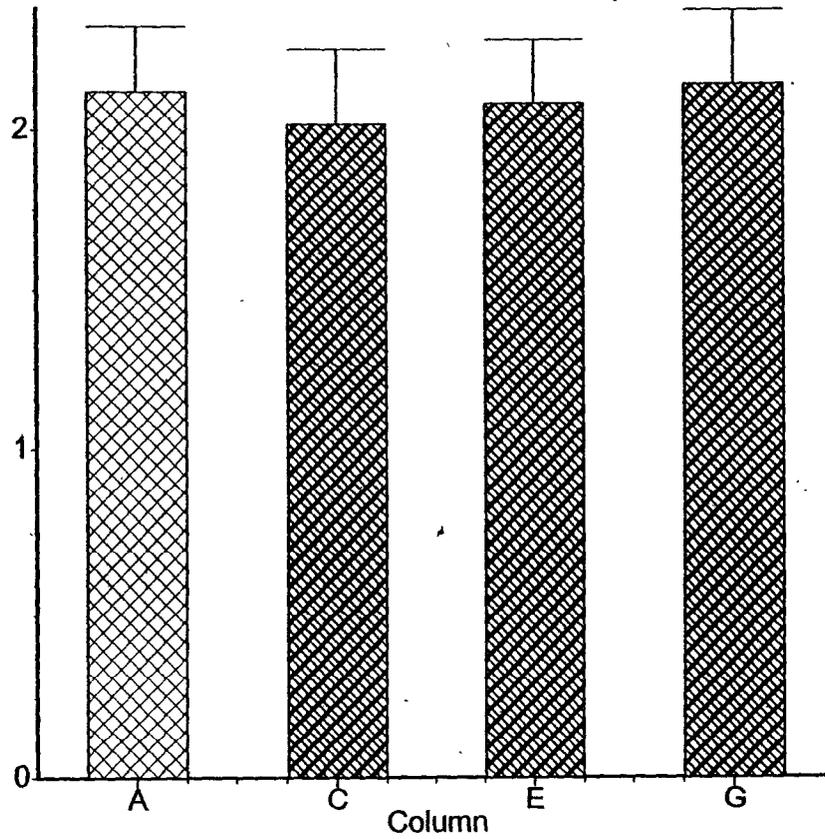
Comparison	Mean Rank Difference	P value
BASE PLACEBO vs. BASE 0.6MM	5.208	ns P>0.05
BASE PLACEBO vs. BASE 2.5MM/10%	2.042	ns P>0.05
BASE PLACEBO vs. BASE 2.5MM/5%	-1.125	ns P>0.05
BASE 0.6MM vs. BASE 2.5MM/10%	-3.167	ns P>0.05
BASE 0.6MM vs. BASE 2.5MM/5%	-6.333	ns P>0.05
BASE 2.5MM/10% vs. BASE 2.5MM/5%	-3.167	ns P>0.05

Summary of Data

Group	Number of Points	Median	Minimum	Maximum
BASE PLACEBO	12	2.105	1.860	2.470
BASE 0.6MM	7	2.010	1.720	2.470
BASE 2.5MM/10%	9	2.040	1.820	2.450
BASE 2.5MM/5%	9	2.040	1.930	2.560

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF ALL BASELINES

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: Baseline versus Final
[Placebo]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of BASE PLACEBO and FINAL PLACEBO differ significantly?

The two-tailed P value is 0.0387, considered significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 36.000

U' = 108.00

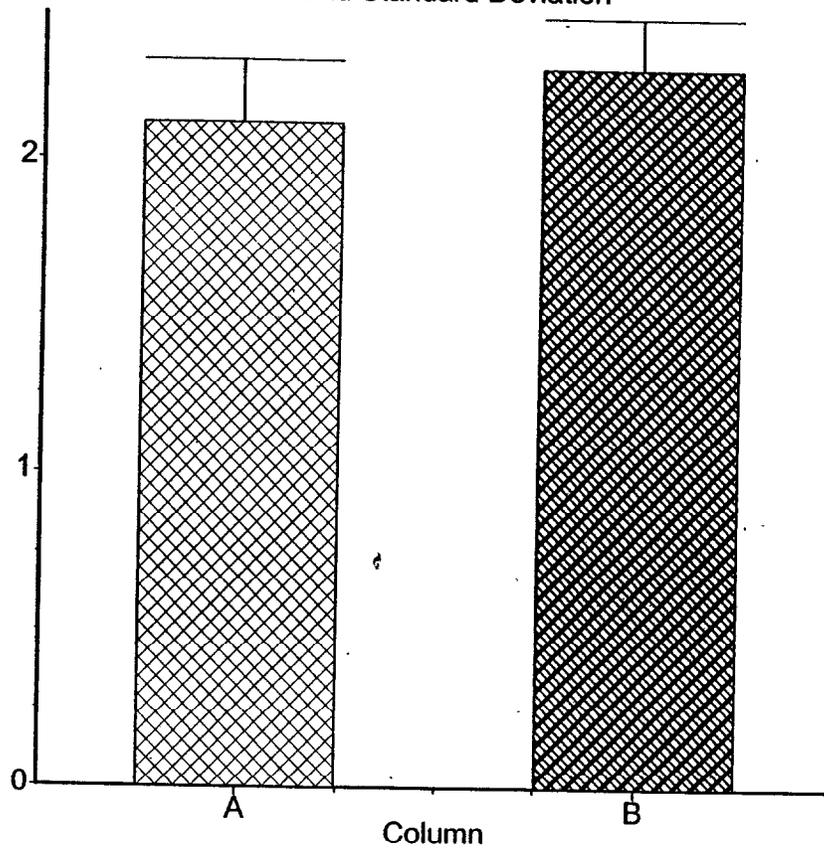
Sum of ranks in BASE PLACEBO = 114.00. Sum of ranks in FINAL PLACEBO = 186.00.

Summary of Data

Parameter:	BASE PLACEBO	FINAL PLACEBO
Mean:	2.118	2.297
# of points:	12	12
Std deviation:	0.2007	0.1621
Std error:	0.05793	0.04680
Minimum:	1.860	2.090
Maximum:	2.470	2.610
Median:	2.105	2.275
Lower 95% CI:	1.990	2.194
Upper 95% CI:	2.245	2.400

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF PLACEBO BASE vs FINAL

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: Baseline versus Final
[222 (600,000 cs) 10% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of BASE 0.6MM and FINAL 0.6MM differ significantly?

The two-tailed P value is 0.0023, considered very significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 2.000

U' = 47.000

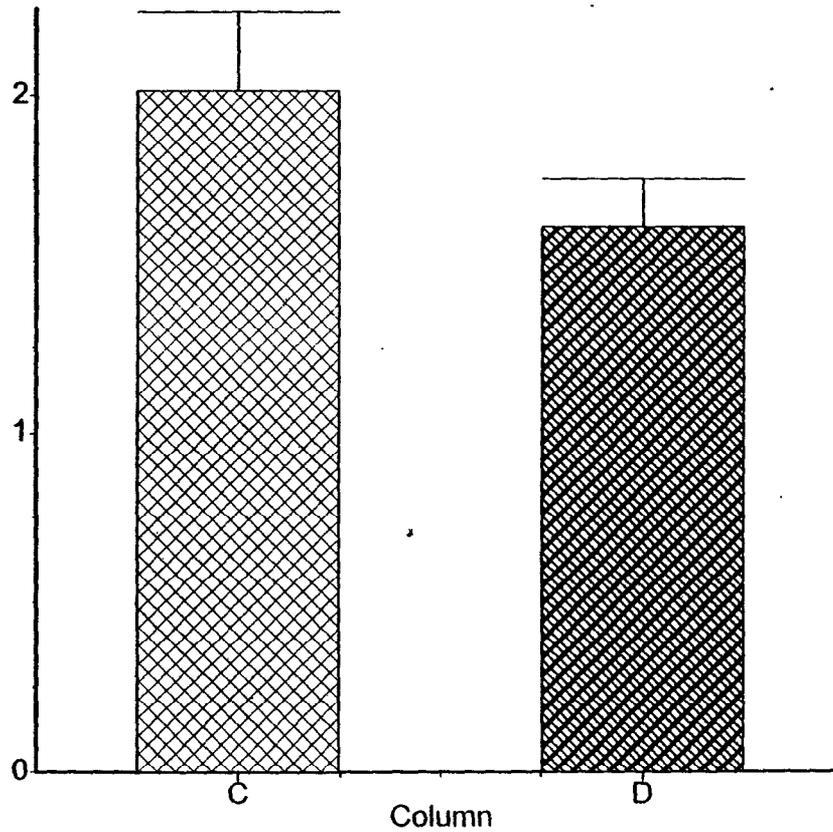
Sum of ranks in BASE 0.6MM = 75.000. Sum of ranks in FINAL 0.6MM = 30.000.

Summary of Data

Parameter:	BASE 0.6MM	FINAL 0.6MM
Mean:	2.014	1.611
# of points:	7	7
Std deviation:	0.2356	0.1402
Std error:	0.08904	0.05298
Minimum:	1.720	1.430
Maximum:	2.470	1.800
Median:	2.010	1.640
Lower 95% CI:	1.796	1.482
Upper 95% CI:	2.232	1.741

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF 600,000cs BASE vs FINAL

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: 48 Hour Final Plaque Means
[Placebo versus 222 (600,000 cs) 10% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of FINAL PLACEBO and FINAL 0.6MM differ significantly?

The two-tailed P value is < 0.0001 , considered extremely significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 0.000

U' = 84.000

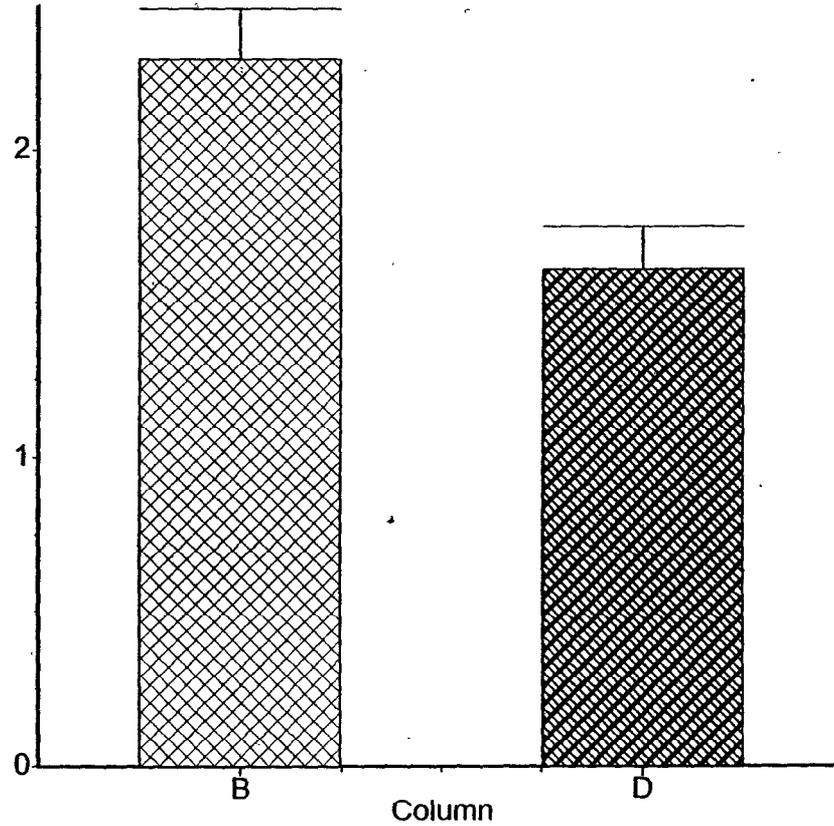
Sum of ranks in FINAL PLACEBO = 162.00. Sum of ranks in FINAL 0.6MM = 28.000.

Summary of Data

Parameter:	FINAL PLACEBO	FINAL 0.6MM
Mean:	2.297	1.611
# of points:	12	7
Std deviation:	0.1621	0.1402
Std error:	0.04680	0.05298
Minimum:	2.090	1.430
Maximum:	2.610	1.800
Median:	2.275	1.640
Lower 95% CI:	2.194	1.482
Upper 95% CI:	2.400	1.741

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF FINALS [PLACEBO vs 600,000cs]

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: Baseline versus Final
[555 (2,500,000 cs) 10% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of BASE 2.5MM/10% and FINAL 2.5MM/10% differ significantly?

The two-tailed P value is 0.0005, considered extremely significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 4.000

U' = .77.000

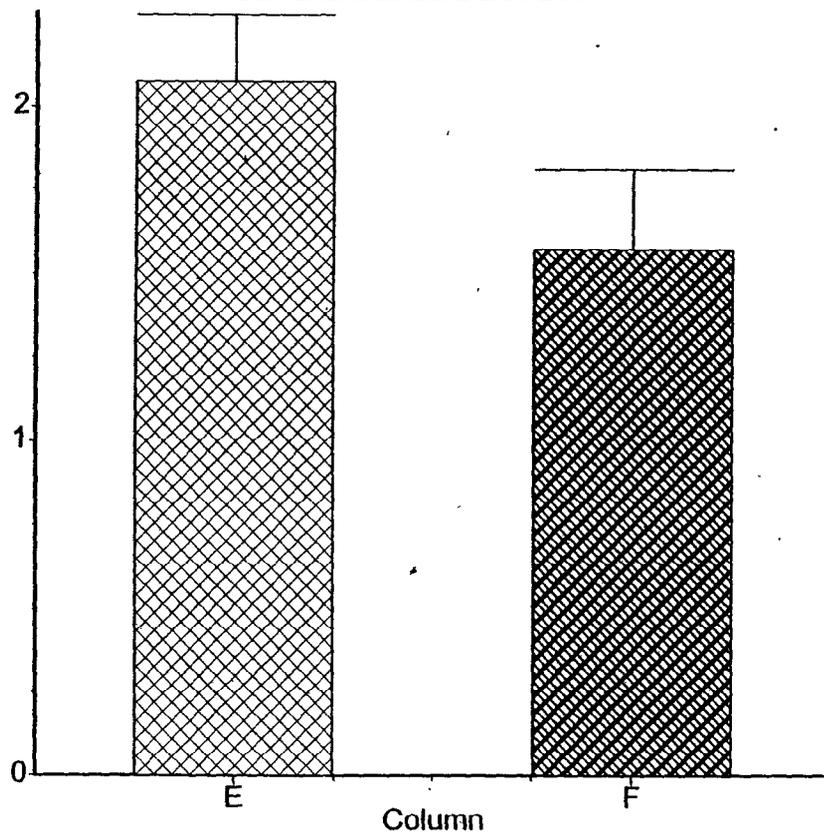
Sum of ranks in BASE 2.5MM/10% = 122.00. Sum of ranks in FINAL 2.5MM/10% = 49.000.

Summary of Data

Parameter:	BASE 2.5MM/10%	FINAL 2.5MM/10%
Mean:	2.077	1.574
# of points:	9	9
Std deviation:	0.2026	0.2368
Std error:	0.06754	0.07892
Minimum:	1.820	1.250
Maximum:	2.450	1.960
Median:	2.040	1.500
Lower 95% CI:	1.921	1.392
Upper 95% CI:	2.232	1.756

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF 2,500,000cs (10%) [BASE vs FINAL

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: 48 Hour Final Plaque Means
[Placebo versus 555 (2,500,000 cs) 10% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of FINAL PLACEBO and FINAL 2.5MM/10% differ significantly?

The two-tailed P value is < 0.0001 , considered extremely significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 0.000

U' = 108.00

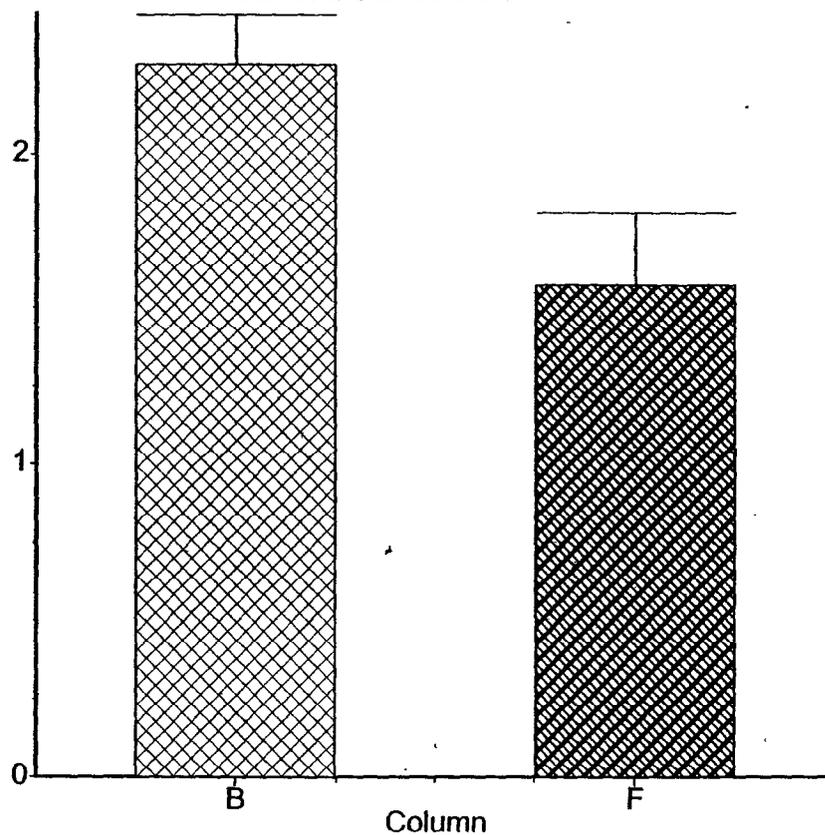
Sum of ranks in FINAL PLACEBO = 186.00. Sum of ranks in FINAL 2.5MM/10% = 45.000.

Summary of Data

Parameter:	FINAL PLACEBO	FINAL 2.5MM/10%
Mean:	2.297	1.574
# of points:	12	9
Std deviation:	0.1621	0.2368
Std error:	0.04680	0.07892
Minimum:	2.090	1.250
Maximum:	2.610	1.960
Median:	2.275	1.500
Lower 95% CI:	2.194	1.392
Upper 95% CI:	2.400	1.756

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF FINALS [PLACEBO vs 2,500,000cs (10 %)]

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: Baseline versus Final [666 (2,500,000 cs) 5% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of BASE 2.5MM/5% and FINAL 2.5MM/5% differ significantly?

The two-tailed P value is < 0.0001 , considered extremely significant.
The P value is exact.

Calculation details

Mann-Whitney U-statistic = 0.000

U' = 81.000

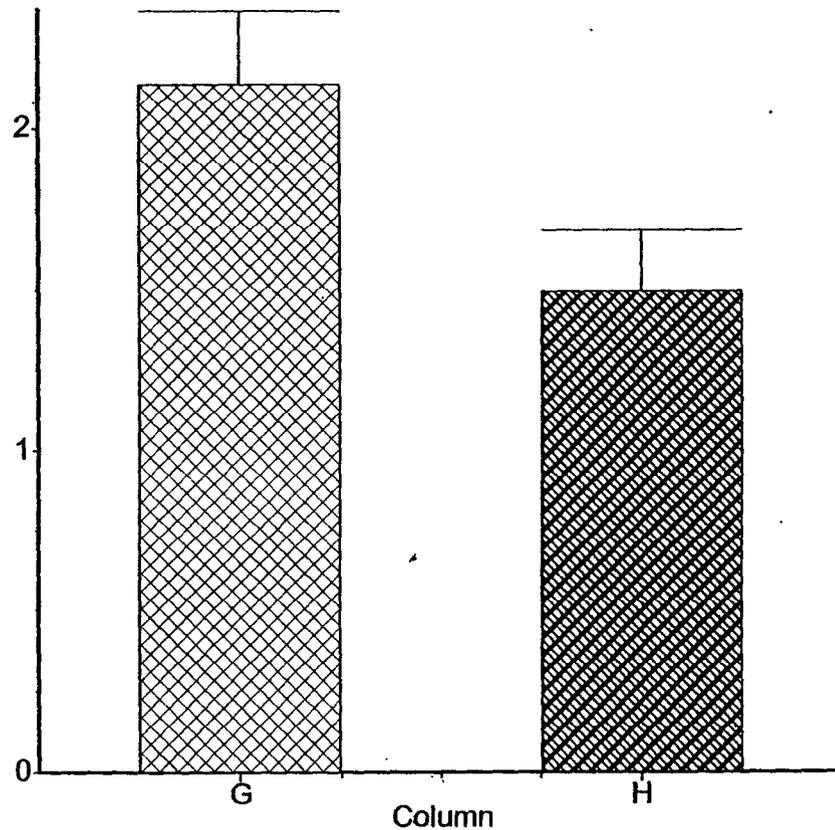
Sum of ranks in BASE 2.5MM/5% = 126.00. Sum of ranks in FINAL 2.5MM/5% = 45.000.

Summary of Data

Parameter:	BASE 2.5MM/5%	FINAL 2.5MM/5%
Mean:	2.136	1.490
# of points:	9	9
Std deviation:	0.2336	0.1914
Std error:	0.07786	0.06381
Minimum:	1.930	1.240
Maximum:	2.560	1.900
Median:	2.040	1.430
Lower 95% CI:	1.956	1.343
Upper 95% CI:	2.315	1.637

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF 2,500,000cs (5%) [BASE vs FINAL

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: 48 Hour Final Plaque Means
[Placebo versus 666 (2,500,000 cs) 5% PDMS]

LS MINT - MOL WT CLINICAL STUDIES

Mann-Whitney Test

Do the medians of FINAL PLACEBO and FINAL 2.5MM/5% differ significantly?

The two-tailed P value is < 0.0001 , considered extremely significant.

The P value is exact.

Calculation details

Mann-Whitney U-statistic = 0.000

U' = 108.00

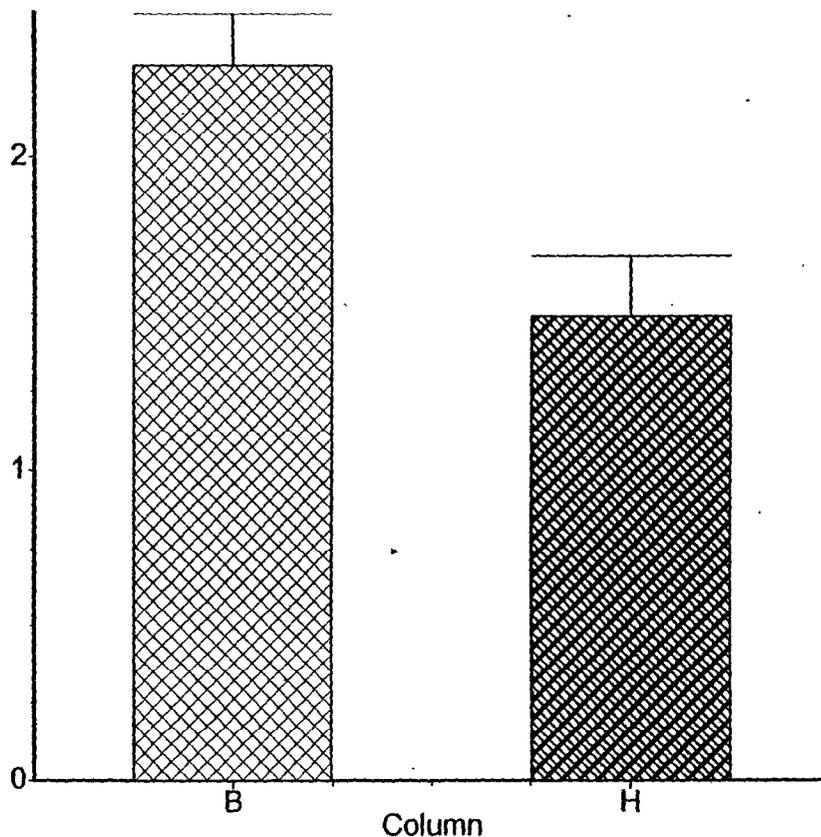
Sum of ranks in FINAL PLACEBO = 186.00. Sum of ranks in FINAL 2.5MM/5% = 45.000.

Summary of Data

Parameter:	FINAL PLACEBO	FINAL 2.5MM/5%
Mean:	2.297	1.490
# of points:	12	9
Std deviation:	0.1621	0.1914
Std error:	0.04680	0.06381
Minimum:	2.090	1.240
Maximum:	2.610	1.900
Median:	2.275	1.430
Lower 95% CI:	2.194	1.343
Upper 95% CI:	2.400	1.637

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LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF FINALS [PLACEBO vs 2,500,000cs (5%)]

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666

Comparison: Parametric ANOVA among all FINALS including PLACEBO

LS MINT - MOL WT CLINICAL STUDIES

One-way Analysis of Variance (ANOVA)

The P value is < 0.0001, considered extremely significant.
Variation among column means is significantly greater than expected by chance.

Tukey-Kramer Multiple Comparisons Test

If the value of q is greater than 3.829 then the P value is less than 0.05.

Comparison	Mean Difference	q	P value
FINAL PLACEBO vs FINAL 0.6MM	0.6852	10.922	*** P<0.001
FINAL PLACEBO vs FINAL 2.5MM/10%	0.7222	12.416	*** P<0.001
FINAL PLACEBO vs FINAL 2.5MM/5%	0.8067	13.867	*** P<0.001
FINAL 0.6MM vs FINAL 2.5MM/10%	0.03698	0.5563	ns P>0.05
FINAL 0.6MM vs FINAL 2.5MM/5%	0.1214	1.827	ns P>0.05
FINAL 2.5MM/10% vs FINAL 2.5MM/5%	0.08444	1.358	ns P>0.05

Difference	Mean Difference	95% Confidence Interval	
		From	To
FINAL PLACEBO - FINAL 0.6MM	0.6852	0.4450	0.9255
FINAL PLACEBO - FINAL 2.5MM/10%	0.7222	0.4995	0.9449
FINAL PLACEBO - FINAL 2.5MM/5%	0.8067	0.5839	1.029
FINAL 0.6MM - FINAL 2.5MM/10%	0.03698	-0.2176	0.2915
FINAL 0.6MM - FINAL 2.5MM/5%	0.1214	-0.1331	0.3760
FINAL 2.5MM/10% - FINAL 2.5MM/5%	0.08444	-0.1537	0.3225

Assumption test: Are the standard deviations of the groups equal?

ANOVA assumes that the data are sampled from populations with identical SDs. This assumption is tested using the method of Bartlett.

Bartlett statistic (corrected) = 2.181

The P value is 0.5357.

Bartlett's test suggests that the differences among the SDs is not significant.

Assumption test: Are the data sampled from Gaussian distributions?

ANOVA assumes that the data are sampled from populations that follow Gaussian distributions. This assumption is tested using the method Kolmogorov and Smirnov:

Group	KS	P Value	Passed normality test?
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FINAL PLACEBO	0.1614	>0.10	Yes
FINAL 0.6MM	0.1750	>0.10	Yes
FINAL 2.5MM/10%	0.1790	>0.10	Yes
FINAL 2.5MM/5%	0.1786	>0.10	Yes

Intermediate calculations. ANOVA table

Source of variation	Degrees of freedom	Sum of squares	Mean square
Treatments (between columns)	3	4.531	1.510
Residuals (within columns)	33	1.149	0.03481
Total	36	5.680	

$$F = 43.393 = (MS_{\text{treatment}} / MS_{\text{residual}})$$

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
FINAL PLACEBO	12	2.297	0.1621	0.04680	2.275
FINAL 0.6MM	7	1.611	0.1402	0.05298	1.640
FINAL 2.5MM/10%	9	1.574	0.2368	0.07892	1.500
FINAL 2.5MM/5%	9	1.490	0.1914	0.06381	1.430

Group	Minimum	Maximum	95% Confidence Interval	
			From	To
FINAL PLACEBO	2.090	2.610	2.194	2.400
FINAL 0.6MM	1.430	1.800	1.482	1.741
FINAL 2.5MM/10%	1.250	1.960	1.392	1.756
FINAL 2.5MM/5%	1.240	1.900	1.343	1.637

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Comparison: Nonparametric ANOVA among all FINALS including PLACE

LS MINT - MOL WT CLINICAL STUDIES

Kruskal-Wallis Test (Nonparametric ANOVA)

The P value is < 0.0001, considered extremely significant. Variation among column medians is significantly greater than expected by chance.

The P value is approximate (from chi-square distribution) because at least one column has two or more identical values.

Calculation detail

Group	Number of Points	Sum of Ranks	Mean of Ranks
FINAL PLACEBO	12	378.00	31.500
FINAL 0.6MM	7	110.50	15.786
FINAL 2.5MM/10%	9	122.00	13.556
FINAL 2.5MM/5%	9	92.500	10.278

Kruskal-Wallis Statistic KW = 24.747 (corrected for ties)

Dunn's Multiple Comparisons Test

Comparison	Mean Rank Difference	P value
FINAL PLACEBO vs. FINAL 0.6MM	15.714 *	P<0.05
FINAL PLACEBO vs. FINAL 2.5MM/10%	17.944 **	P<0.01
FINAL PLACEBO vs. FINAL 2.5MM/5%	21.222 ***	P<0.001
FINAL 0.6MM vs. FINAL 2.5MM/10%	2.230 ns	P>0.05
FINAL 0.6MM vs. FINAL 2.5MM/5%	5.508 ns	P>0.05
FINAL 2.5MM/10% vs. FINAL 2.5MM/5%	3.278 ns	P>0.05

Summary of Data

Group	Number of Points	Median	Minimum	Maximum
FINAL PLACEBO	12	2.275	2.090	2.610
FINAL 0.6MM	7	1.640	1.430	1.800
FINAL 2.5MM/10%	9	1.500	1.250	1.960
FINAL 2.5MM/5%	9	1.430	1.240	1.900

* * *

Comparison: Parametric ANOVA among all TEST MINT FINALS

LS MINT - MOL WT CLINICAL STUDIES

One-way Analysis of Variance (ANOVA)

The P value is 0.4554, considered not significant.
Variation among column means is not significantly greater than expected by chance.

Tukey-Kramer Multiple Comparisons Test

If the value of q is greater than 3.555 then the P value is less than 0.05.

Comparison	Mean Difference	q	P value
FINAL 0.6MM vs FINAL 2.5MM/10%	0.03698	0.5251	ns P>0.05
FINAL 0.6MM vs FINAL 2.5MM/5%	0.1214	1.724	ns P>0.05
FINAL 2.5MM/10% vs FINAL 2.5MM/5%	0.08444	1.282	ns P>0.05

Difference	Mean Difference	95% Confidence Interval From	To
FINAL 0.6MM - FINAL 2.5MM/10%	0.03698	-0.2134	0.2874
FINAL 0.6MM - FINAL 2.5MM/5%	0.1214	-0.1290	0.3718
FINAL 2.5MM/10% - FINAL 2.5MM/5%	0.08444	-0.1498	0.3187

Assumption test: Are the standard deviations of the groups equal?

ANOVA assumes that the data are sampled from populations with identical SDs. This assumption is tested using the method of Bartlett.

Bartlett statistic (corrected) = 1.646

The P value is 0.4392.

Bartlett's test suggests that the differences among the SDs is not significant.

Assumption test: Are the data sampled from Gaussian distributions?

ANOVA assumes that the data are sampled from populations that follow Gaussian distributions. This assumption is tested using the method Kolmogorov and Smirnov:

Group	KS	P Value	Passed normality test?
FINAL 0.6MM	0.1750	>0.10	Yes
FINAL 2.5MM/10%	0.1790	>0.10	Yes
FINAL 2.5MM/5%	0.1786	>0.10	Yes

Intermediate calculations. ANOVA table

Source of variation	Degrees of freedom	Sum of squares	Mean square
Treatments (between columns)	2	0.06371	0.03185
Residuals (within columns)	22	0.8595	0.03907
Total	24	0.9232	

$$F = 0.8153 = (MStreatment/MSresidual)$$

Summary of Data

Group	Number of Points	Mean	Standard Deviation	Standard Error of Mean	Median
FINAL 0.6MM	7	1.611	0.1402	0.05298	1.640
FINAL 2.5MM/10%	9	1.574	0.2368	0.07892	1.500
FINAL 2.5MM/5%	9	1.490	0.1914	0.06381	1.430

Group	Minimum	Maximum	95% Confidence Interval	
			From	To
FINAL 0.6MM	1.430	1.800	1.482	1.741
FINAL 2.5MM/10%	1.250	1.960	1.392	1.756
FINAL 2.5MM/5%	1.240	1.900	1.343	1.637

* * *

Comparison: Nonparametric ANOVA among all TEST MINT FINALS

LS MINT - MOL WT CLINICAL STUDIES

Kruskal-Wallis Test (Nonparametric ANOVA)

The P value is 0.3188, considered not significant.
 Variation among column medians is not significantly greater than expected by chance.

The P value is approximate (from chi-square distribution) because at least one column has two or more identical values.

Calculation detail

Group	Number of Points	Sum of Ranks	Mean of Ranks
FINAL 0.6MM	7	110.50	15.786
FINAL 2.5MM/10%	9	122.00	13.556
FINAL 2.5MM/5%	9	92.500	10.278

Kruskal-Wallis Statistic KW = 2.286 (corrected for ties)

Dunn's Multiple Comparisons Test

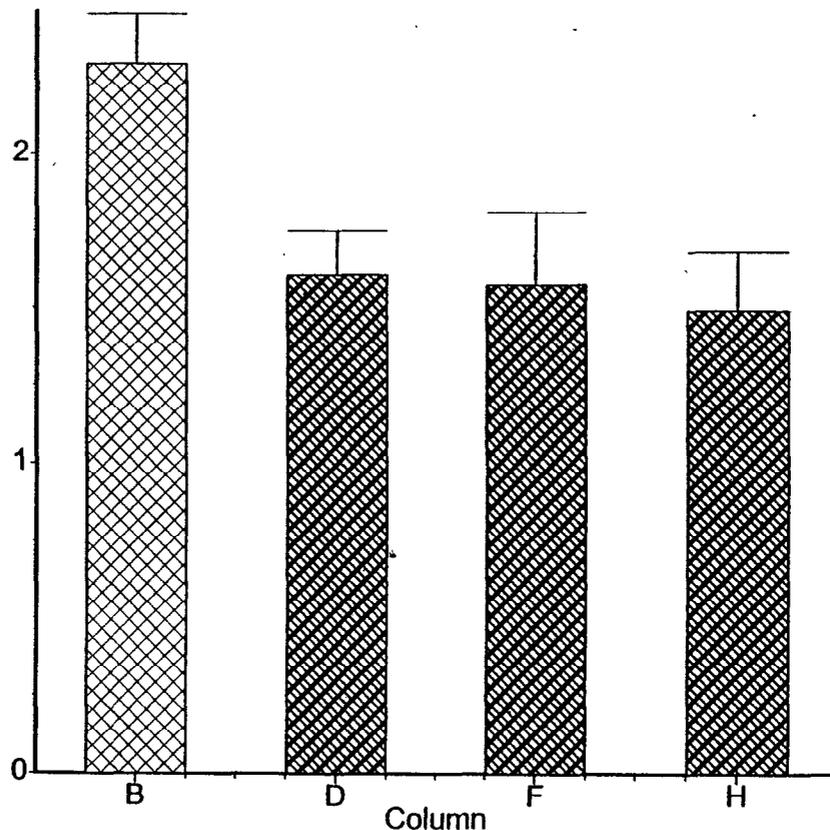
Comparison	Mean Rank Difference	P value
FINAL 0.6MM vs. FINAL 2.5MM/10%	2.230	ns P>0.05
FINAL 0.6MM vs. FINAL 2.5MM/5%	5.508	ns P>0.05
FINAL 2.5MM/10% vs. FINAL 2.5MM/5%	3.278	ns P>0.05

Summary of Data

Group	Number of Points	Median	Minimum	Maximum
FINAL 0.6MM	7	1.640	1.430	1.800
FINAL 2.5MM/10%	9	1.500	1.250	1.960
FINAL 2.5MM/5%	9	1.430	1.240	1.900

* * *

LS MINT - MOL WT CLINICAL STUDIES
Mean and Standard Deviation



GRAPHICAL COMPARISON OF ALL FINALS

<u>Column</u>	<u>Test Product</u>	<u>Time</u>	<u>Code</u>
A	Placebo Mint	Base	111
B	Placebo Mint	Final	111
C	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Base	222
D	10% PDMS = 600,000 cs in melt-emulsion @ 1.5% in mint	Final	222
E	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	555
F	10% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	555
G	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Base	666
H	5% PDMS = 2,500,000 cs in melt-emulsion @ 1.5% in mint	Final	666