

Europ. Pharm., 5th Ed. (2005), Ch. 5.3, 5.2.2. - A completely randomised (0,4,4,4)-design - An in-vitro assay of influenza vaccines

Document-Id: Document-63 (Revision:3)
Document Type: Quantitative Response Assay/14
Last Modified: 02.06.2014 12:05:54
Database: PLA 3.0 Customer Support
Database GUID: 83d38d90-634b-4dc2-ac0b-15697a1768d2

Calculation

Calculation performed: 02.06.2014 12:05:54, Matthias Schmitt (PLA 3.0.0 Build 623, nbmsc03, 10014)
Report generated: 02.06.2014 12:06:01, Matthias Schmitt (PLA 3.0.0 Build 623, nbmsc03, 10014)

Signatures

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Responsibility

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Approval

.....
Review



DOCUMENT-63



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Overview

General Properties

Analysis	General
Response Adjustment	None
Response Transformation	None
Model	Slope Ratio
Multiplex Assay	Yes
Potency Estimation Confidence Interval	95.0%
Calculate mean potency estimate of test samples	No
ANOVA Model	ANOVA (Pure Error Separation)
ANOVA with consideration of additional factors	Yes
Logarithm Base	Natural logarithm (base e)
Invert Potency	No

Documentation

General	
Date	25.02.2014 14:18:37

Assay

Setup

Sample Setup

Setup	Standard Sample: Standard S	Test Sample: Preparation T	Test Sample: Preparation U
Preparation Scheme	PreparationScheme-1	PreparationScheme-1	PreparationScheme-1
Step Count	4	4	4
Replicate Count	2	2	2
Potency Definition	By Stock Solution	By Stock Solution	By Stock Solution
Assigned Assumed Potency	15 µg HA/ml	15 µg HA/ml	15 µg HA/ml
Dilution Scale	7.5, 15, 22.5, 30	7.5, 15, 22.5, 30	7.5, 15, 22.5, 30
Analysis	Standard Sample: Standard S	Test Sample: Preparation T	Test Sample: Preparation U
Data Selection Scheme	DataSelectionScheme-1	DataSelectionScheme-1	DataSelectionScheme-1
Outlier Detection	None	None	None
Range	Full	Full	Full
Optimization	No	No	No

Observations

Response values in bold are used for analysis as a result of your configuration.

Standard Sample: Standard S

Selected Steps: 1, 2, 3, 4

Dose Value	7.5	15	22.5	30
Dose Step	1	2	3	4
Response 1	18	22.8	30.4	35.7
Response 2	18	24.5	30.4	36.6
Mean	18.00000	23.65000	30.40000	36.15000
SD	0.00000	1.20208	0.00000	0.63640
CV[%]	0.00000	5.08280	0.00000	1.76043

Test Sample: Preparation T

Selected Steps: 1, 2, 3, 4

Dose Value	7.5	15	22.5	30
Dose Step	1	2	3	4
Response 1	15.1	23.1	28.9	34.4
Response 2	16.8	24.2	27.4	37.8
Mean	15.95000	23.65000	28.15000	36.10000
SD	1.20208	0.77782	1.06066	2.40416
CV[%]	7.53656	3.28887	3.76789	6.65973

Test Sample: Preparation U

Selected Steps: 1, 2, 3, 4

Dose Value	7.5	15	22.5	30
Dose Step	1	2	3	4
Response 1	15.4	20.2	24.2	27.4
Response 2	15.7	18.6	23.1	27
Mean	15.55000	19.40000	23.65000	27.20000
SD	0.21213	1.13137	0.77782	0.28284
CV[%]	1.36419	5.83181	3.28887	1.03986

Result

Analysis of Variance (ANOVA)

Total number of observations: 24

Source of Variation	d.f.	Sum of Squares	Mean Squares	F-Ratio	Probability
Treatments	11	1096.20458	99.65496		
Regression	3	1087.66519	362.55506	339.49752	7.27604E-12
Intersection	2	3.47389	1.73694	1.62648	0.23712
Non-Linearity (LoF)	6	5.06550	0.84425	0.79056	0.59432
Residual (Pure) Error	12	12.81500	1.06792		
Total	23	1109.01958	48.21824		

Regression

Restricted Model (Common Slope and Asymptotes)			
Parameter	Estimate	Error	Quality of Regression
Intercept	11.04167	0.51670	r ² 0.98074
Common Standard S Slope	0.84748	0.02905	r ² adjusted 0.97786
Common Preparation T Slope	0.80748	0.02905	
Common Preparation U Slope	0.54970	0.02905	
Unrestricted Regression			
Parameter	Estimate	Error	Quality of Regression
Standard S Intercept	11.75000	0.89495	r ² 0.99888
Standard S Slope	0.81600	0.04357	r ² adjusted 0.99850
Preparation T Intercept	9.72500	0.89495	
Preparation T Slope	0.86600	0.04357	
Preparation U Intercept	11.65000	0.89495	
Preparation U Slope	0.52267	0.04357	

Validity Tests

Overview:

	Passed	Failed (Rejected)	Failed (Warning)	Passed (Info)	Not Calculated
Assay Suitability	0	0	0	0	0
Sample Suitability	2	0	0	0	0
Overall Test Result	Passed				

Sample Suitability Tests

F-Test (Hypothesis Test): Significance of Non-Linearity Standard S, Preparation T, Preparation U		Passed
Test Severity	Warning	
F _{critical} (95.0%) F	2.99612 0.79056	
Test Sample Test: FTestNonSimilarity Standard S, Preparation T, Preparation U		Passed
Test Severity	Warning	
F _{critical} (95.0%) F	3.88529 1.62648	

Potency Estimation

Relative Potency	Preparation T	Standard S
Potency Ratio	0.95280	
95% Confidence Interval	0.89121 - 1.01807	
Relative Confidence Interval	93.54% - 106.85% (13.31%)	
Stock Solution		
Assumed/Assigned Potency	15.00000 µg HA/ml	15.00000 µg HA/ml
Factor rel. Estimated Sample Potency	0.95280	0.95280
Estimated Sample Potency (Stock Solution)	14.29202 µg HA/ml	
95% Confidence Interval	13.36811 - 15.27108 µg HA/ml	
Relative Confidence Interval	93.54% - 106.85% (13.31%)	
Relative Potency	Preparation U	Standard S
Potency Ratio	0.64863	
95% Confidence Interval	0.59028 - 0.70725	
Relative Confidence Interval	91.00% - 109.04% (18.03%)	
Stock Solution		
Assumed/Assigned Potency	15.00000 µg HA/ml	15.00000 µg HA/ml
Factor rel. Estimated Sample Potency	0.64863	0.64863
Estimated Sample Potency (Stock Solution)	9.72948 µg HA/ml	
95% Confidence Interval	8.85416 - 10.60878 µg HA/ml	
Relative Confidence Interval	91.00% - 109.04% (18.03%)	

Graphics

