

Europ. Pharm., 5th Ed. (2005), Ch. 5.3, 5.2.2. - Logit analysis of a test preparation against a reference - An in-vitro assay of a diphtheria vaccine

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Calculation

Calculation performed: 02.06.2014 13:14:22, Matthias Schmitt (PLA 3.0.0 Build 623, nbmsc03, 10014)
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Signatures

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Responsibility

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Approval

.....
Review

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Overview

General Properties

Analysis	General
Model	Logit
Multiplex Assay	No
Potency Estimation Confidence Interval	95.0%
Logarithm Base	Natural logarithm (base e)
Invert Potency	No
Theoretical Variance	1
Calculate mean potency estimate of test samples	No

Documentation

General	
Date	25.02.2014 14:39:51

Assay: Test preparation T

Setup

Sample Setup

Setup	Standard Sample: Standard S	Test Sample: Test preparation T
Preparation Scheme	PreparationScheme-1	PreparationScheme-2
Step Count	4	4
Replicate Count	1	1
Potency Definition	By Stock Solution	By Stock Solution
Assigned Assumed Potency	140 IU/vial	132 IU/vial
Dilution Scale	1, 1.6, 2.5, 4	1, 1.6, 2.5, 4

Observations

Standard Sample: Standard S

Selected Steps: no steps selected

Dose	1	1.6	2.5	4
Dose Step	1	2	3	4
Response 1	0/12	3/12	6/12	10/11

Test Sample: Test preparation T

Selected Steps: no steps selected

Dose	1	1.6	2.5	4
Dose Step	1	2	3	4
Response 1	0/11	4/12	8/11	10/11

Result

Analysis of Variance (ANOVA)

Total number of observations: 8

Source of Variation	d.f.	Sum of Squares	Mean Squares	Chi-Square	Probability
Treatments	7	28.59527	4.08504	28.59527	0.00017
Preparations	1	0.04071	0.04071	0.04071	0.84009
Regression	1	26.39748	26.39748	26.39748	2.77903E-07
Non-Parallelism	1	0.00662	0.00662	0.00662	0.93514
Non-Linearity	4	2.15046	0.53761	2.15046	0.70811
Standard S	2	1.09388	0.54694	1.09388	0.57872
Test preparation T	2	1.05658	0.52829	1.05658	0.58961
Total	7	28.59527	4.08504		

Regression

Restricted Model (Common Slope and Asymptotes)			
Parameter	Estimate	Error	Quality of Regression
Common Slope	4.10143	0.79828	Iterations 5
Standard S Intercept	-3.51218	0.76995	
Test preparation T Intercept	-2.89187	0.69223	
Unrestricted Regression			
Parameter	Estimate	Error	Quality of Regression
Standard S Slope	4.03750	1.11156	Iterations 5
Standard S Intercept	-3.45994	0.99447	
Test preparation T Slope	4.16746	1.14682	
Test preparation T Intercept	-2.93776	0.89932	

Validity Tests

Overview

Number of Tests applied: 2

	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

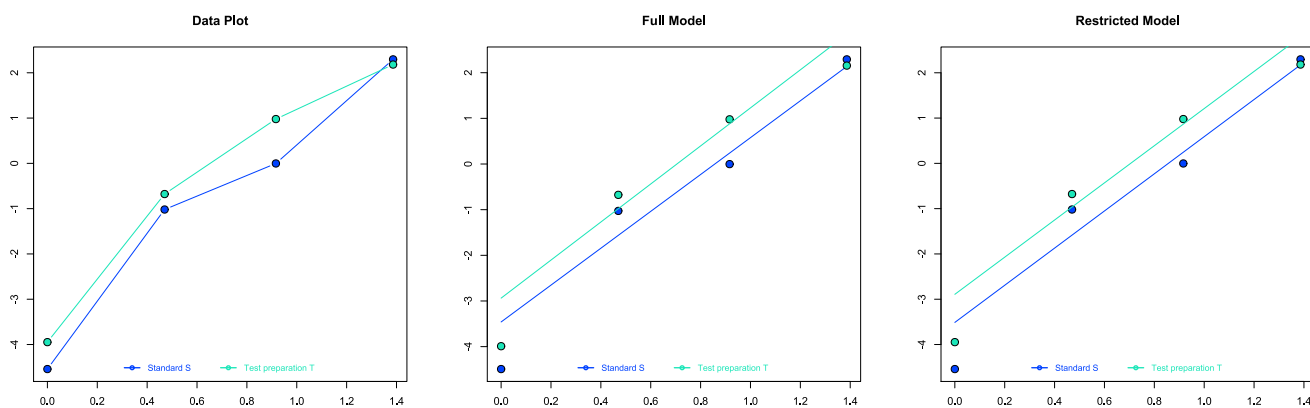
Chi-Square-Test (Hypothesis Test): Significance of Non-Linearity Standard S, Test preparation T		Passed
Test Severity	Warning	
Chi-Square _{critical(95%)}	9.48773	
Chi-Square	2.15046	
Chi-Square-Test (Hypothesis Test): Significance of Non-Parallelism Standard S, Test preparation T		Passed
Test Severity	Warning	
Chi-Square _{critical(95%)}	3.84146	
Chi-Square	0.00662	

Potency Estimation

Relative Potency	Test preparation T	Standard S
Potency Ratio	1.16328	
95% Confidence Interval	0.86522 - 1.57933	
Relative Confidence Interval	74.38% - 135.77% (61.39%)	
Stock Solution		
Assumed/Assigned Potency	132.00000 IU/vial	140.00000 IU/vial
Factor rel. Estimated Sample Potency	1.23378	1.16328
Estimated Sample Potency (Stock Solution)	162.85898 IU/vial	
95% Confidence Interval	121.13107 - 221.10555 IU/vial	
Relative Confidence Interval	74.38% - 135.77% (61.39%)	

Graphics

Linear Predictor



Probability

