D.J. Finney, p. 376, "Statistical Method in Biological Assay" 3rd Ed. (1978) - Insulin, Mouse convulsion - with Suitability tests

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Signatures

Responsibility	Review	Approval

Comments

Comment by Matthias Schmitt: (06.03.2014 12:26:54)

Remarks: Example taken from 'Statistical Method in Biological Assay' by D.J. Finney, 3rd Edition, 1978, Griffin. Data as given on page 376. Calculated potency and 95% confidence limits are in agreement with the computer-print on page 387.

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Overview

Property	Value
Model	Probit
Simultaneous regression	No
Potency estimation confidence level	95.00%
Logarithm base	Binary logarithm (base 2)
Invert potency	No
Theoretical variance	1.0
Calculate mean potency estimate of test samples	No

Documentation

Date 06.03.2014 12:26:19

Assay: Test (T)

Setup	Standard (S)	Test (T)
Preparation scheme	PreparationScheme-1	PreparationScheme-2
Number of steps	9	5
Replicate count	1	1
Potency definition	by stock solution	by stock solution
Assigned/assumed potency	20 IU/mg	20 IU/mg
Dilution scale	3.4, 5.2, 7, 8.5, 10.5, 13, 18, 21, 28	6.5, 10, 14, 21.5, 29

Observations

Standard (S)

Dose		3.40000	5.20000	7.00000	8.50000	10.50000	13.00000
Dose step		1	2	3	4	5	6
Response	1	0/33	5/32	11/38	14/37	18/40	21/37

Dose		18.00000	21.00000	28.00000
Dose step		7	8	9
Response	1	23/31	30/37	27/30

Test (T)

Dose		6.50000	10.00000	14.00000	21.50000	29.00000
Dose step		1	2	3	4	5
Response	1	2/40	10/30	18/40	21/35	27/37

Result

Analysis of variance (ANOVA)

Total number of observations: 14

Source of variation	d.f.	Sum of squares	Mean squares	Chi-square	Probability
Treatments	13	136.56551	10.50504	136.56551	1.025 E-22
Preparations	1	0.59441	0.59441	0.59441	0.44072
Regression	1	130.26783	130.26783	130.26783	3.581 E-30
non-Parallelism	1	0.28243	0.28243	0.28243	0.59512
non-Linearity	10	5.42085	0.54208	5.42085	0.86135
Standard (S)	7	2.05821	0.29403	2.05821	0.95655
Test (T)	3	3.36263	1.12088	3.36263	0.33902
Total	13	136.56551	10.50504	N/A	N/A

Regression

Restricted model (common slope and asymptotes)

Parameter	Estimate	Error	Quality of regression	
Slope	0.96446	0.08450	Iterations	6
Standard (S) Intercept	-3.36602	0.30208		
Test (T) Intercept	-3.92634	0.34727		

Unrestricted regression

Parameter	Estimate	Error	Quality of regression	
Standard (S) Slope	0.99821	0.10605	Iterations	6
Standard (S) Intercept	-3.48268	0.37462		
Test (T) Slope	0.90231	0.14146		
Test (T) Intercept	-3.68185	0.56324		

Effective Concentration - EC50

Sample	Calculated value	Estimated EC50
Standard (S)	11.22713	224.54252 IU/mg
Test (T)	16.91791	338.35811 IU/mg

Validity tests

	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

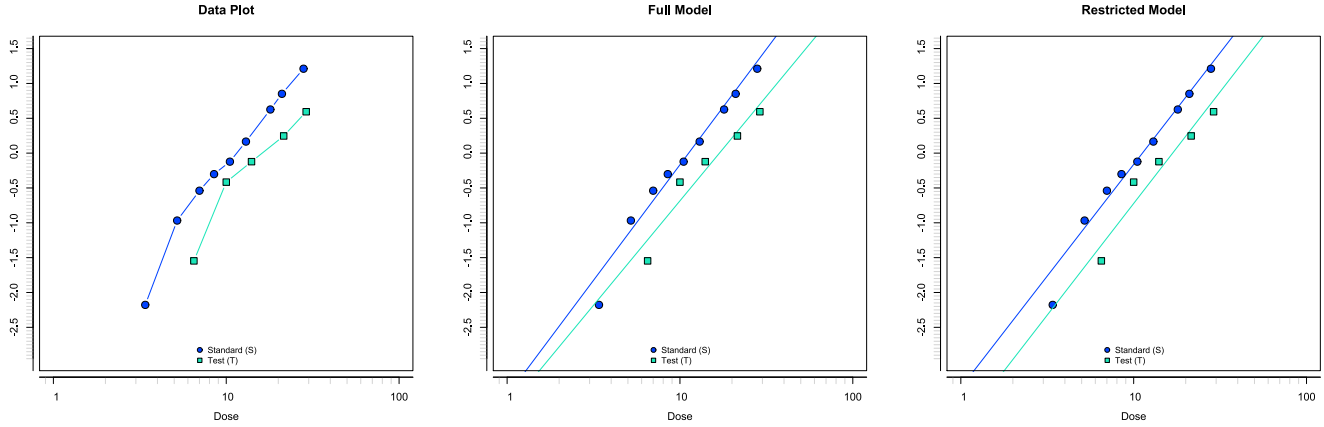
Chi-square-test (hypothesis test): Significance of non-parallelism Standard (S) Test (T)		Passed
Severity Level $\chi^2_{critical}(95\%)$ χ^2 p	Warning 3.84146 0.28243 0.59512	
Additional test: Relative potency value Test (T)		Passed
Severity Level Margins Value	Warning 0.6 ; 1.4 0.66852	

Potency estimation

Relative potency	Test (T)	Standard (S)
Potency ratio 95% Confidence interval Relative confidence interval	0.66852 0.55339 - 0.80406 82.78% - 120.28% (37.50%)	
Stock solution		
Assigned/assumed potency Factor rel. estimated sample potency	20.00000 IU/mg 0.66852	20.00000 IU/mg 0.66852
Estimated sample potency (stock solution) 95% Confidence interval Relative confidence interval Recovery	13.37038 IU/mg 11.06781 - 16.08124 IU/mg 82.78% - 120.28% (37.50%) 66.85%	

Graphics

Linear predictor



Probability