Project	Validation CombiStats version 7.0
Assay	Example 5.1.3 from the Ph. Eur.

Remarks: This is example 5.1.3 from the European Pharmacopoeia but with 1 value replaced by an 'outlier'. By using Huber's weights w=h the influence of this outlier can be reduced without having to exclude it.

Standard				
Id.	S			
Ass. pot.	670 IU/mg			
Reconsitution	16.7 mg/25ml			
Pre-dilution	1 ml/40 ml			
Doses	S1	S2	S3	S4
(1)	252	207	168	113
(2)	249	201	187	107
(3)	247	193	162	111
(4)	250	207	155	108
(5)	235	207	140	98

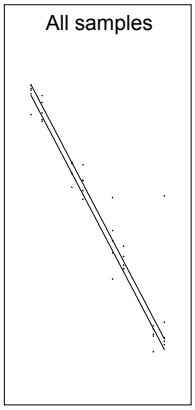
Sample 1				
Id.	T			
Ass. pot.	20000 IU/vial			
Reconsitution	1 vial/40 ml			
Pre-dilution	1 ml/40 ml			
Doses	T1	T2	T3	T4
(1)	242	206	146	115
(2)	236	197	153	102
(3)	246	197	148	104
(4)	231	191	159	106
(5)	232	186	146	188

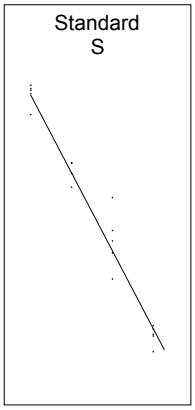
Model: y=(x) where x=c.+b*ln(dose)
Design: Randomised block
Weight function: w=h
Variance: Observed residuals
Dilution step (Increasing): 1.5

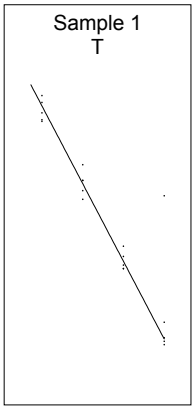
Common slope(factor): b = -110.701 (-115.637 to -105.766)
Correlation | r |: 0.989049 (Weighted)

Source of variation	Degrees of freedom	Sum of squares	Mean square	Chi-square	Probability
Preparations	1	104.793	104.793	1.49041	0.222
Regression	1	95708.7	95708.7	1361.21	0.000 (***)
Non-parallelism	1	85.9617	85.9617	1.22258	0.269
Non-linearity	4	82.2383	20.5596	1.16963	0.883
Standard	2	74.7300	37.3650	1.06284	0.588
Sample 1	2	7.50630	3.75315	0.106758	0.948
Treatments	7	95981.7	13711.7	1365.09	0.000 (***)
Blocks	4	545.737	136.434	7.76170	0.101
Residual error	28	1968.72	70.3116		
Total	39	98100.6	2515.40		

Sample 1			
Id.	T		
(IU/vial)	Lower limit	Estimate	Upper limit
Potency	18035.7	18924.8	19861.1
Rel. to Ass.	90.2%	94.6%	99.3%
Rel. to Est.	95.3%	100.0%	104.9%







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