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

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

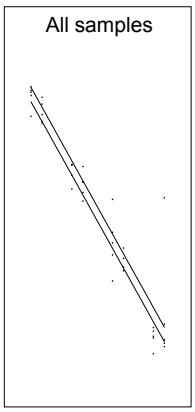
Sample 1				
Id.	T			
Ass. pot.	20000 IU/vial			
Reconsitution	1 vial/40 ml			
Pre-dilution	1 ml/40 ml			
Doses	T1	T2	T3	T4
(1)	242	206	146	115
(2)	236	197	153	102
(3)	246	197	148	104
(4)	231	191	159	106
(5)	232	186	146	188

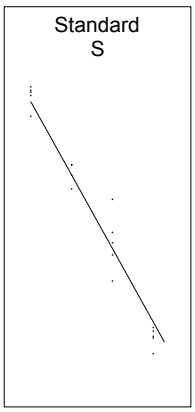
Model: Parallel lines
Design: Randomised block
Transformation: y' = y
Variance: Observed residuals
Dilution step (Increasing): 1.5

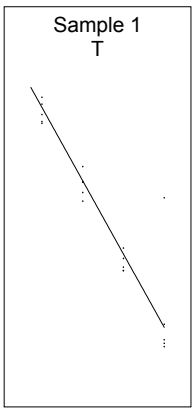
Common slope(factor) = -104.374 (-114.017 to -94.7305)
Correlation | r |: 0.955215

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	108.900	108.900	0.412	0.526
Regression	1	89549.1	89549.1	338.993	0.000 (***)
Non-parallelism	1	612.500	612.500	2.319	0.139
Non-linearity	4	610.680	152.670	0.578	0.681
Standard	2	238.140	119.070	0.451	0.642
Sample 1	2	372.540	186.270	0.705	0.503
Treatments	7	90881.2	12983.0	49.148	0.000 (***)
Blocks	4	160.650	40.1625	0.152	0.961
Residual error	28	7396.55	264.163		
Total	39	98438.4	2524.06		

Sample 1			
Id.	T		
(IU/vial)	Lower limit	Estimate	Upper limit
Potency	16699.6	18477.5	20460.8
Rel. to Ass.	83.5%	92.4%	102.3%
Rel. to Est.	90.4%	100.0%	110.7%







Executed by: Calculated by: Approved by:

ID: EDQM/DBO/FRA