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~~

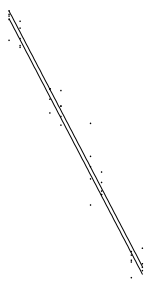
Model: Parallel lines
Design: Randomised block
Transformation: y' = y
Variance: Observed residuals
Dilution step (Increasing): 1.5

Common slope(factor) = -111.187 (-115.750 to -106.624)
Correlation | r |: 0.990840

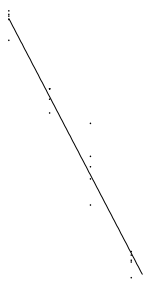
Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	1	149.767	149.767	2.681	0.113
Regression	1	96242.1	96242.1	>1000	0.000 (***)
Non-parallelism	1	28.7971	28.7971	0.515	0.479
Non-linearity	4	256.034	64.0085	1.146	0.356
Standard	2	238.140	119.070	2.131	0.138
Sample 1	2	17.8940	8.94699	0.160	0.853
Treatments	7	96676.7	13811.0	247.198	0.000 (***)
Blocks	4	767.457	191.864	3.434	0.022 (*)
Residual error	27	1508.49	55.8701		
Total	38	98339.9	2587.89		

Sample 1			
Id.	T		
(IU/vial)	Lower limit	Estimate	Upper limit
Potency	18389.3	19221.4	20094.7
Rel. to Ass.	91.9%	96.1%	100.5%
Rel. to Est.	95.7%	100.0%	104.5%

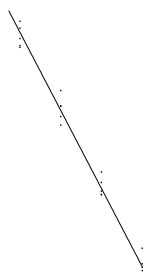
All samples



Standard
S



Sample 1
T



Executed by: Calculated by: Approved by:

ID: EDQM/DBO/FRA