



Project	Validation CombiStats version 7.0
Assay	Example 5.1.1 from the Ph. Eur.

Remarks: This is example 5.1.1 from the European Pharmacopoeia with additional table for equivalence testing. The extra table shows clearly that the slope of Sample 2 is significantly different from the standard because 0 is not included in the difference interval and 1 is not included in the ratio interval. Whether or not this non-parallelism is acceptable depends on the goal-posts defined for this assay (currently unavailable).

Standard		
Id.	S	
Ass. pot.	1 unit/mg	
Doses	0.25 unit	1.0 unit
(1)	300	289
(2)	310	221
(3)	330	267
(4)	290	236
(5)	364	250
(6)	328	231
(7)	390	229
(8)	360	269
(9)	342	233
(10)	306	259

Sample 1		
Id.	T	
Ass. pot.	1 unit/mg	
Doses	0.25 unit	1.0 unit
(1)	310	230
(2)	290	210
(3)	360	280
(4)	341	261
(5)	321	241
(6)	370	290
(7)	303	223
(8)	334	254
(9)	295	216
(10)	315	235

Sample 2		
Id.	U	
Ass. pot.	1 unit/mg	
Doses	0.25 unit	1.0 unit
(1)	250	236
(2)	268	213
(3)	273	283
(4)	240	269
(5)	307	251
(6)	270	294
(7)	317	223
(8)	312	250
(9)	320	216
(10)	265	265

Model: Parallel lines  
 Design: Completely randomised  
 Transformation:  $y' = y$   
 Variance: Observed residuals

Common slope(factor) = -47.0559 (-55.6804 to -38.4314)  
 Correlation | r |: 0.765367

Source of variation	Degrees of freedom	Sum of squares	Mean square	F-ratio	Probability
Preparations	2	6256.63	3128.32	4.086	0.022 (*)
Regression	1	63830.8	63830.8	83.377	0.000 (***)
Non-parallelism	2	8218.23	4109.12	5.367	0.007 (**)
Treatments	5	78305.7	15661.1	20.457	0.000 (***)
Residual error	54	41340.9	765.572		
Total	59	119647	2027.91		

	Slope per Sample	Difference with Standard	Ratio with Standard
Standard	-60.3047 (-75.2427 to -45.3666)	0	1
Sample 1	-57.6357 (-72.5738 to -42.6976)	2.66899 (-18.4567 to 23.7946)	0.955742 (0.659070 to 1.37737)
Sample 2	-23.2274 (-38.1655 to -8.28930)	37.0773 (15.9516 to 58.2029)	0.385167 (0.135203 to 0.685490)

Sample 1			
Id.	T		
(unit/mg)	Lower limit	Estimate	Upper limit
Potency	0.783648	1.14205	1.68690
Rel. to Ass.	78.4%	114.2%	168.7%
Rel. to Est.	68.6%	100.0%	147.7%

Sample 2			
Id.	U		
(unit/mg)	Lower limit	Estimate	Upper limit
Potency	1.14813	1.66889	2.55503
Rel. to Ass.	114.8%	166.9%	255.5%
Rel. to Est.	68.8%	100.0%	153.1%