



Project	Validation CombiStats
Assay	Example 5.4.1 from the Ph. Eur.

Remarks: This is example 5.4.1 from the European Pharmacopoeia but using a 5-parameter logistic curve instead of 4-parameters.

Standard		
Ass. pot.	0.4 IU/ml	
Doses	(1)	(2)
1/10	2.912	2.917
1/20	2.579	2.654
1/40	2.130	2.212
1/80	1.651	1.638
1/160	1.073	0.973
1/320	0.585	0.666
1/640	0.463	0.356
1/1280	0.266	0.234
1/2560	0.228	0.197
1/5120	0.176	0.215

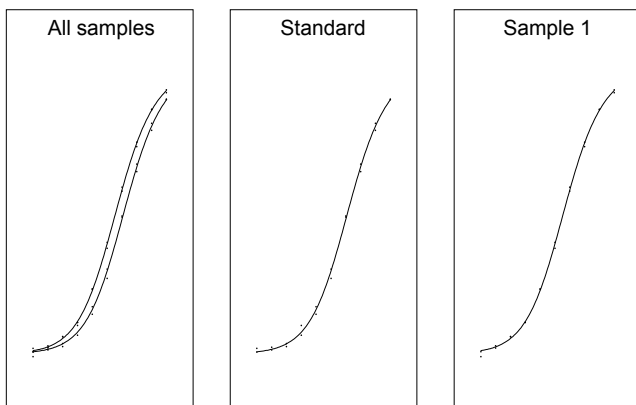
Sample 1		
Ass. pot.	? IU/ml	
Doses	(1)	(2)
1/10	3.017	2.987
1/20	2.801	2.808
1/40	2.401	2.450
1/80	1.918	1.963
1/160	1.364	1.299
1/320	0.861	0.854
1/640	0.497	0.496
1/1280	0.340	0.344
1/2560	0.242	0.217
1/5120	0.178	0.125

Model: Sigmoid curves (5-parameters)  
 Design: Completely randomised  
 Transformation:  $y' = \logit(y)$   
 Variance: Observed residuals

Common slope(factor) = 1.18041 (1.15672 to 1.20409)  
 Correlation | r |: 0.997888 (Weighted), 0.999518 (Unweighted)  
 Asymptotes: 3.25804 and 0.154367  
 Asymmetry factor: g = 0.806338

Source of variation	Degrees of freedom	Sum of squares	Mean square	Chi-square	Probability
Preparations	1	0.00120101	0.00120101	0.840467	0.359
Regression	1	9.60311	9.60311	6720.28	0.000 (***)
Non-parallelism	1	0.000121809	0.000121809	0.0852423	0.770
Non-linearity	16	0.0120056	0.000750349	8.40154	0.936
Standard	8	0.00640260	0.000800325	4.48056	0.811
Sample 1	8	0.00560298	0.000700373	3.92098	0.864
Treatments	19	9.61644	0.506128	6729.60	0.000 (***)
Residual error	20	0.0285795	0.00142897		
Total	39	9.64502	0.247308		

Sample 1			
(IU/ml)	Lower limit	Estimate	Upper limit
Potency	0.556676	0.583385	0.611391
Rel. to Ass.	?	?	?
Rel. to Est.	95.4%	100.0%	104.8%



Executed by:

Calculated by:

Approved by: