



Example Annex A, 3.27

Remarks: When no slope can be calculated, it is possible to specify a fixed slope to force a result. To mimic Spearman/Kaerber calculations specify a rectangular transformation with fixed slope equal to  $1/\ln(\text{dilution factor})$ . This should only be done in cases where less than 2 non-extreme responses are observed as shown here. The confidence limits are a good approximation to the Irwin/Cheeseman limits.

Sample 1	
Preparation	Batch A
Ass. pot.	4.3 log <sub>10</sub> IU/vial
Reconstitution vol.	1 vial / 500 µl
Inoculation vol.	100 µl / well
Doses	(1)
-1.6 log <sub>10</sub>	8/8
-2.2 log <sub>10</sub>	8/8
-2.8 log <sub>10</sub>	8/8
-3.4 log <sub>10</sub>	4/8
-4.0 log <sub>10</sub>	0/8
-4.6 log <sub>10</sub>	0/8
-5.2 log <sub>10</sub>	0/8

Sample 2	
Preparation	Batch B
Ass. pot.	4.0 log <sub>10</sub> IU/vial
Reconstitution vol.	1 vial / 500 µl
Inoculation vol.	100 µl / well
Doses	(1)
-1.6 log <sub>10</sub>	8/8
-2.2 log <sub>10</sub>	8/8
-2.8 log <sub>10</sub>	8/8
-3.4 log <sub>10</sub>	8/8
-4.0 log <sub>10</sub>	0/8
-4.6 log <sub>10</sub>	0/8
-5.2 log <sub>10</sub>	0/8

Sample 3	
Preparation	Batch C
Ass. pot.	4.0 log <sub>10</sub> IU/vial
Reconstitution vol.	1 vial / 500 µl
Inoculation vol.	100 µl / well
Doses	(1)
-1.6 log <sub>10</sub>	8/8
-2.2 log <sub>10</sub>	8/8
-2.8 log <sub>10</sub>	8/8
-3.4 log <sub>10</sub>	7/8
-4.0 log <sub>10</sub>	0/8
-4.6 log <sub>10</sub>	0/8
-5.2 log <sub>10</sub>	0/8

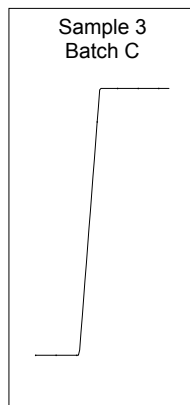
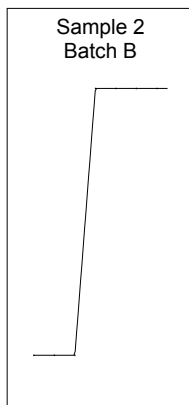
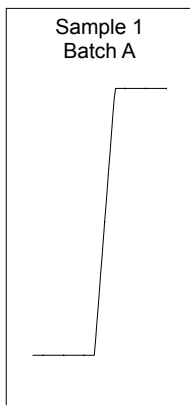
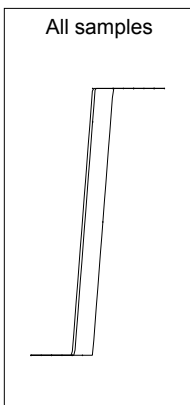
Model: Determination ED50  
 Design: Completely randomised  
 Transformation:  $y' = y$   
 Theoretical variance: 1

Common slope(factor) = 0.723824 (fixed, p = 0.999)  
 Correlation | r |: 1.00000 (Weighted)

Sample 1			
Preparation	Batch A		
(log <sub>10</sub> IU/vial)	Lower limit	Estimate	Upper limit
log <sub>10</sub> ED50/vial	3.89108	4.09897	4.30686
Rel. to Ass.	-0.408916	-0.201030	+0.00685562
Rel. to Est.	-0.207886	0.00000	+0.207886

Sample 2			
Preparation	Batch B		
(log <sub>10</sub> IU/vial)	Lower limit	Estimate	Upper limit
log <sub>10</sub> ED50/vial	4.39888	4.39897	4.39906
Rel. to Ass.	+0.398884	+0.398970	+0.399056
Rel. to Est.	-8.62441E-05	0.00000	+8.62441E-05

Sample 3			
Preparation	Batch C		
(log <sub>10</sub> IU/vial)	Lower limit	Estimate	Upper limit
log <sub>10</sub> ED50/vial	4.18647	4.32397	4.46147
Rel. to Ass.	+0.186467	+0.323970	+0.461473
Rel. to Est.	-0.137503	0.00000	+0.137503



Executed by:

Calculated by:

Approved by: