

05 CoMA to CPA-USP81 Cloxacillin

Document-Id: Document-1992 (Revision: 2)
Document type: Combination of microbial assays/1
Last modified: 02.09.2021 14:44:49
Database: O130_Permanent_PLA_305
Database GUID: 996faea8-9ec8-4fb7-8524-ea8686ffdf5d

Calculation information

Calculation performed: 02.09.2021 14:44:49, Benjamin Schneider (PLA 3.0.5 Build 816, NBARW01, 10014)
Report generated: 03.09.2021 13:22:29, Benjamin Schneider (PLA 3.0.5 Build 816, NBARW01, 10014)

Signatures

Responsibility

Review

Approval

Comments

Comment by Benjamin Schneider: (25.08.2021 14:10:01)

Example combination of microbial assay documents. Cylinder-plate assays (based on USP <81>) are aggregated to determine the combined potency. In addition, test samples from the original assay documents are put into combination group 1 and 2 respectively. This results in a separate analysis for each group. The test system includes tests on the combined potency, the confidence interval of the estimated combined potency, and the CV (%) of the absolute potency values.

Documentation

Date: 25.08.2021 14:06:20
Substance: Cloxacillin, Penicillin, Cloxacillin is an antibiotic agent used for the treatment of beta-hemolytic streptococcal and pneumococcal infections as well as staphylococcal infections.
Variable: MAA type: Cylinder plate assay



DOCUMENT-1992



996FAEA8-9EC8-4FB7-8524-EA8686FFDF5D

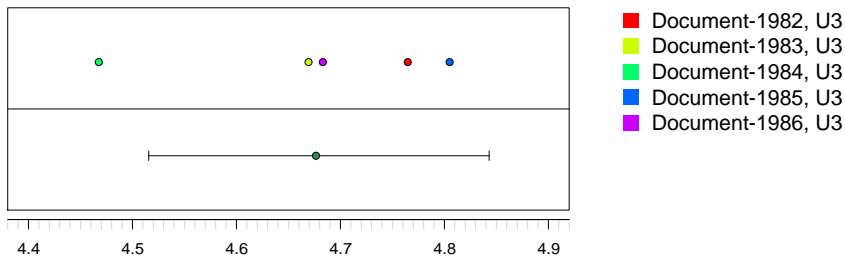
Overview

Property	Value
Logarithm base	Decimal logarithm (base 10)
Confidence level	95.00%
Perform outlier test	yes

Combination group Combination group 1: Setup

	Assay	Assay element	Absolute potency	Overall test result
1	Document-1982	U3	4.76473	Passed
2	Document-1983	U3	4.66931	Passed
3	Document-1984	U3	4.46756	Passed
4	Document-1985	U3	4.80500	Passed
5	Document-1986	U3	4.68305	Passed

Combination group Combination group 1: Result



Combination result

	Results
Estimated potency	4.67646
Confidence interval (95.00%)	4.51563 - 4.84301
Half width of CI	1.03562

Test results

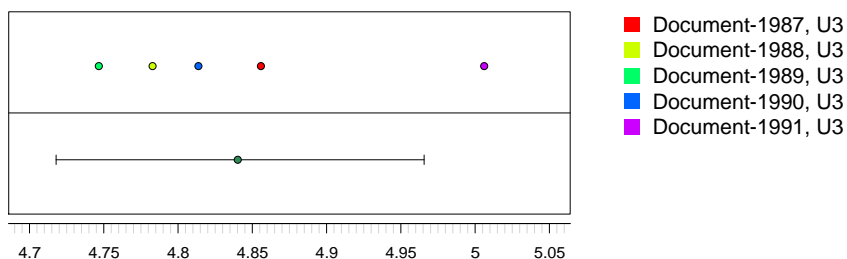
	Passed	Failed (rejected)	Failed (warning)	Info
Suitability	3	0	0	0
Overall test result	Passed			

Test: Combined potency - Value Severity level: Rejection		Passed
Calculated value	4.67646	
Margins	4.00000 to 6.00000	
Test: Combined potency - Confidence interval Severity level: Warning		Passed
Calculated value	4.51563 ; 4.84301	
Margins	4.00000 to 6.00000	
Test: Potency - CV (%) Severity level: Warning		Passed
Calculated value	2.78799	
Upper margin	5.00000	

Combination group Combination group 2: Setup

	Assay	Assay element	Absolute potency	Overall test result
1	Document-1987	U3	4.85580	Passed
2	Document-1988	U3	4.78285	Passed
3	Document-1989	U3	4.74667	Passed
4	Document-1990	U3	4.81372	Passed
5	Document-1991	U3	5.00611	Passed

Combination group Combination group 2: Result



Combination result

	Results
Estimated potency	4.84020
Confidence interval (95.00%)	4.71791 - 4.96567
Half width of CI	1.02592

Test results

	Passed	Failed (rejected)	Failed (warning)	Info
Suitability	3	0	0	0
Overall test result	Passed			

Test: Combined potency - Value Severity level: Rejection		Passed
Calculated value	4.84020	
Margins	4.00000 to 6.00000	
Test: Combined potency - Confidence interval Severity level: Warning		Passed
Calculated value	4.71791 ; 4.96567	
Margins	4.00000 to 6.00000	
Test: Potency - CV (%) Severity level: Warning		Passed
Calculated value	2.07864	
Upper margin	5.00000	