

Assay Combination

Document-Id: Document-79 (Revision:31)
Document type: Combination of assay results/16
Last modified: 24.03.2020 10:44:10
Database: PLA 3.0.4 BP26
Database GUID: a23398ab-7853-4e3d-aa1a-5bedeec03463

Document history

Rev.	Timestamp	Operator	Reason for change
31	05.12.2019 10:31:46	Dr. Matthias Schmitt	e

Calculation

Calculation performed: 24.03.2020 10:44:10, Dr. Matthias Schmitt (PLA 3.0.4 Build 762, nbmsc04, 10014)
Report generated: 24.03.2020 10:44:32, Dr. Matthias Schmitt (PLA 3.0.4 Build 762, nbmsc04, 10014)

Signatures

Responsibility

Review

Approval

Table of contents

1.....	3
2.....	4



DOCUMENT-79






A23398AB-7853-4E3D-AA1A-5BEDEEC03463

Overview

General properties

Property	Value
Combined potency type	Relative potency
Weighting	By homogeneity
Logarithm type	Natural logarithm (base e)
Report homogeneity test	Yes

Common legend for the plots

 Combined potency
 Passed sample
 Technical outlier

Group name: 1

Paracetamol, Lot. 4711

Combination of assay results

Sample	Assay	Assay element	Rel. pot. valid	Abs. potency valid
1	Document-69	Control Sample	No	No
2	Document-70	Control Sample	Yes	No
3	Document-71	Control Sample	Yes	No
4	Document-72	Control Sample	Yes	No
5	Document-73	Control Sample	Yes	No

Relative potency

Combination calculation of relative potencies

Sample	Relative potency	Lower limit	Upper limit	W	df
1	1.00278	0.95089	1.05751	1591.5163	16
2	1.01475	0.96131	1.07117	1535.2787	16
3	1.00820	0.96282	1.05573	2118.2291	16
4	1.03800	0.99374	1.08424	2366.0794	16
5	1.04234	1.00258	1.08369	2969.7385	16

Tests on combination result

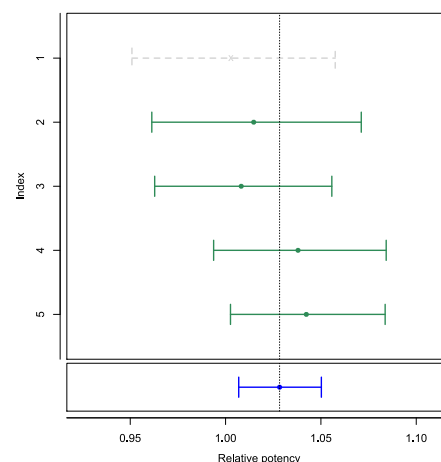
Homogeneity test		Homogeneous
χ^2	1.85044	
$\chi^2_{critical}$ (95.00%)	7.81473	
df	3	

	Passed	Failed (rejected)	Failed (warning)	Passed (info)	Not calculated
Suitability	2	0	0	0	0

Test on potency value		Passed
Severity level	Warning	
Margins Value	0.8; 1.25 1.02834	
Test on potency confidence interval		Passed
Severity level	Warning	
Upper margins Upper confidence limit	20 1.05024	

Calculation of the combined relative potency and 95% confidence limits

Results	
Selected method	Homogeneously weighted (EP)
Combined potency	1.02834
Confidence interval	1.00690 - 1.05024
Relative confidence interval	97.9% - 102.1%
Combination of assay results state	Passed



Group name: 2

Substance Name

Combination of assay results

Sample	Assay	Assay element	Rel. pot. valid	Abs. potency valid
1	Document-74	Control Sample	Yes	No
2	Document-75	Control Sample	Yes	No
3	Document-76	Control Sample	Yes	No
4	Document-77	Control Sample	Yes	No
5	Document-78	Control Sample	Yes	No

Relative potency

Combination calculation of relative potencies

Sample	Relative potency	Lower limit	Upper limit	W	df
1	1.06206	1.01914	1.10679	2640.6583	16
2	1.00176	0.95845	1.04702	2300.8672	16
3	1.00962	0.93045	1.09552	673.95964	16
4	0.98310	0.93306	1.03582	1646.8100	16
5	0.96668	0.92603	1.00912	2434.5729	16

Tests on combination result

Homogeneity test		
χ^2	12.55690	Heterogeneous
$\chi^2_{critical}$ (95.00%)	9.48773	
df	4	

	Passed	Failed (rejected)	Failed (warning)	Passed (info)	Not calculated
Suitability	2	0	0	0	0

Test on potency value		Passed
Severity level	Warning	
Margins Value	0.8; 1.25 1.00519	
Test on potency confidence interval		Passed
Severity level	Warning	
Upper margins Upper confidence limit	20 1.03076	

Calculation of the combined relative potency and 95% confidence limits

Results	
Selected method	Heterogeneously weighted (EP)
Combined potency	1.00519
Confidence interval	0.98025 - 1.03076
Relative confidence interval	97.5% - 102.5%
Inter assay variation	2.537 E-04
Combination of assay results state	Passed

