

# Statistical Analysis Report

This report was created by QuBAS version 1.0.0  
Thursday 9<sup>th</sup> March, 2017 at 16:11  
Method ID: demo test method  
Report ID: 193

# Statistical Analysis Report

## 1 Assay Details

Name	Type
1	Reference Standard
06/21/2016	Quality Control Sample
2	Test Sample
R/3/5	Test Sample

Table 1: Assay samples

Name	Content
plate reader	type 1
Ref	1
T1	2
T2	R/3/5
QCId	06/21/2016
assay number	test

Table 2: Metadata

## 2 Summary

System Suitability	Test Sample	Sample Suitability	Relative Potency	95% Confidence Interval	
				Lower Bound	Upper Bound
PASS	2	PASS	0.984	0.927	1.045
	R/3/5	FAIL	0.976	0.918	1.038

Table 3: Summary of results

## 3 Analysis Details

Analysis type:	Four Parameter Logistic Model (4PL)
Sign of slope parameter:	Positive
Dose transformation in original data:	None
Dose transformation in software:	Log <sub>10</sub>
Response transformation in software:	Log <sub>10</sub>
Variance estimate:	Calculated using residuals

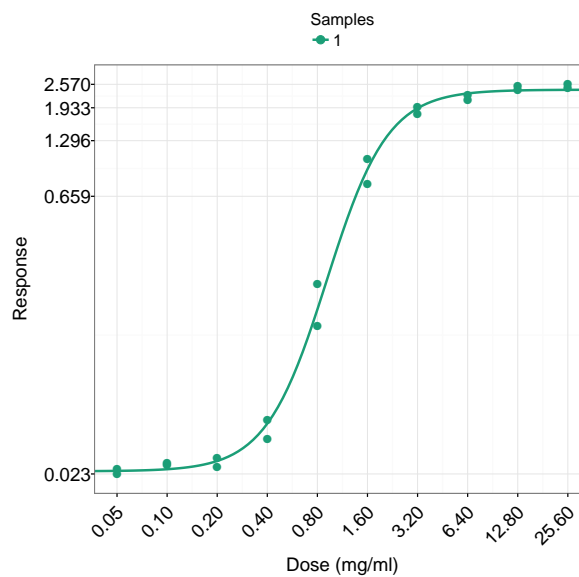
## 4 Reference Standard: 1

Name	Dose	Geometric Mean Response	%GCV of Response
1	0.05	0.023	4.03
1	0.10	0.026	1.39
1	0.20	0.026	8.51
1	0.40	0.039	18.44
1	0.80	0.177	43.79
1	1.60	0.891	23.70
1	3.20	1.874	5.68
1	6.40	2.200	4.54
1	12.80	2.453	3.19
1	25.60	2.518	2.89

GCV = Geometric Coefficient of Variation

**Table 4:** Summary of 1

### 4.1 Model fit



**Figure 1:** Model fit to 1

Note the model parameters in Table 5 are for the fit using the transformed data and so do not directly correspond to the fit shown above, which is plotted on the original scale.

Parameter	Estimate	95% Confidence Interval	
		Lower Bound	Upper Bound
Left asymptote (A)	-1.632	-1.685	-1.578
Slope parameter	5.450	4.662	6.239
Log <sub>10</sub> (EC <sub>50</sub> )	-0.04074	-0.07055	-0.01093
Right asymptote (D)	0.3815	0.3336	0.4294

**Table 5:** Parameters of the unconstrained model fit to 1

## 4.2 System suitability tests

Parameter	Test	Lower Limit	Upper Limit	Estimate	Result
<b>Goodness of fit tests</b>					
Significance test for goodness of fit	p-value for F test	0.05	NA	0.9259	PASS
<b>Parameter value tests</b>					
Significance test for dose-response	p-value for t test	NA	0.05	< 0.001	PASS

NA = Not Applicable

**Table 6:** Suitability tests for 1

## 5 Quality Control sample: 06/21/2016

Name	Dose	Geometric Mean Response	%GCV of Response
06/21/2016	0.05	0.025	15.18
06/21/2016	0.10	0.024	10.67
06/21/2016	0.20	0.030	5.80
06/21/2016	0.40	0.057	4.83
06/21/2016	0.80	0.341	5.21
06/21/2016	1.60	1.286	0.50
06/21/2016	3.20	2.002	1.92
06/21/2016	6.40	2.202	2.99
06/21/2016	12.80	2.332	0.50
06/21/2016	25.60	2.122	3.73

GCV = Geometric Coefficient of Variation

**Table 7:** Summary of 06/21/2016

## 5.1 Model fits

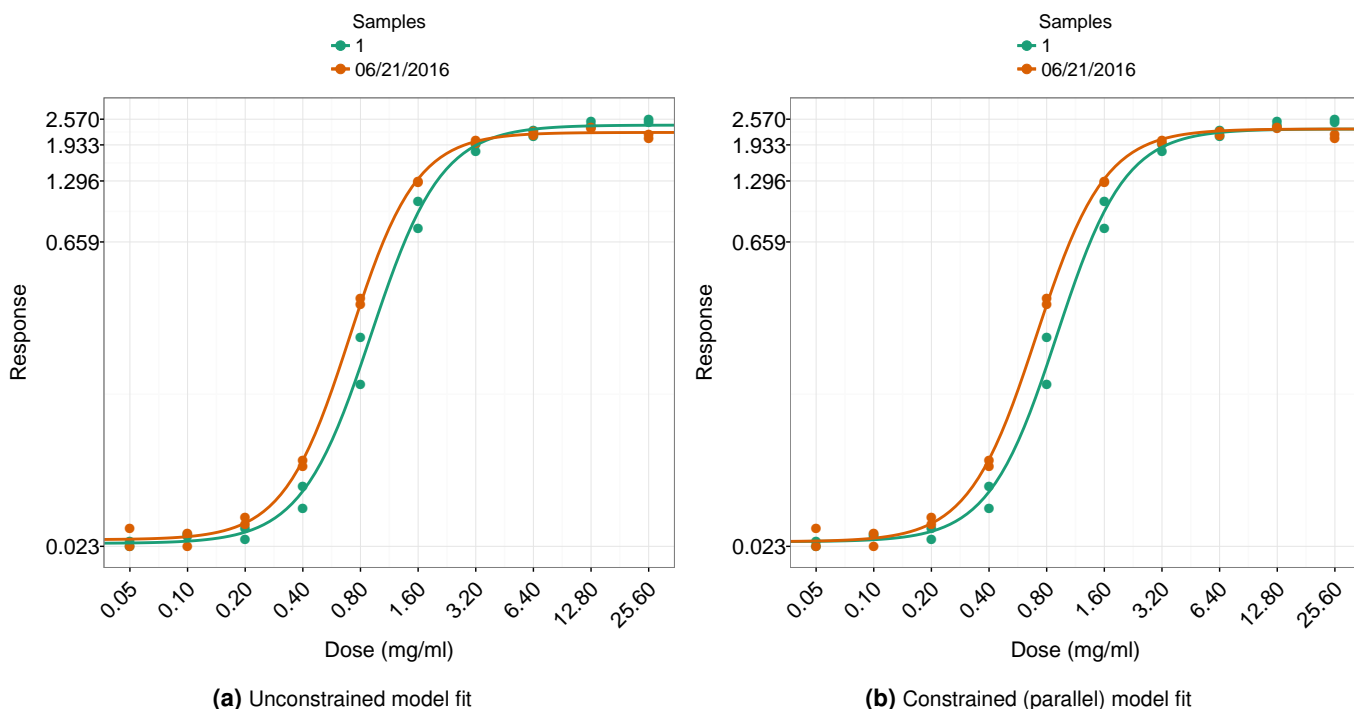


Figure 2: Model fits to 1 and 06/21/2016

Note the model parameters in Table 8 are for the fit using the transformed data and so do not directly correspond to the fit shown above, which is plotted on the original scale.

Model	Parameter	Name	Estimate	95% Confidence Interval	
				Lower Bound	Upper Bound
Unconstrained	Left asymptote (A)	06/21/2016	-1.614	-1.641	-1.587
	Slope parameter	06/21/2016	5.762	5.342	6.183
	Log <sub>10</sub> (EC <sub>50</sub> )	06/21/2016	-0.1519	-0.1661	-0.1377
	Right asymptote (D)	06/21/2016	0.3462	0.3249	0.3675
Constrained (parallel)	Left asymptote (A)	Common	-1.623	-1.652	-1.595
	Slope parameter	Common	5.605	5.169	6.042
	Log <sub>10</sub> (EC <sub>50</sub> )	1	-0.04380	-0.06376	-0.02384
	Log <sub>10</sub> (EC <sub>50</sub> )	06/21/2016	-0.1500	-0.1700	-0.1300
	Right asymptote (D)	Common	0.3628	0.3386	0.3869

Table 8: Parameters of the unconstrained model fit to 06/21/2016 and the constrained (parallel) model fit to 1 and 06/21/2016

## 5.2 Relative Potency

Parameter	Estimate	95% Confidence Interval		Ratio of Upper and Lower Bounds of the Relative Potency CI
		Lower Bound	Upper Bound	
Relative Potency	1.277	1.206	1.352	1.122

CI = Confidence Interval

Table 9: Relative Potency of 06/21/2016

## 6 Test Sample: 2

Name	Dose	Geometric Mean Response	%GCV of Response
2	0.05	0.022	1.29
2	0.10	0.025	15.34
2	0.20	0.026	0.28
2	0.40	0.038	7.59
2	0.80	0.174	13.71
2	1.60	0.836	9.23
2	3.20	1.863	4.26
2	6.40	2.280	0.97
2	12.80	2.509	1.37
2	25.60	2.517	1.43

GCV = Geometric Coefficient of Variation

Table 10: Summary of 2

### 6.1 Model fits

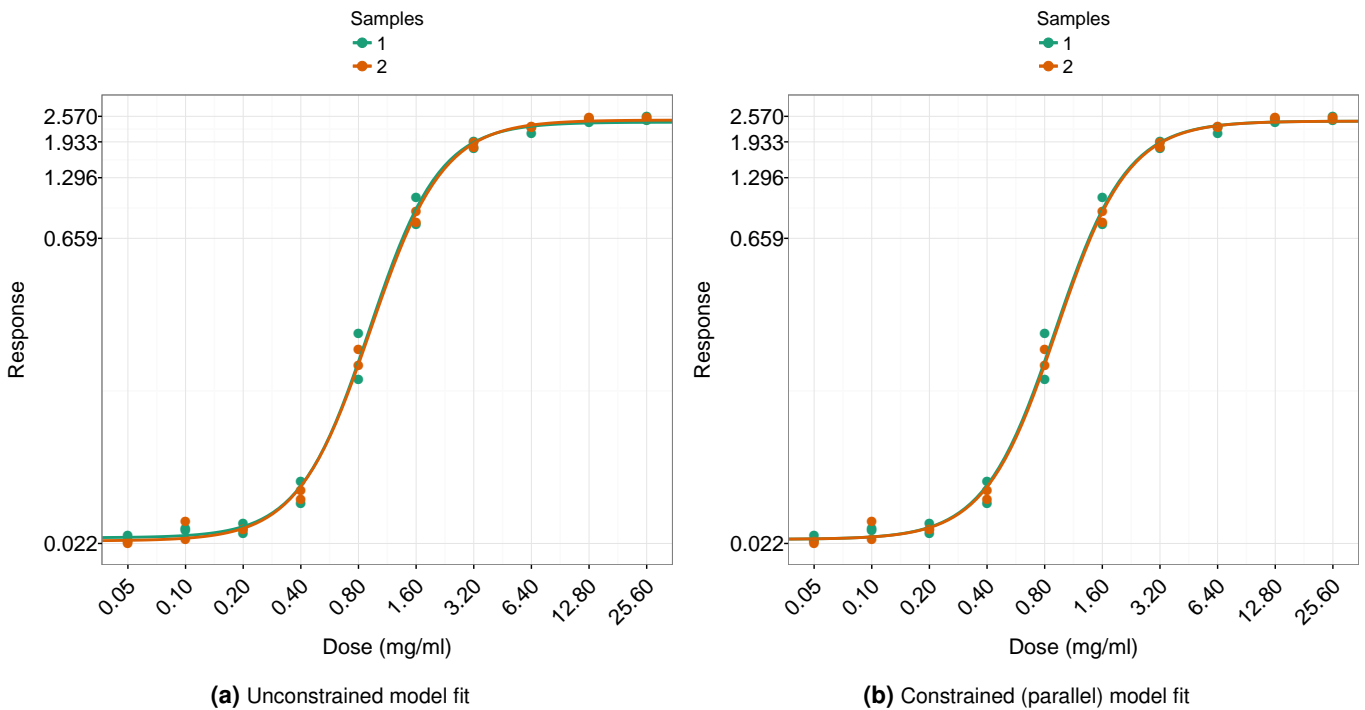


Figure 3: Model fits to 1 and 2

Note the model parameters in Table 11 are for the fit using the transformed data and so do not directly correspond to the fit shown above, which is plotted on the original scale.

Model	Parameter	Name	Estimate	95% Confidence Interval	
				Lower Bound	Upper Bound
Unconstrained	Left asymptote (A)	2	-1.647	-1.681	-1.613
	Slope parameter	2	5.254	4.781	5.727
	Log <sub>10</sub> (EC <sub>50</sub> )	2	-0.03499	-0.05421	-0.01576
	Right asymptote (D)	2	0.3918	0.3609	0.4227
Constrained (parallel)	Left asymptote (A)	Common	-1.639	-1.669	-1.610
	Slope parameter	Common	5.350	4.932	5.767
	Log <sub>10</sub> (EC <sub>50</sub> )	1	-0.04127	-0.06218	-0.02037
	Log <sub>10</sub> (EC <sub>50</sub> )	2	-0.03448	-0.05539	-0.01357
	Right asymptote (D)	Common	0.3866	0.3603	0.4130

**Table 11:** Parameters of the unconstrained model fit to 2 and the constrained (parallel) model fit to 1 and 2

## 6.2 Sample suitability tests

Parameter	Test	Lower Limit	Upper Limit	Estimate	Result
<b>Goodness of fit tests</b>					
Significance test for goodness of fit	p-value for F test	0.05	NA	0.2284	PASS

NA = Not Applicable

**Table 12:** Suitability tests for 2

## 6.3 Relative Potency

Parameter	Estimate	95% Confidence Interval		Ratio of Upper and Lower Bounds of the Relative Potency CI
		Lower Bound	Upper Bound	
Relative Potency	0.984	0.927	1.045	1.127

CI = Confidence Interval

**Table 13:** Relative Potency of 2

## 7 Test Sample: R/3/5

Name	Dose	Geometric Mean Response	%GCV of Response
R/3/5	0.05	0.023	9.86
R/3/5	0.10	0.025	0.57
R/3/5	0.20	0.024	0.30
R/3/5	0.40	0.035	3.28
R/3/5	0.80	0.174	18.17
R/3/5	1.60	0.853	0.79
R/3/5	3.20	1.777	0.34
R/3/5	6.40	2.143	0.10
R/3/5	12.80	2.497	0.83
R/3/5	25.60	2.432	1.87

GCV = Geometric Coefficient of Variation

Table 14: Summary of R/3/5

### 7.1 Model fits

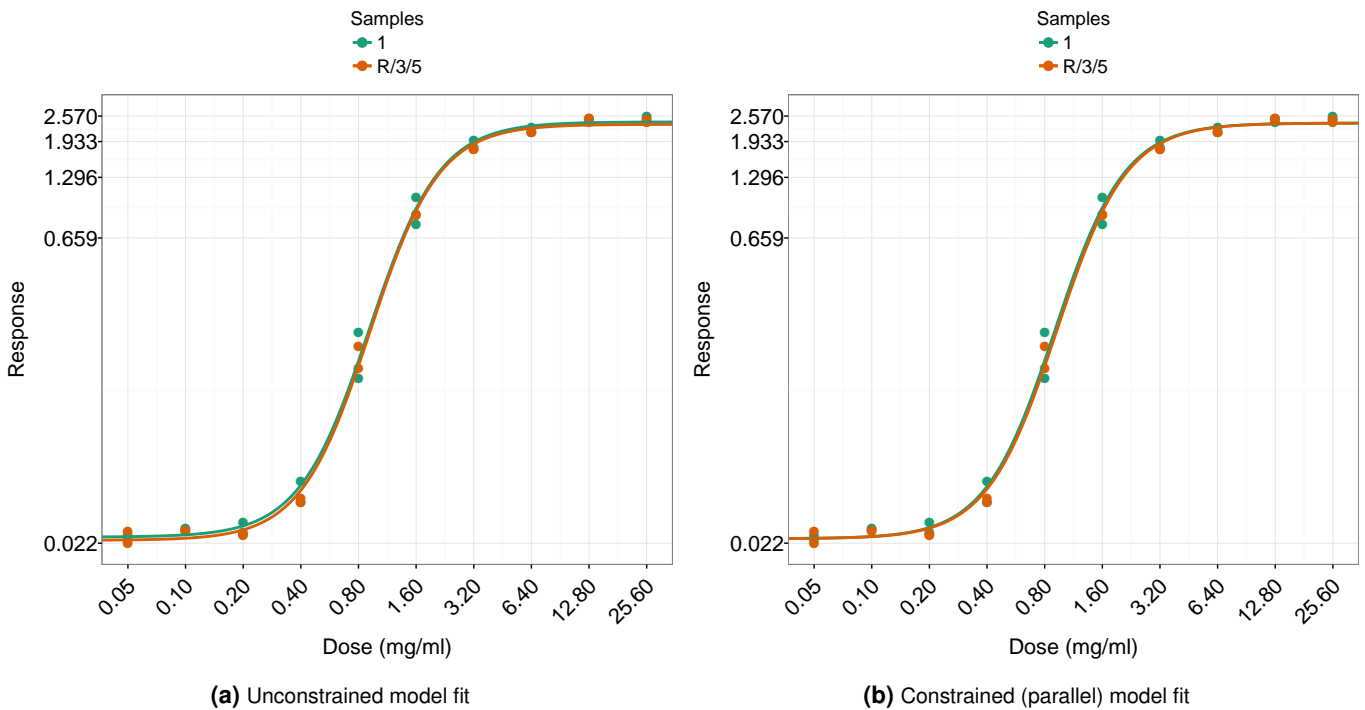


Figure 4: Model fits to 1 and R/3/5

Note the model parameters in Table 15 are for the fit using the transformed data and so do not directly correspond to the fit shown above, which is plotted on the original scale.



Model	Parameter	Name	Estimate	95% Confidence Interval	
				Lower Bound	Upper Bound
Unconstrained	Left asymptote (A)	R/3/5	-1.647	-1.685	-1.610
	Slope parameter	R/3/5	5.535	4.964	6.106
	Log <sub>10</sub> (EC <sub>50</sub> )	R/3/5	-0.03790	-0.05887	-0.01693
	Right asymptote (D)	R/3/5	0.3697	0.3357	0.4037
Constrained (parallel)	Left asymptote (A)	Common	-1.640	-1.670	-1.609
	Slope parameter	Common	5.490	5.039	5.940
	Log <sub>10</sub> (EC <sub>50</sub> )	1	-0.04454	-0.06602	-0.02305
	Log <sub>10</sub> (EC <sub>50</sub> )	R/3/5	-0.03406	-0.05556	-0.01257
	Right asymptote (D)	Common	0.3757	0.3486	0.4028

**Table 15:** Parameters of the unconstrained model fit to R/3/5 and the constrained (parallel) model fit to 1 and R/3/5

## 7.2 Sample suitability tests

Parameter	Test	Lower Limit	Upper Limit	Estimate	Result
<b>Goodness of fit tests</b>					
Significance test for goodness of fit	p-value for F test	0.05	NA	0.0245	<b>FAIL</b>

NA = Not Applicable

**Table 16:** Suitability tests for R/3/5

**Sample suitability** has failed.

## 7.3 Relative Potency

Parameter	Estimate	95% Confidence Interval		Ratio of Upper and Lower Bounds of the Relative Potency CI
		Lower Bound	Upper Bound	
Relative Potency	0.976	0.918	1.038	1.131

CI = Confidence Interval

**Table 17:** Relative Potency of R/3/5

## 8 Data

Data Map Location		Name	Dose	Response	Included in the Analysis
Row	Column				
1	11	1	0.050000000	0.023900000	Yes
5	11	1	0.050000000	0.022600000	Yes
1	10	1	0.100000000	0.025800000	Yes
5	10	1	0.100000000	0.025300000	Yes
1	9	1	0.200000000	0.027500000	Yes
5	9	1	0.200000000	0.024500000	Yes
1	8	1	0.400000000	0.043700000	Yes
5	8	1	0.400000000	0.034400000	Yes
1	7	1	0.800000000	0.228300000	Yes
5	7	1	0.800000000	0.136600000	Yes
1	6	1	1.600000000	1.036200000	Yes
5	6	1	1.600000000	0.767000000	Yes
1	5	1	3.200000000	1.948300000	Yes
5	5	1	3.200000000	1.801800000	Yes
1	4	1	6.400000000	2.270200000	Yes
5	4	1	6.400000000	2.132100000	Yes
1	3	1	12.800000000	2.508500000	Yes
5	3	1	12.800000000	2.399600000	Yes
1	2	1	25.600000000	2.569800000	Yes
5	2	1	25.600000000	2.468200000	Yes
4	11	06/21/2016	0.050000000	0.022600000	Yes
8	11	06/21/2016	0.050000000	0.027600000	Yes
4	10	06/21/2016	0.100000000	0.022700000	Yes
8	10	06/21/2016	0.100000000	0.026200000	Yes
4	9	06/21/2016	0.200000000	0.028900000	Yes
8	9	06/21/2016	0.200000000	0.031300000	Yes
4	8	06/21/2016	0.400000000	0.055100000	Yes
8	8	06/21/2016	0.400000000	0.058900000	Yes
4	7	06/21/2016	0.800000000	0.328700000	Yes
8	7	06/21/2016	0.800000000	0.353200000	Yes
4	6	06/21/2016	1.600000000	1.281700000	Yes
8	6	06/21/2016	1.600000000	1.290800000	Yes
4	5	06/21/2016	3.200000000	1.975300000	Yes
8	5	06/21/2016	3.200000000	2.029100000	Yes
4	4	06/21/2016	6.400000000	2.156900000	Yes
8	4	06/21/2016	6.400000000	2.248800000	Yes
4	3	06/21/2016	12.800000000	2.340700000	Yes
8	3	06/21/2016	12.800000000	2.324200000	Yes
4	2	06/21/2016	25.600000000	2.178000000	Yes
8	2	06/21/2016	25.600000000	2.068100000	Yes
2	11	2	0.050000000	0.021900000	Yes
6	11	2	0.050000000	0.022300000	Yes
2	10	2	0.100000000	0.027900000	Yes
6	10	2	0.100000000	0.022800000	Yes
2	9	2	0.200000000	0.025700000	Yes
6	9	2	0.200000000	0.025600000	Yes
2	8	2	0.400000000	0.039700000	Yes
6	8	2	0.400000000	0.035800000	Yes

Table 18: Data

Table 18: Data (continued)

Data Map Location		Name	Dose	Response	Included in the Analysis
Row	Column				
2	7	2	0.80000000	0.19080000	Yes
6	7	2	0.80000000	0.15910000	Yes
2	6	2	1.60000000	0.88980000	Yes
6	6	2	1.60000000	0.78540000	Yes
2	5	2	3.20000000	1.91870000	Yes
6	5	2	3.20000000	1.80880000	Yes
2	4	2	6.40000000	2.29580000	Yes
6	4	2	6.40000000	2.26460000	Yes
2	3	2	12.80000000	2.48540000	Yes
6	3	2	12.80000000	2.53360000	Yes
2	2	2	25.60000000	2.49220000	Yes
6	2	2	25.60000000	2.54280000	Yes
3	11	R/3/5	0.05000000	0.02180000	Yes
7	11	R/3/5	0.05000000	0.02490000	Yes
3	10	R/3/5	0.10000000	0.02510000	Yes
7	10	R/3/5	0.10000000	0.02490000	Yes
3	9	R/3/5	0.20000000	0.02400000	Yes
7	9	R/3/5	0.20000000	0.02390000	Yes
3	8	R/3/5	0.40000000	0.03430000	Yes
7	8	R/3/5	0.40000000	0.03590000	Yes
3	7	R/3/5	0.80000000	0.15430000	Yes
7	7	R/3/5	0.80000000	0.19540000	Yes
3	6	R/3/5	1.60000000	0.85770000	Yes
7	6	R/3/5	1.60000000	0.84820000	Yes
3	5	R/3/5	3.20000000	1.77250000	Yes
7	5	R/3/5	3.20000000	1.78110000	Yes
3	4	R/3/5	6.40000000	2.14140000	Yes
7	4	R/3/5	6.40000000	2.14430000	Yes
3	3	R/3/5	12.80000000	2.51150000	Yes
7	3	R/3/5	12.80000000	2.48240000	Yes
3	2	R/3/5	25.60000000	2.40050000	Yes
7	2	R/3/5	25.60000000	2.46410000	Yes

Table 18: Data

Table 18: Data (continued)

Thursday 9<sup>th</sup> March, 2017

## Audit report for: demo test method

QuBAS uses a continuous real time validation system that validates the system and all file operations and calculations by Diverse Self-checking Pair Programming (DSCPP) every use. See QuBAS Help files.

QuBAS was designed and built under ISO9001 and GAMP 5 Quality Management Systems by Quantics Biostatistics.

### Validation status during this analysis:

Audit trail
QuBAS version: 1.0.0
Date of report: 09-March-2017 16:11 UTC
Report ID: 193
Analysis run and electronically signed by: Test Routine on 09 March 2017 16:10
<b>Data file</b>
File name: 1x8x12 meta data V1_1.csv
Imported by: Test Routine on 09 Mar 2017 16:08
MD5: 416b407e286c70cb1bd522adaaceddf2
<b>Routine analysis</b>
Method configuration file: 1
Authorised by Super Super on 09 Mar 2017 16:06

Process	Result	Date/time
<b>Validation of installation</b>		
R install check	PASS	09-March-2017 14:04
App install check	PASS	09-March-2017 14:04
Engine install check	PASS	09-March-2017 14:04
Licence check	PASS	09-March-2017 14:04
<b>DSCPP Processes</b>		
input XML validation	PASS	09-March-2017 16:10 UTC
Parsing report ID	PASS	09-March-2017 16:10 UTC
Parsing configuration file	PASS	09-March-2017 16:10 UTC
Parsing statistical model	PASS	09-March-2017 16:10 UTC
Parsing branch B configuration	PASS	09-March-2017 16:10 UTC
Analysis (branch A)	PASS	09-March-2017 16:10 UTC
Output validation for branch A	PASS	09-March-2017 16:10 UTC
Analysis (branch B)	PASS	09-March-2017 16:10 UTC
Output validation for branch B	PASS	09-March-2017 16:10 UTC
Check results from both branches	PASS	09-March-2017 16:11 UTC
Generate report from branch A	PASS	09-March-2017 16:11 UTC
Generate report from branch B	PASS	09-March-2017 16:11 UTC
Check that both reports are identical	PASS	09-March-2017 16:11 UTC

Validation Results
This is a routine analysis:
Audit trail is complete: <b>PASS</b>
All systems, file operation and analysis validation checks: <b>PASS</b>
Results 100% QC check: <b>PASS</b>
Reports text 100% QC check: <b>PASS</b>
<b>This report is valid for use in GxP systems</b>