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1. BIOWAVER REQUEST FOR DIFFERENT STRENGTHS

1.1. Qualitative and Quantitative Composition of the Test Product

The product is presented in two dosage strengths of BDP (metered doses of 100 and 200 mcg per actuation). These product strengths, including the metered and delivered doses, are identical to Clenil® Modulite® which is marketed in the UK (Clenil® Modulite® 100; Clenil® Modulite® 200). A summary is provided in Table 1.

Table 1: Qualitative and Quantitative Composition of the Test Product BDP pMDI 100mcg and 200mcg per actuation

Formulation	**% w/w**		**Functions**
Strength	**100 mcg per actuation**	**200 mcg per actuation**	
Beclometasone Dipropionate	0.17	0.34	Active ingredient
Ethanol Anhydrous	[redacted]	[redacted]	Co-solvent
Glycerol	[redacted]	[redacted]	Non-volatile co-solvent
HFA 134a	[redacted]	[redacted]	Propellant

1.2. In Vitro Data for Biowaiver Request

In-vitro therapeutic equivalence between the reference marketed product Clenil® Modulite® (hereafter referred to as the REFERENCE Product) and Beclometasone Dipropionate pressurised inhalation solution (hereafter referred to as the TEST Product) has been evaluated for both strengths.

In vitro equivalence studies were performed in line with "*Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for the demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) in adults and for use in the treatment of Asthma in children and adolescents*", CPMP/EWP/4151/00 Rev. 1.

The guideline states that the "use of only comparative in vitro data, obtained with an accepted method (e.g. multistage impactor/impinger), may be considered acceptable if the product satisfies all of the following criteria (compared with the reference product)".

The TEST product satisfies all the required criteria, and therefore Lupin has conducted an *in vitro* only assessment to demonstrate therapeutic equivalence between the TEST and REFERENCE products.

This product was developed for submission in a marketing authorization application in the UK (under a national procedure). Accordingly, the TEST product was assessed against REFERNCE product sourced in the UK.

The in vitro equivalence studies in support of MAA are an IVBE study on Delivered Dose Uniformity (DDU) and Aerodynamic Particle Size Distribution (APSD) presented in Report LBC-20-065, an IVBE study on Spray Pattern and Plume Geometry presented in Report RPT-CS-CMC-000021, and, because the product labeling specifies the use of a spacer/holding chamber device, an IVBE study on ASPD when used with the spacer presented in Report LBC-20-104.

1.2.1. Delivered Dose Uniformity and Aerodynamic Particle Size Distribution

1.2.1.1. Batch Details for the Reference Product and TEST Product for DDU and APSD Testing

A summary of batch details of samples used for DDU and APSD testing is provided in Table 2.

Table 2: Batch Details for Reference Product and TEST Product for DDU and PSD testing

Identifying Parameters	**Test Product (T)**	**Reference Marketed Product (RefMP) from UK source**
Product Name	Beclometasone Dipropionate pressurised inhalation solution	Clenil® Modulite®, pressurised inhalation solution
Strength	100 and 200 mcg per actuation	100 and 200 mcg per actuation
Manufactured by/ Manufactured for/ Distributed by	[redacted]	[redacted]
Description	Solution for inhalation contained in an 19mL aluminium canister sealed with a metering valve, fitted in a propylene plastic actuator with a plastic protective cap and a dose indicator. The dose is released by pressing the canister into the actuator. Each container delivers 200 doses after priming.	Solution for inhalation contained in an 19mL aluminium canister sealed with a metering valve, fitted in a propylene plastic actuator with a plastic protective cap and a dose indicator. The dose is released by pressing the canister into the actuator. Each container delivers 200 doses after priming.
Strength	100 mcg per actuation	
Batch No.	[redacted]	[redacted]
Manufacturing Date	[redacted]	[redacted]
Expiry Date	[redacted]	[redacted]

Identifying Parameters	Test Product (T)			Reference Marketed Product (RefMP) from UK source		
Drug Content (mg/canister)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Strength	200 mcg per actuation					
Batch No.	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Manufacturing Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Expiry Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Drug Content (mg/canister)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Note: Three consecutive batches of test product were used during the study analysis.

1.2.1.2. Delivered Dose Uniformity (DDU)

The Delivered Dose Uniformity (DDU) test was performed [redacted] Test product and RefMP with three different batches of each strength using a dose unit sampling apparatus (DUSA) equivalent to Ph. Eur. Dose Collection Apparatus to collect DDU samples at a flow rate of [redacted]

Delivered Dose Uniformity analysis was carried out using [redacted] from each batch of each product. The delivered dose (DD) [redacted] Three batches of Test product and RefMP [redacted] for both product strengths were tested to obtain [redacted] for each batch of Test Product and RefMP. [redacted] A total of [redacted] results were obtained [redacted] for each of Test product and RefMP for each product strengths.

1.2.1.2.1. Results

The DD results [redacted] of Test product were compared with the corresponding results of RefMP and equivalence was established for both strengths based on T/R ratios of average delivered dose of all inhalers tested.

The unblinded results of Delivered Dose Uniformity at flow rate of [redacted] is presented in Table 3 and Table 4 for 100mcg/actuation and 200mcg/actuation product strengths, respectively.

The ratios for the average delivered dose between Test and RefMP for 100 and 200 mcg product strengths are within the acceptance criteria of ±15%.

The acceptance criteria for Therapeutic Equivalence are:

- The ratio of average delivered dose of Test product should be within ±15% (85-115%) to that of the RefMP considering [redacted] for delivered dose content.

Table 3: Unblinded results of Delivered Dose Uniformity at flow rate of [redacted]- 100mcg/Actuation product strength

Product	Mean (mcg)		Mean Ratio (T/R) N=30	
	Arithmetic	Geometric	Arithmetic	Geometric
RefMP	87.9837	87.8791	1.00	1.00
Test	87.9289	87.9166		

Table 4: Unblinded results of Delivered Dose Uniformity at flow rate of [redacted]- 200mcg/Actuation product strength

Product	Mean (mcg)		Mean Ratio (T/R) N=30	
	Arithmetic	Geometric	Arithmetic	Geometric
RefMP	176.7260	176.6158	1.01	1.01
Test	178.4445	178.3936		

1.2.1.3. Aerodynamic Particle Size Distribution (APSD) by [redacted]

IVBE APSD data is presented using 5 stage groupings supporting the MAA in the UK. Groupings provided in Table 5 were used during the determination of in vitro bioequivalence.

Table 5: Cascade impactor grouping

Groupings	MAA-UK
Group 1	[redacted]
Group 2	[redacted]
Group 3	[redacted]
Group 4	[redacted]
Group 5	[redacted]

The APSD test was performed [redacted] of Test product and RefMP from three different batches of each strength using [redacted] at a flow rate

of [redacted], followed by quantitative analysis of Beclometasone dipropionate deposited on each stage using a validated method.

The APSD test was performed at [redacted] corresponding to [redacted] respectively for 100 mcg per actuation product strength.

The APSD test was performed at [redacted] corresponding to [redacted] respectively for 200 mcg per actuation product strength.

The test was performed on [redacted] from each batch. A total of [redacted] of APSD results were obtained across B and E life for each of Test product and RefMP for each product strengths. The results of Test product were compared with the corresponding results of RefMP for each of the product strength and equivalence was established by obtaining the T/R ratios for average mass of Beclometasone dipropionate for each of five [redacted] stage groups (i.e. Group-1 to Group-5).

1.2.1.3.1. Results

The unblinded results of Average mass of NGI Group 1 to Group 5 at Flow rate [redacted] along with calculation for 90% CI on log transformed data against RefMP presented in Table 6 and Table 7 for 100mcg/actuation and in Table 8 and Table 9 for the 200mcg/actuation product strengths, respectively.

The acceptance criteria for Therapeutic Equivalence are:

- For the average mass of Beclometasone dipropionate on Groups 1 through 5, the mean ratio of Test to Reference should be within ±15% (85-115%) for each product strength.
- The 90% CI of log transformed data for the geometric mean ratio of Test to RefMP should be reported as a supportive data.

Table 6: Unblinded results of Average mass of [redacted] Group 1 to Group 5 at Flow rate [redacted] for 100mcg per actuation product Strength

Group	Product	Mean		Mean Ratio (T/R)	
		Arithmetic	Geometric	Arithmetic	Geometric
1	RefMP	54.1005	53.9065	1.02	1.02
	Test	55.3402	55.2028		
2	RefMP	4.5940	4.4929	1.00	1.01
	Test	4.6132	4.5556		
3	RefMP	17.1662	17.1476	0.95	0.95
	Test	16.3627	16.3195		
4	RefMP	11.5410	11.5201	0.96	0.96

Group	Product	Mean		Mean Ratio (T/R)	
		Arithmetic	Geometric	Arithmetic	Geometric
	Test	11.0714	11.0598		
5	RefMP	3.1723	3.1637	0.96	0.96
	Test	3.0343	3.0301		

Table 7: 90% CI on log transformed data of T/R Ratios for [redacted] Group 1 to Group 5 for 100mcg per actuation product Strength

Group	T/R Ratio	90% CI	Geomean Test	Geomean RefMP
Group 1	102.40	[99.95, 104.92]	55.2028	53.9065
Group 2	101.40	[95.43, 107.73]	4.5556	4.4929
Group 3	95.17	[93.35, 97.02]	16.3195	17.1476
Group 4	96.00	[94.41, 97.62]	11.0598	11.5201
Group 5	95.77	[93.88, 97.71]	3.0301	3.1637

Table 8: Unblinded results of Average mass of the Group 1 to Group 5 for APSD at Flow rate [redacted] for 200mcg per actuation product Strength

Group	Product	Mean		Mean Ratio (T/R)	
		Arithmetic	Geometric	Arithmetic	Geometric
1	RefMP	109.5921	109.0593	1.01	1.01
	Test	110.6053	110.4003		
2	RefMP	9.9783	9.8981	0.97	0.96
	Test	9.6419	9.4558		
3	RefMP	33.2889	33.2494	0.99	0.99
	Test	32.8015	32.7537		
4	RefMP	20.4977	20.4569	1.02	1.02
	Test	20.9840	20.9604		
5	RefMP	5.6667	5.6484	1.01	1.01
	Test	5.7266	5.7195		

Table 9: 90% CI on log transformed data of T/R Ratios for [redacted] Group 1 to Group 5 for 200mcg per actuation product Strength

Group	T/R Ratio	90% CI	Geomean Test (mcg)	Geomean Reference (mcg)
Group 1	101.23	[98.67, 103.85]	110.4003	109.0593
Group 2	95.53	[90.52, 100.82]	9.4558	9.8981
Group 3	98.51	[96.93, 100.11]	32.7537	33.2494
Group 4	102.46	[100.69, 104.26]	20.9604	20.4569
Group 5	101.26	[99.21, 103.34]	5.7195	5.6484

1.2.1.4. Aerodynamic Particle Size Distribution (APSD) by [redacted] using Volumatic® spacer [redacted] delay time between actuation and sampling onset

IVBE APSD data using Volumatic® spacer with [redacted] delay time between actuation and sampling onset are presented using 5 stage groupings supporting the MAA in the UK. Groupings provided in Table 10 were used during the determination of in vitro bioequivalence.

Table 10: Cascade impactor grouping

Groupings	MAA-UK
Group 1	[redacted]
Group 2	[redacted]
Group 3	[redacted]
Group 4	[redacted]
Group 5	[redacted]

The APSD test using a Volumatic® spacer with a [redacted] delay time was performed [redacted] of Test product and RefMP from three different batches of each strength using [redacted] at a flow rate of [redacted] followed by quantitative analysis of Beclometasone dipropionate deposited on each stage using a validated method.

The APSD test using the Volumatic® spacer with [redacted] delay time was performed [redacted] respectively for 100 mcg per actuation product strength.

The APSD test was performed [redacted] respectively for 200 mcg per actuation product strength.

The test was performed on [redacted] from each batch. A total of [redacted] of APSD results were obtained [redacted] each of Test product and RefMP for each product strengths. The results of Test product were compared with the corresponding results of RefMP for each of the product strength and equivalence was established by obtaining the T/R ratios for average mass of Beclometasone dipropionate [redacted] of each of five [redacted] stage groups (i.e. Group-1 to Group-5).

1.2.1.4.1. Results

The unblinded results of Average mass of [redacted] Group 1 to Group 5 at Flow rate [redacted] along with calculation for 90% CI on log transformed data against RefMP presented in Table 11 and Table 12 for 100mcg/actuation and 200mcg/actuation product strengths, respectively. The 90% CI of the T/R ratio for Average mass for either strength are summarized in Table 13 and Table 14.

The acceptance criteria for Therapeutic Equivalence was as follows:

- For the average mass of Beclometasone dipropionate on Groups 1 through 5, the mean ratio of Test to Reference should be within ±15% (85-115%) for each product strength.
- The 90% CI of log transformed data for the geometric mean ratio of Test to RefMP should be reported as a supportive data.

Table 11: Unblinded results of Average mass of [redacted] Group 1 to Group 5 using Volumatic® spacer with [redacted] delay time at Flow rate [redacted] for 100mcg per actuation product Strength

Group	Product	Mean (mcg)		Mean Ratio (T/R)	
		Arithmetic	Geometric	Arithmetic	Geometric
1	RefMP	23.8165	23.6113	1.07	1.07
	Test	25.5257	25.3024		
2	RefMP	3.3208	3.2945	1.01	1.00
	Test	3.3469	3.2982		
3	RefMP	37.5345	37.4831	0.98	0.98
	Test	36.7831	36.7487		
4	RefMP	18.1656	18.1394	0.97	0.97
	Test	17.6770	17.6593		
5	RefMP	2.8483	2.8446	0.98	0.98
	Test	2.7872	2.7851		

Table 12: 90% CI of the T/R ratio for Average mass of [redacted] Group 1 to Group 5 for the 100 mcg Strength

Group	T/R Ratio	90% CI	Geomean Test (mcg)	Geomean RefMP (mcg)
Group 1	107.16	[102.82,111.69]	25.3024	23.6113
Group 2	100.11	[95.41,105.05]	3.2982	3.2945
Group 3	98.04	[96.56,99.54]	36.7487	37.4831
Group 4	97.35	[95.85,98.88]	17.6593	18.1394
Group 5	97.91	[96.52,99.32]	2.7851	2.8446

Table 13: Unblinded results of Average mass of [redacted] Group 1 to Group 5 using Volumatic® spacer with [redacted] time at Flow rate [redacted] for 200mcg per actuation product Strength

Group	Product	Mean (mcg)		Mean Ratio (T/R)	
		Arithmetic	Geometric	Arithmetic	Geometric
1	RefMP	45.8607	45.4701	1.04	1.04
	Test	47.8298	47.4102		
2	RefMP	6.9861	6.8974	1.00	1.00
	Test	6.9689	6.8742		
3	RefMP	73.8305	73.7161	0.99	0.99
	Test	72.9322	72.8247		
4	RefMP	34.1377	34.1177	1.00	1.00
	Test	34.2629	34.2377		
5	RefMP	5.6086	5.6040	1.01	1.01
	Test	5.6660	5.6336		

Table 14: 90% CI of the T/R ratio for Average mass of [redacted] Group 1 to Group 5 for the 200 mcg Strength

Group	T/R Ratio	90% CI	Geomean Test (mcg)	Geomean Reference (mcg)
Group 1	104.27	[100.02,108.69]	47.4102	45.4701
Group 2	99.66	[94.70,104.88]	6.8742	6.8974
Group 3	98.79	[97.08,100.53]	72.8247	73.7161
Group 4	100.35	[99.21,101.51]	34.2377	34.1177
Group 5	100.53	[98.14,102.98]	5.6336	5.6040

1.2.1.5. Conclusion

The TP/RP ratios for mean delivered dose met the pre-defined acceptance criteria of 85-115%.

The TP/RP ratios for each [redacted] stage group met the predefined acceptance criteria of 85-115%.

The TP/RP ratios for each [redacted] stage group using Volumatic® spacer with [redacted] delay time met the predefined acceptance criteria of 85-115%.

In addition, the 90% confidence intervals for the geometric mean T/R ratios of five [redacted] groups for both IVBE studies (with and without Volumatic® spacer) are contained within the range of 80- 125%.

Therefore, the Test Product and Reference Product of 100 mcg and 200 mcg strength are considered equivalent.

1.2.2. Spray Pattern and Plume Geometry

1.2.2.1. Batch Details for the Reference Product and TEST Product for SP and PG Testing

Batch details for samples used for SP and PG testing are provided in Table 15.

Table 15: Batch Details for Reference Product and TEST Product for SP and PG Testing

Identifying Parameters	Test Product (T)	Reference Marketed Product (RefMP) from UK source
Product Name	Beclometasone Dipropionate pressurised inhalation solution	Clenil® Modulite®, pressurised inhalation solution
Strength	100 and 200 mcg per actuation	100 and 200 mcg per actuation

Identifying Parameters	Test Product (T)			Reference Marketed Product (RefMP) from UK source		
Manufactured by/ Manufactured for/ Distributed by	[redacted]			[redacted]		
Description	Solution for inhalation contained in an 19mL aluminium canister sealed with a metering valve, fitted in a propylene plastic actuator with a plastic protective cap and a dose indicator. The dose is released by pressing the canister into the actuator. Each container delivers 200 doses after priming.			Solution for inhalation contained in an 19mL aluminium canister sealed with a metering valve, fitted in a propylene plastic actuator with a plastic protective cap and a dose indicator. The dose is released by pressing the canister into the actuator. Each container delivers 200 doses after priming.		
Strength	100 mcg per actuation					
Batch No.	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Manufacturing Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Expiry Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Drug Content (mg/canister)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Strength	200 mcg per actuation					
Batch No.	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Manufacturing Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Expiry Date	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Drug Content (mg/canister)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Note: Three consecutive batches of test product were used during the study analysis.

1.2.2.2. Spray Pattern

Spray pattern analysis was carried out at [redacted] and [redacted] distances from the actuator mouthpiece for each of the products. The [redacted] TP and [redacted] RP inhalers of each 100 mcg and 200 mcg strength were tested for the following parameters: Area (mm2), Dmin (mm), Dmax (mm), and Ovality.

1.2.2.2.1. Results

The results of the analysis for the 100 mcg product at [redacted] are presented in Table 16 while the results of the 200 mcg product are presented in Table 17 . The results of the analysis for the 100 mcg product at [redacted] are presented in Table 18 while the results of the 200 mcg product are presented in Table 19 .

Table 16: Spray Pattern Results for 100 mcg TP and RP at [redacted] Distance (n=10)[1]

Strength	Product	Lot	[redacted]			
			Area [mm^2]	D_{min} [mm]	D_{max} [mm]	Ovality
100 mcg	TP	[redacted]	272	17.8	19.4	1.09
		[redacted]	267	17.7	19.3	1.09
		[redacted]	269	17.6	19.3	1.10
		Average	**269**	**17.7**	**19.3**	**1.09**
	RP	[redacted]	247	17.0	18.4	1.08
		[redacted]	247	17.1	18.4	1.08
		[redacted]	250	17.1	18.6	1.09
		Average	**248**	**17.1**	**18.5**	**1.08**
	TP/RP (Criteria: 85-115%)		**109%**	**104%**	**105%**	**101%**

Table 17: Spray Pattern Results for 200 mcg TP and RP at [redacted] Distance (n=10)

Strength	Product	Lot	[redacted]			
			Area [mm^2]	D_{min} [mm]	D_{max} [mm]	Ovality
200 mcg	TP	[redacted]	269	17.6	19.3	1.10
		[redacted]	262	17.5	19.0	1.09
		[redacted]	273	17.8	19.5	1.09
		Average	**268**	**17.7**	**19.3**	**1.09**
	RP	[redacted]	258	17.4	18.9	1.09
		[redacted]	246	16.9	18.5	1.10
		[redacted]	248	17.1	18.5	1.08
		Average	**251**	**17.1**	**18.6**	**1.09**
	TP/RP (Criteria: 85-115%)		**107%**	**103%**	**104%**	**100%**

[1] 10 inhalers with [redacted] per inhaler

Table 18: Spray Pattern Results for 100 mcg TP and RP at [redacted] Distance (n=10)

Strength	Product	Lot	[redacted]			
			Area [mm^2]	D_{min} [mm]	D_{max} [mm]	Ovality
100 mcg	TP	[redacted]	466	23.0	25.8	1.12
		[redacted]	456	22.6	25.6	1.13
		[redacted]	452	22.6	25.5	1.13
		Average	**458**	**22.7**	**25.6**	**1.13**
	RP	[redacted]	428	22.0	24.8	1.13
		[redacted]	423	21.9	24.5	1.12
		[redacted]	428	22.0	24.7	1.12
		Average	**426**	**22.0**	**24.7**	**1.12**
	TP/RP (Criteria: 85-115%)		**108%**	**103%**	**104%**	**101%**

Table 19: Spray Pattern Results for 200 mcg TP and RP at [redacted] Distance (n=10)

Strength	Product	Lot	[redacted]			
			Area [mm^2]	D_{min} [mm]	D_{max} [mm]	Ovality
200 mcg	TP	[redacted]	466	23.0	25.7	1.12
		[redacted]	469	23.0	26.0	1.13
		[redacted]	483	23.3	26.5	1.14
		Average	**473**	**23.1**	**26.1**	**1.13**
	RP	[redacted]	450	22.5	25.4	1.13
		[redacted]	443	22.3	25.1	1.13
		[redacted]	441	22.4	25.1	1.12
		Average	**445**	**22.4**	**25.2**	**1.13**
	TP/RP (Criteria: 85-115%)		**106%**	**103%**	**103%**	**100%**

1.2.2.2.2. Conclusion

The TP/RP ratios for all analyses range from 100% to 109% and meet the 85% to 115% acceptance criteria.

All parameters evaluated are within the ±15% criteria and therefore, two products are considered equivalent for each strength.

1.2.2.3. Plume Geometry

Plume geometry analysis was carried out at a distance of [redacted] from the actuator mouthpiece for each of the products. The [redacted] TP and [redacted] RP inhalers of each 100 mcg and 200 mcg strength were tested for the following parameters: Plume Angle (°) and Plume Width (mm).

1.2.2.3.1. Results

The results of the analysis for the 100 mcg product at [redacted] are presented in Table 20 while the results for the 200 mcg product are presented in Table 21.

Table 20: Plume Geometry Results for 100 mcg TP and RP at 7 cm Distance (N=10)[2]

Strength	Product	Lot	Plume Angle [°]	Plume Width [mm]
100 mcg	TP	[redacted]	20.5	25.3
		[redacted]	20.6	25.4
		[redacted]	20.5	25.4
		Average	**20.5**	**25.4**
	RP	[redacted]	20.5	25.4
		[redacted]	20.6	25.5
		[redacted]	20.5	25.3
		Average	**20.5**	**25.4**
	TP/RP (Criteria: 85-115%)		**100%**	**100%**

Table 21: Plume Geometry Results for 200 mcg TP and RP at [redacted] Distance (N=10)

Strength	Product	Lot	Plume Angle [°]	Plume Width [mm]
100 mcg	TP	[redacted]	20.5	25.3
		[redacted]	20.5	25.4
		[redacted]	20.6	25.6
		Average	**20.5**	**25.4**

[2] 10 inhalers with [redacted] per inhaler

Strength	Product	Lot	Plume Angle [°]	Plume Width [mm]
	RP	[redacted]	20.6	25.5
		[redacted]	20.5	25.3
		[redacted]	20.5	25.3
		Average	**20.5**	**25.4**
	TP/RP (Criteria: 85-115%)		**100%**	**100%**

1.2.2.3.2. Conclusion

The TP/RP ratios for all analyses are centered at 100% and thus, are well within the 85% to 115% acceptance criteria.

All parameters evaluated are within the ±15% criteria and therefore two products are considered equivalent for each strength.