

Customer Details: Torax Biosciences Ltd

Customer Contact Name: Mark Agnew
Customer Email: info@toraxbiosciences.co.uk
Purchase Order Number: N/A

Date of Report: 24.02.21
Date on Test: 18.02.21
Date Received: 27.01.21

MelBec Reference Number: 24324
No. of samples: 1

Sample Details:
Manufacturer/Supplier: Torax Biosciences Ltd
Name of Product: ToraSan Gel
Batch code: TS20210126
Storage: Room temperature

Experimental Conditions as outlined in the standard:

Neutraliser: BU Broth
Bacterial Strains: *E. coli* K12 NCTC 10538
Product Dilution: Neat (as supplied)
Test Product Application: 5ml applied to dry hands. Hands rubbed for 60s.
Incubation Temperature: 36°C ± 1°C

Conclusion:

The test product was not inferior to the reference product and hence has met the requirements of EN 1500.

Results:
Inoculum (N) – 3.74 x 10⁸ cfu/ml

Reference Handrub: Reference (60% Propan-2-ol)

Subject	Hand	Mean Pre Value	Mean L+R	Mean Log Pre Value	Mean Post Value	Mean L+R	Mean Log Post Value	Log Reduction Factor
1	L	1.72E+06	2.46E+06	6.39	5.50E+03	7.00E+03	3.85	2.55
	R	3.20E+06			8.50E+03			
2	L	2.39E+06	2.57E+06	6.41	3.30E+03	2.14E+03	3.33	3.08
	R	2.74E+06			9.70E+02			
3	L	8.20E+05	9.90E+05	6.00	6.20E+02	5.15E+02	2.71	3.28
	R	1.16E+06			4.10E+02			
4	L	3.00E+05	5.50E+05	5.74	3.20E+02	3.75E+02	2.57	3.17
	R	8.00E+05			4.30E+02			
5	L	4.10E+06	4.50E+06	6.65	1.01E+03	3.51E+03	3.54	3.11
	R	4.90E+06			6.00E+03			
6	L	8.10E+05	8.45E+05	5.93	5.00E+02	4.70E+02	2.67	3.25
	R	8.80E+05			4.40E+02			
7	L	4.40E+06	6.45E+06	6.81	9.40E+03	5.05E+03	3.70	3.11
	R	8.50E+06			7.00E+02			
8	L	1.45E+07	1.46E+07	7.16	9.40E+02	2.37E+03	3.37	3.79
	R	1.46E+07			3.80E+03			
9	L	3.90E+06	4.00E+06	6.60	2.60E+03	2.50E+03	3.40	3.20
	R	4.10E+06			2.40E+03			
10	L	4.60E+06	3.70E+06	6.57	1.90E+03	2.05E+03	3.31	3.26
	R	2.80E+06			2.20E+03			
11	L	5.40E+06	5.85E+06	6.77	4.10E+02	1.36E+03	3.13	3.64
	R	6.30E+06			2.30E+03			
12	L	1.13E+06	2.02E+06	6.30	4.00E+03	2.09E+03	3.32	2.98
	R	2.90E+06			1.80E+02			
13	L	6.20E+06	7.15E+06	6.85	3.50E+03	1.10E+04	4.04	2.81
	R	8.10E+06			1.84E+04			
14	L	5.40E+05	5.90E+05	5.77	7.40E+02	4.55E+02	2.66	3.11
	R	6.40E+05			1.70E+02			
15	L	1.40E+06	1.33E+06	6.12	4.80E+02	5.15E+02	2.71	3.41
	R	1.26E+06			5.50E+02			
16	L	9.00E+06	5.04E+06	6.70	7.70E+02	1.13E+03	3.05	3.65
	R	1.07E+06			1.49E+03			
17	L	5.40E+06	5.55E+06	6.74	2.90E+03	1.65E+03	3.22	3.53
	R	5.70E+06			4.00E+02			
18	L	1.64E+06	9.35E+05	5.97	8.10E+02	7.75E+02	2.89	3.08
	R	2.30E+05			7.40E+02			

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Test Product: ToraSan Gel

Subject	Hand	Mean Pre Value	Mean L+R	Mean Log Pre Value	Mean Post Value	Mean L+R	Mean Log Post Value	Log Reduction Factor
1	L	3.50E+06	3.80E+06	6.58	2.20E+03	3.15E+03	3.50	3.08
	R	4.10E+06			4.10E+03			
2	L	3.80E+06	5.20E+06	6.72	1.80E+03	1.78E+03	3.25	3.47
	R	6.60E+06			1.75E+03			
3	L	1.81E+06	1.57E+06	6.19	3.00E+02	2.50E+02	2.40	3.80
	R	1.32E+06			2.00E+02			
4	L	2.50E+05	2.10E+05	5.32	1.90E+02	2.00E+02	2.30	3.02
	R	1.70E+05			2.10E+02			
5	L	2.46E+06	4.23E+06	6.63	1.00E+03	2.50E+03	3.40	3.23
	R	6.00E+06			4.00E+03			
6	L	1.53E+06	1.57E+06	6.19	7.00E+02	1.23E+03	3.09	3.11
	R	1.60E+06			1.75E+03			
7	L	6.60E+06	6.40E+06	6.81	6.60E+02	1.84E+03	3.26	3.54
	R	6.20E+06			3.01E+03			
8	L	7.00E+06	8.50E+06	6.93	4.50E+02	1.83E+03	3.26	3.67
	R	1.00E+07			3.20E+03			
9	L	1.43E+06	1.15E+06	6.06	1.30E+03	1.29E+03	3.11	2.95
	R	8.70E+05			1.28E+03			
10	L	9.20E+05	5.10E+05	5.71	5.80E+02	6.20E+02	2.79	2.92
	R	1.00E+05			6.60E+02			
11	L	3.90E+06	2.64E+06	6.42	3.30E+02	2.95E+02	2.47	3.95
	R	1.38E+06			2.60E+02			
12	L	1.81E+06	9.94E+05	6.00	3.50E+02	2.75E+02	2.44	3.56
	R	1.77E+05			2.00E+02			
13	L	7.00E+06	6.55E+06	6.82	4.60E+02	4.15E+02	2.62	4.20
	R	6.10E+06			3.70E+02			
14	L	7.80E+05	4.43E+05	5.65	2.60E+02	2.51E+02	2.40	3.25
	R	1.06E+05			2.42E+02			
15	L	1.61E+06	1.49E+06	6.17	8.40E+02	5.87E+02	2.77	3.40
	R	1.37E+06			3.33E+02			
16	L	2.44E+06	2.66E+06	6.42	5.10E+02	4.16E+03	3.62	2.81
	R	2.88E+06			7.80E+03			
17	L	2.50E+06	2.02E+06	6.30	1.25E+02	1.05E+02	2.02	4.28
	R	1.53E+06			8.50E+01			
18	L	5.10E+05	1.15E+06	6.06	8.30E+02	2.47E+03	3.39	2.67
	R	1.79E+06			4.10E+03			

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Summary:

	Mean of Pre-Values (Log)	Mean of Post-Values (Log)
Reference Product	6.42	3.19
Test Product	6.28	2.89

	Mean Log Reduction
Reference Product	3.23
Test Product	3.39

	RP-PP	PP-RP
Mean lg R RP	3.17	3.27
Mean lg R PP	3.32	3.45
Difference of Means	-0.15	-0.18

Absolute Difference of Differences $(-0.15 - (-0.18)) = 0.03$.
 (<2.0 hence acceptable).

Validations:

Neutraliser Control B (NV_B $3.0 \times 10^4 - 1.6 \times 10^5$ cfu/ml) – Inoculum 1.26×10^5 cfu/ml

Organism	Cfu/ml
<i>E. coli</i> K12	1.05×10^2

Method Validation C (NV $3.0 \times 10^2 - 1.6 \times 10^3$ cfu/ml) – Inoculum 1.12×10^3 cfu/ml

Product	<i>E. coli</i> (cfu/ml)
Test Product 24324	8.75×10^1

Verification:

A complete set of results from at least 18 volunteers is available.

The overall means of the Ig prevalues for RP and PP is at least 5.00.

There are no more than three individual Ig reductions less than 3.00 occurring in RP.

The absolute difference of mean differences between Ig reductions of RP and PP of group RP → PP and group PP → RP is less than 2.00.

Control of weighted mean counts: quotient $>5 < 15$.

N is between 1.5×10^8 and 5.0×10^8

NV is between 3.0×10^2 and 1.6×10^3

NV_B is between 3.0×10^4 and 1.6×10^5

B is $\geq 0.0005 \times NV_B$

C is $\geq 0.5 \times NV_0$

Reduction Factor Difference:

Subject	Reduction Factor Difference
1	-0.54
2	-0.39
3	-0.51
4	0.15
5	-0.12
6	0.15
7	-0.44
8	0.12
9	0.25
10	0.34
11	-0.32
12	-0.57
13	-1.38
14	-0.13
15	0.01
16	0.84
17	-0.76
18	0.41

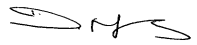
Hodges-Lehmann 97.5% Upper Confidence Limits:

Sorted Differences	Mean Pairwise Differences									
	0.84	0.41	0.34	0.25	0.15	0.15	0.12	0.01	-0.12	-0.13
0.84	0.84									
0.41	0.63	0.41								
0.34	0.59	0.38	0.34							
0.25	0.55	0.33	0.30	0.25						
0.15	0.50	0.28	0.24	0.20	0.15					
0.15	0.49	0.28	0.24	0.20	0.15	0.15				
0.12	0.48	0.27	0.23	0.19	0.13	0.13	0.12			
0.01	0.42	0.21	0.17	0.13	0.08	0.08	0.06	0.01		
-0.12	0.36	0.15	0.11	0.07	0.01	0.01	0.00			
-0.13	0.35	0.14	0.10	0.06	0.01	0.01				
-0.32	0.26	0.05	0.01							
-0.39	0.23	0.01								
-0.44	0.20									
-0.51	0.16									
-0.54	0.15									
-0.57	0.13									
-0.76	0.04									
-1.38										

The median is between the 9th and 10th value: $(-0.12 + (-0.13)) / 2 = -0.13$

The mean pairwise differences that do not exceed the median (here -0.13) are computed. The critical values for Wilcoxon's matched pairs signed ranks test the entry for $n=18$ and a one-sided 0.025 level of significance, the critical value of 40 is found. Hence, $c = 40 + 1 = 41$. The 41st entry is 0.13. Hence, the Hodges-Lehmann upper one sided 97.5% confidence limit for the difference in lg reductions between RP and PP is 0.13 which is less than the agreed inferiority margin of 0.6 lg units. Therefore, the hypothesis of inferiority of PP (test product) is rejected and it can be concluded that the test preparation PP is not inferior to RP (reference product).

Report Authorised By:



Dawn Mellors

Technical Director

This is the end of the test report