

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Name:	SHAPELINE/BIOTA TRIM	Product Code(s):	PROVEN-025-30-E
Customer:	PROVEN	Batch Number:	67487
Formulation Version	V2.0	Expiry Date:	MAY 2026
Date of Manufacture:	MAY 2024		

Product has been manufactured in accordance with the Product Formulation and Release Specification (PFRS). Please see copy of PFRS for details.

Test	Method ¹	Acceptance Criteria	Result
Physical Analysis			
Appearance ²	SOP 232 OP6 Cultech	Clear Size 00 Hard Shell Capsule containing an Off White/Cream Flowing Powder with Speckles	Conforms
Average Fill Weight	SOP 232 OP6 Cultech	Capsule contents 500mg ± 7.5% (462.5to 537.5mg)	495.0 mg
Average Filled Capsule Weight	SOP 232 OP6 Cultech	Capsule weight 618mg ± 7.5% (571.7 to 664.4mg)	613.0 mg
Uniformity of Weight	USP <2091> Cultech	Size 00 capsule shell weighing 118mg Complies with USP<2091>	Conforms
Active Ingredient Analysis			
Total Lactic Acid Bacteria Count	SOP 476 OP6 Cultech	≥50 Billion CFU/cap	62.87 Billion CFU/cap
Microbial Analysis			
Total Yeast and Mould	M022 Intertek	≤ 1 x 10 ² CFU/g	<20 CFU/g
<i>Enterobacteriaceae</i>	M009 Intertek	≤ 1 x 10 ² CFU/g	<10 CFU/g
<i>Escherichia coli</i>	M011 Intertek	Absent**** in 1g	Absent
<i>Salmonella</i>	M040 Intertek	Absent**** in 10g	Absent
<i>Staphylococcus aureus</i>	M014 Intertek	Absent**** in 1g	Absent

¹Or other validated internal Cultech or External Laboratory method

²Naturally sourced ingredients vary in both physical and organoleptic properties, consequently the appearance of products containing these may vary from batch to batch.

****Absent means <1 x 10¹ CFU

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Test	Method ¹	Acceptance Criteria	Result
Allergen Testing			
Gluten ³	SOP 104 OP6 ELISA Cultech	≤20ppm	Conforms
Total Milk ³	SOP 106 OP6 ELISA Cultech	Not Detected (<MDL*)	Conforms
Lactose ³	SOP 105 OP6 Enzymatic/LP025 Cultech/Eurofins	Not Detected (<MDL*)	Conforms

³Fully analysed on first three batches for validation. Then move to analysis on a skip lot (every fifth) batch basis.

**MDL Method Detection Limit (Total Milk <2.5ppm, Lactose – <100ppm)

Created By:	KARYS RAYNER
Position:	QC TECHNICIAN
Signature:	
Date:	30/08/2024

On behalf of the Quality Manager, Cultech Ltd

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