

## **CERTIFICATE OF ANALYSIS**

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Product Name: FOR WOMEN

Customer: PROVEN PROBIOTICS Product Code(s): PROVEN-022-30-H

Formulation Version V5.0 Batch Number: 67495

Date of Manufacture: MAY 2024 Expiry Date: MAY 2026

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

Test	Method <sup>1</sup>	Acceptance Criteria	Result
Physical Analysis			
Appearance <sup>3</sup>	SOP 232 OP6 Cultech	Clear Size 0 Hard Shell Capsule containing a Dusky Pink Free-Flowing Powder with Darker Pink Speckles	Conforms
Average Fill Weight	SOP 232 OP6 Cultech	Capsule contents 400mg ± 7.5% (370 to 430mg)	396.4 mg
Average Filled Capsule Weight	SOP 232 OP6 Cultech	Capsule weight 495mg ± 7.5% (457.9 to 532.1mg) Size 0 capsule shell weighing 95mg	491.4 mg
Uniformity of Weight	USP <2091> Cultech	Complies with USP<2091>	Conforms
Active Ingredient Analysis			
Total Lactic Acid Bacteria Count	SOP 477 OP6 Cultech	≥17.5 Billion CFU/cap	25.88 Billion CFU/cap
Microbial Analysis			
Total Yeast and Mould	M022 Intertek	$\leq 1 \times 10^4  \text{CFU/g}$	<20 CFU/g
Escherichia coli	M011 Intertek	*Absent in 1g	Absent
Enterobacteriaceae	M009 Intertek	≤ 1 x 10 <sup>2</sup> CFU/g	<10 CFU/g
Salmonella	M040 Intertek	*Absent in 10g	Absent
Staphylococcus aureus	M014 Intertek	*Absent in 1g	Absent
Allergen Testing			
Gluten <sup>3</sup>	SOP 104 OP6 ELISA Cultech	≤20ppm	Conforms
Total Milk <sup>3</sup>	SOP 106 OP6 ELISA Cultech	≤2.5ppm**	Conforms
Lactose <sup>3</sup>	SOP 105 OP6 Enzymatic Cultech	≤100ppm**	Conforms

<sup>&</sup>lt;sup>1</sup>Or other validated internal Cultech or External Laboratory method

<sup>&</sup>lt;sup>2</sup>Naturally sourced ingredients vary in both physical and organoleptic properties, consequently the appearance of products containing these may vary from batch to batch.

<sup>&</sup>lt;sup>3</sup>Fully analysed on first three batches for validation. Then move to analysis on a skip lot (every fifth) batch basis.

<sup>\*</sup>Absent means <1 x 10<sup>1</sup> CFU

<sup>\*\*</sup>LOD Limit of Detection





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Created By: KARYS RAYNER

**Position:** QC TECHNICIAN

Signature:

Date: 31/05/2024

On behalf of the Quality Manager, Cultech Ltd
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