



Eurofins BioPharma Product Testing NZ Ltd

Client Number 9633

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www.eurofins.co.nz/biopharma-services/

Authorised Representative

Fergus O'Connell
Head of Quality

Programme

Biological Testing Laboratory

Accreditation Number 1341

Initial Accreditation Date 22 October 2019

Conformance Standard

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

Laboratory Services Summary

1.03	Drugs and Pharmaceuticals
1.12	Waters
1.13	Cosmetics, Perfumes and Essential Oils
1.71	Biological Condition

Operations Manager
Authorisation:

Issue 9

Date:10/03/26

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1.03 Drugs and Pharmaceuticals

(a) Microbiological quality (including sterility)

Microbial limits tests in accordance with BP, EP, JP, USP (as harmonised) for the following organisms, except where otherwise indicated:

Bile tolerant gram-negative bacteria

Bioburden

ISO 11737-1:2018

Candida albicans (Detection)

Clostridia

E. coli

Pseudomonas aeruginosa

Salmonella

Staphylococcus aureus

Total aerobic microbial count

Yeasts and mould

1.12 Waters

(a) Potable waters

(b) Non-potable waters

(e) Cooling tower and industrial waters

Total Viable Aerobic count – MF

BP

1.13 Cosmetics, Perfumes and Essential Oils

(a) Microbiological quality

In accordance with the Australian Cosmetics and Toiletries Manufacturers Association Code of Good Manufacturing Practice and Technical Notes (1989) and USP (current edition).

Anaerobes (Clostridia) (modified)

Candida albicans

E. coli

Pseudomonas

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Salmonella
Staphylococcus aureus
Total aerobic count
Yeasts and mould count

1.71 Biological Condition

(a) Air

Sedimentation (incubation and counting)	USP
Impaction Plates (incubation and counting)	USP

(b) Plant hygiene evaluation

Contact plates	USP
Contact swabs	USP

References:

BP	British Pharmacopoeia
CTFAA	CTFAA Code of GMP – Microbiological Notes, The Cosmetic Toiletry, and Fragrance Association of Australia Inc., 1989
EP	European Pharmacopoeia
JP	Japanese Pharmacopoeia
USP	United States Pharmacopoeia

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