

Certificate of Good Manufacturing Practice

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To whom it may concern

TT60-200-16-3

This is to certify that **Eurofins BioPharma Product Testing NZ Limited; Pharmaceutical Chemistry Section and Pharmaceutical Microbiology Section** operating at **35 O'Rorke Road, Penrose, Auckland, New Zealand** has been audited to the *New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Part 1: Manufacture of Pharmaceutical Products* and has been found to comply with the requirements with respect to the following activities:

1. The chemical and physical laboratory assessment and microbial limit testing of raw materials, including purified water, in-process and finished products for:
 - Nutritional or 'nutraceutical' (vitamin, mineral & herbal) products where minor therapeutic claims are made, including products intended for the Australian market where they are termed 'listable'
 - Medicinal products including those intended for the Australian market where they are termed registered medicines.
2. The analytical and instrumental techniques as applied to 1:
 - Wet Chemistry
 - Titrimetry
 - pH
 - Refractive index
 - Polarimetry
 - Residue on ignition
 - Sulphated Ash
 - Loss on drying
 - Thin Layer Chromatography (TLC)
 - Karl Fisher moisture content
 - Brookfield Viscometry
 - UV/Visible Spectrometry
 - Gas Chromatography (GC)
 - High Performance Liquid Chromatography (HPLC)
 - Fourier Transform Infrared Spectroscopy (FTIR)
 - Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES)
3. Microbiological analysis according to APHA, client methods and CTMAA methodology as specified for sunscreen products for export to Australia.
4. Storage of stability samples under ICH conditions within environmental chambers (excluding chemical testing of stability samples).

All testing performed according to pharmacopoeial requirements, client-supplied methods, validated in-house methods or methods specified in published standards, as required by the appropriate Regulatory Authority.

This certification is based on an audit carried out by an officer of the Ministry of Health at the company's 35 O'Rorke Road site on 3 and 4 September 2018.

This certificate is valid until 18 April 2020.



Derek Fitzgerald
Manager, Compliance Management
18 October 2018

