Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Certificate No: **MI-2010-CE-08346-3**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an audit in accordance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 15 January 2009.

The competent authority of Australia confirms the following:

The manufacturer Phytomed Medicinal Herbs Ltd (NZ)
438 / 438A Rosebank Road
Avondale, Auckland
New Zealand

has been audited in connection with market authorisation(s), listing manufacturers located outside of Australia.

From the knowledge gained during audit of this manufacturer, the latest of which was conducted on 28 March 2011, it is considered that the manufacturer complies with the Good Manufacturing Practice requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 15 January 2009.

This certificate reflects the status of the manufacturing site at the time of the audit noted above. It should not be relied upon to reflect the compliance status after the expiry date. After this time the issuing authority should be consulted.

This certificate remains valid, provided that re-audits are conducted as determined by the issuing Authority. The authenticity of this certificate may be verified with the issuing Authority.

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Signature Date: 4 July 2011

Office of Manufacturing Quality
Therapeutic Goods Administration
GMP@tga.gov.au

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Part 2

MANUFACTURING OPERATIONS

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Ointment	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Capsule, hard	Listed Therapeutic Good	Release for supply
Medicine manufacture	Non Sterile	Essential Oil	Listed Therapeutic Good	Finished Product Manufacture

Conditions:
Testing is carried out by contracted third party laboratories under Phytomed Medicinal Herbs Ltd (NZ) supervision.

Expiry Date: 28 March 2014

Name and signature of the authorised person of the Competent Authority of Australia

Dragana Milic
Audit Manager
Office of Manufacturing Quality
Therapeutic Goods Administration

4 July 2011

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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

(2011/003534)

Phil Rasmussen
Managing Director
Phytomed Medicinal Herbs Ltd (NZ)
PO Box 83-068
Edmonton, Waitakere 0652
Auckland, New Zealand

Dear Mr Rasmussen,

GMP CERTIFICATE OF MANUFACTURING FACILITY

Please find enclosed the GMP Certificate of Manufacturing Facility
MI-2010-CE-08346-3

The certificate remains valid only if re-audits are conducted when scheduled by the Therapeutic Goods Administration. The frequency of audits is not a reflection of the expiry date shown on the certificate but is consistent with the re-audit frequency applicable to Australian manufacturers of the same class of products.

The TGA will contact the relevant sponsor(s) to arrange the re-audit of your facility.

Yours sincerely

Dragana Milic
Audit Manager
Office of Manufacturing Quality

4 July 2011