

Australian Government

Department of Health and AgeingTherapeutic Goods Administration

2013/003039

Dr Lynda Hammons Vice President of Quality Assurance and Regulatory Affairs Natures Sunshine Products Inc 1655 North Main Street Spanish Fork Utah 84660 USA

Dear Dr Hammons,

Subject: Issue of GMP certificate MI-2011-CE-06988-3

Please find enclosed the GMP certificate for your manufacturing premises.

You may note its changed layout with new security provisions: blue and grey curved dotted lines at the bottom half of each page. These provisions are intended to prevent unauthorised copying as part of a process to introduce issuing certificates electronically in the near future. This will also include using electronic signatures only.

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

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

Yours sincerely

Douglas Fenwick

Inspection Group Manager

Office of Manufacturing Quality

17 April 2013





Australian Government

Department of Health and Ageing Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2011-CE-06988-3

Issued to:

Natures Sunshine Products Inc

Manufacturing Site Address:

1655 North Main Street

Spanish Fork Utah 84660 United States Of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section/s 25(1)(g), 26(1)(g) and/or 26A(3) of the *Therapeutic Goods Act 1989* in connection with marketing authorisation/s listing manufacturers located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 23 – 27 March 2012, 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 inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 27 May 2014

ISSUE DATE: 17 April 2013

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

Signed:

Douglas Fenwick Inspection Group Manager Office of Manufacturing Quality

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible. This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804

Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au





Department of Health and Ageing Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2011-CE-06988-3

MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Tablets	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Solid Unit Dosage Forms - Hard Capsules	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Powder, oral	Listed Therapeutic Good	Finished Product Manufacture
Medicine manufacture	Non Sterile	Herb, dried	Listed Therapeutic Good	Finished Product Manufacture

The following conditions are applicable to these manufacturing operations:

The manufacture of registered therapeutic goods is restricted to complementary medicines.

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

Signed:

Douglas Fenwick
Inspection Group Manager
Office of Manufacturing Quality

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