



*Health and Youth Care Inspectorate- Plwrmaceutica/ Affairs*

CERTIFICATE NUMBER: NVH 17/1013620A

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER** <sup>2</sup>

**Part 1**

Issued following an inspection in accordance with:

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Netherlands confirms the following:

The manufacturer: *Synthon Chile Ltc/a.*

Site address: *El Castaño No 145, Lampl, Santiago, 0000, Chile*

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:

*Art. 100 of the Medicines Act*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2017-03-09, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC <sup>1</sup>

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

<sup>1</sup> The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC. It also may be required for imports coming from third countries into a Member State.

<sup>2</sup> Guidance on the interpretation of the template can be found in the 1/efp menu of EudraGMDP database.

<sup>3</sup> The requirements of the GMP recommendations of WHO.

Part2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
<b>Sterile Plant</b>				<i>confidential</i>
<b>OSD Main Plant</b>				<i>confidential</i>
<b>OSD High Containment Plant</b>				<i>confidential</i>

2017-06-19

Name and signature of the authorised person of the  
Competent Authority: Netherlands

A handwritten signature in blue ink, consisting of several loops and a long horizontal stroke.

*Drs. Gerrit Johannes "Gert" Ringel  
Health Care Inspectorate - Pharmaceuticals Affairs  
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Health and Youth Care Inspectorate  
*Ministry of Health, Welfare and Sport*

> Postal address P. O. Box 2518 6401 DA Heerlen The Netherlands

**AANGETEKEND**

Synthon Chile Ltda.  
Att. Mrs. Faundez, QA manager  
El Castaño N° 145  
Valle Grande Lampa  
Santiago, Chili

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Utrecht  
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Information with  
G.J. van Ringen  
GMPinspections@lgj.nl

Date Oct 23, 2017  
Subject GMP certificate


Our reference  
2017-  
2058397/V1013620/GJR/cs

Enclosure(s)  
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Dear Mrs. Faundez,

Please find attached the adjusted GMP Certificate of Synthon as promised.

Yours sincerely,

  
Ger van Ringen  
Coordinating/specialist senior inspector IGZ<sup>1</sup>

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<sup>1</sup> In our signature, we use the organisation name referred to in laws within the area of public health and youth care.