Health and Youth Care Inspectorate – Pharmaceutical Products

CERTIFICATE NUMBER: *NL/H 19/2014267*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

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 Ltda.***
Site address: ***El Castaño No 145, Lampa, 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 ***2019-10-10*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

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

Any restrictions related to the scope of this certificate :

Building	Room	Line/equipment	QC testing	Products
Sterile Plant				***Glatiramer acetate solution for injection in Pre-filled Syringes***
OSD Main Plant				***Ivabridine Tablets, Cinacalcet Tablets, Deferasirox Tablets***
OSD High Containment Plant				***Lenalidomide Capsules, Everolimus Tablets, Erlotinib Tablets, Fingolimod Capsules***

2019-12-18

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

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Drs Gerrit Johannes van Ringen
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel: *+31 88 1205000*
Fax: *+31 88 1205001*

2019-12-18

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

Drs Gerrit Johannes van Ringen
Health and Youth Care Inspectorate – Pharmaceutical Products
Tel: +31 88 1205000
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Issued as a photographic copy of an electronic document, presented to me, mr. Cornelis van Ark, notary, residing at the municipal of West Maas en Waal, on the twenty-second of April two thousand and twenty.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: THE NETHERLANDS
   This public document
2. has been signed by **C. van Ark**
3. acting in the capacity of notary at West Maas en Waal
4. bears the seal/stamp of aforesaid notary

Certified

5. in Arnhem
6. on 12-05-2020
7. by the registrar of the district court of Gelderland
8. no. 20/996

9. Seal/stamp:
10. Signature:

L.J.H. Geurts