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Health Canada / Santé Canada

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Confirmation no. (given by the issuing regulatory authority):

1. Name and address of site (including building number, where applicable):

2. Manufacturer's licence number(s):[1] N/A

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

Active substance(s):[2]	Activity(ies):[3]
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
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	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
	Chemical synthesis
[redacted]	Chemical synthesis

[1] Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.

[2] Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name).

[3] For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.

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Active substance(s):[2]	Activity(ies):[3]
	Chemical synthesis
	Chemical synthesis

THE ISSUING REGULATORY AUTHORITY HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.[4]

Date of inspection of the plant under (1): Name of inspecting authority if different from the issuing regulatory authority:

- US Food and Drug Administration inspected the facility on April 6-8, 2009
- US Food and Drug Administration inspected the facility on October 29, 30, 31 and November 01, 2012

This written confirmation remains valid until October 29, 2015.

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:
Graham Spry Building, 3rd Floor, 250 Lanark Avenue, Address Locator #2003C, Ottawa, Ontario, Canada, K1A 0K9

Name and function of responsible person:
[redacted], Director General, Health Products and Food Branch Inspectorate, Health Canada

E-mail Telephone no., and Fax no.:
[redacted]@hc-sc.gc.ca
Tel. no.: 613-957-0536
Fax no.: 613-952-9805

Signature

[redacted]

[4] qdefect@ema.europa.eu.