

Federal Agency for Medicines and Health Products

CERTIFICATE NUMBER: **BE/GMP/2018/125**

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 Belgium confirms the following:

The manufacturer: **Schering-Plough Labo NV**

Site address: **Industriepark 30, Heist-op-den-Berg, 2220, Belgium**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **304 H** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:

Article 12 bis, § 1 of the Law of 25th March 1964 related to the Medicinal Products

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-09-19**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.

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	
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.3 Chemical/Physical</i>
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared
	<i>2.2.2 Non-sterile products</i>
	<i>2.2.3 Biological medicinal products</i> 2.2.3.5 Biotechnology products
2.3	Other importation activities
	<i>2.3.1 Site of physical importation</i>
	<i>2.3.2 Importation of intermediate which undergoes further processing</i>

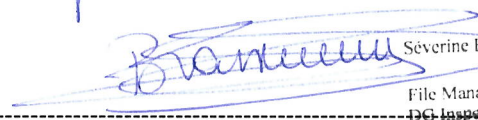


2019-01-17



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

p-o.

 Séverine BRASSEUR
File Manager,
DG Inspection FAMHP

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Federal Agency for Medicines and Health Products
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APOSTILLE (Convention de La Haye du 5 octobre 1961)	
1. Land/Pays/Land	BELGIË - BELGIQUE - BELGIEN
2. Deze openbare akte is ondertekend door : Le présent acte a été signé par : Diese öffentliche Urkunde ist unterschrieben von :	Brasseur, Séverine
3. Handelend in hoedanigheid van : Agissant en qualité de : In seiner/ihrer Eigenschaft als :	Attaché/Attaché/Attaché
4. Is voorzien van het zegel van : Est revêtu du sceau de : Sie ist versehen mit dem Siegel des/der :	FAGG/AFMPS/FAGG/FAMPS
Voor echt verklaard / Attesté / Bestätigt	
5. Te Brussel/A Bruxelles/In Brüssel	6. Op/Le/Am : 14-Feb-19
7. Door FOD Buitenlandse Zaken, Buitenlandse Handel en Ontwikkelingssamenwerking Par le SPF Affaires étrangères, Commerce extérieur et Coopération au Développement Durch FÖD Auswärtige Angelegenheiten, Außenhandel und Entwicklungszusammenarbeit	
8. Onder Nr./Sous le n°/Unter Nr. : 190258078133	
9. Stempel/Sceau/Stempel:	10. Ondertekening/Signature/Unterschrift:
	 Digitally signed by FPS Foreign Affairs Belgium

Prijs/Prix/Preis: **20.00 EUR**

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