CHILE

6/12/06/2017

Je soussigné Maître Yves TOUZET Notaire associé
à Lyon Gème 139 rue Vendôme
CERTIFIE la présente copie conforme au
document qui m'a été présenté comme
un original.

Me Yves TOUZET, Notaire à LYON
COUR D'APPEL

COUR D'APPEL DE LYON
LE PROCUREUR GENERAL

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: *HPF/FR/126/2017*

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 France confirms the following:
The manufacturer: ***MERCK SANTE - SEMOY***
Site address: ***2 rue du Pressoir Vert, SEMOY, 45400, France***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***M 14/472*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Art. L.5124-3 of Public Health Code

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-02-03*** , 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.

---

[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) 1.1.1.2 Lyophilisates
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 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*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility *2.1.2 Microbiological: non-sterility* *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

2.3	**Other importation activities**
	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

Signatory: Mrs Virginie Waysbaum, head of pharmaceutical product inspection and counterfeiting fight department --- The ANSM does not issue paper copies of good manufacturing practice certificates.

2017-05-17

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

[redacted]

Confidential
French National Agency for Medicines and Health Products Safety
Tel: ***Confidential***
Fax: ***Confidential***

Référence interne : 17/03495

CHILI

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1.République française
Le présent acte public
2. a été signé par **Yves TOUZET**
3. agissant en qualité **de notaire**
4. est revêtu du sceau/timbre de **son étude à LYON - COUR D'APPEL**

Attesté

5. à **LYON**
6. le **28 Septembre 2017**
7. par le Procureur Général près la Cour d'appel de Lyon
8. sous le n° 8605 - 3 pays
9. Sceau

10. Signature
Bérengère SINEMIAN

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le contenu du document est correct ou que la République française approuve son contenu."