

6/12/06/2017

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



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*

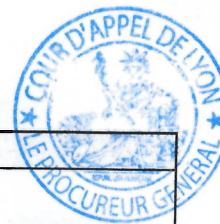
2.2 Batch certification of imported medicinal products

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

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 pag**
9. Sceau
10. Signature
Bérengère SINEMIAN

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