

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 2018/HPF/FR/165

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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: **LABORATOIRES EXPANSCIENCE**
Site address: **rue des Quatre Filles, EPERNON, 28230, France**

Has been inspected under the national inspection programme in connection with manufacturing
authorisation no. **M 14/468** 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
2018-03-16 , 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> 1.2.1.1 Capsules, hard shell
	<i>1.2.2 Batch certification</i>
1.5	Packaging
	<i>1.5.1 Primary Packing</i> 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	<i>1.5.2 Secondary packing</i>
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>
2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	Quality control testing of imported medicinal products
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.2 Non-sterile products</i>
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>

Clarifying remarks (for public users)

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

2018-07-12

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

Laurie Virginie
Responsable Pharmacovigilance

LABORATOIRES EXPANSION
S.A. au capital de 3.081.420 Euros
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Confidential
French National Agency for Medicines and Health
Products Safety
Tel: Confidential
Fax: Confidential

Je soussignée Maître Angélique CHEN
Notaire à Paris, certifie uniquement
la signature de M. Virginie Laurie
apposée
Paris, le 10 août 2018

Chen

**CONSULADO GENERAL DE CHILE
EN PARIS**

EL CONSUL GENERAL DE CHILE QUE SUSCRIBE
CERTIFICA LA AUTENTICIDAD DE LA FIRMA DE DON

J-C NANITELAMIO
FUNCIONARIO DEL MINIST. DE RR. EE. DE FRANCIA



Online EudraGMDP, Ref key: 49003, Issuance Date: 2018-07-12, Signatory: Confidential, Page 3 of 3

Actuación N°	4907	Arancel Artículo N°	4/10
Derechos US\$	12	Diferencia 10%	120
Total percibido en US\$	13,20		
Pagado en moneda local	11€		
Paris,	13 AOUT 2018		



Hans HORMAZÁBAL R.
Ministro de Fe Pública