

**Competent Regional Authority. Dirección General de Salud Pública e Investigación, Desarrollo e Innovación. Comunidad Autónoma de Castilla y León. España**

CERTIFICATE NUMBER : 4208/21

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER<sup>1, 2</sup>**

**Part 1**

Issued following an inspection in accordance with :  
Art. 111(5) of Directive 2001/83/EC as amended  
Art. 80(5) of Directive 2001/82/EC as amended  
Art. 15 of Directive 2001/20/EC

The competent authority of Spain confirms the following:

The manufacturer : **LABORATORIOS LEON FARMA, S.A.**

Site address : **C/ La Vallina s/n, Polígono Industrial Navatejera, Villaquilambre, León, 24008, Spain**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **1136** in accordance with Art. 40 of Directive 2001/83/EC , Art. 44 of Directive 2001/82/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2021-02-23** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC<sup>3</sup>

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.

<sup>1</sup> 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.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products
Veterinary Medicinal Products
Human Investigational 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 Special Requirements 7 Other: Other(en) 1.2.1.2 Capsules, soft shell Special Requirements 7 Other: Other(en) 1.2.1.6 Liquids for internal use Special Requirements 7 Other: Other(en) 1.2.1.8 Other solid dosage forms Special Requirements 7 Other: Other(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: Other(en) 1.2.1.13 Tablets Special Requirements 7 Other: Other(en)
	<i>1.2.2 Batch certification</i>

<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Other(en) 1.5.1.2 Capsules, soft shell Special Requirements 7 Other: Other(en) 1.5.1.6 Liquids for internal use Special Requirements 7 Other: Other(en) 1.5.1.8 Other solid dosage forms Special Requirements 7 Other: Other(en) 1.5.1.11 Semi-solids Special Requirements 7 Other: Other(en) 1.5.1.13 Tablets Special Requirements 7 Other: Other(en)
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.3 Chemical/Physical</i>

<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.3 Chemical/Physical</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.2 Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.4 Other: [HV] Importación del intermedio que no está sometido a posteriores procesos (polvo con hormonas o sustancias con actividad hormonal)/ Importation of intermediate without any further processing activity (powder with hormones or substances with hormonal activity)(en)</i>

Clarifying remarks (for public users)

**[F/HV]Others: Hormones or substances with hormonal activity 1.2.1.8 Other solid dosage forms: vaginal rings (Hormones or substances with hormonal activity); [F/I]Others: Hormones or substances with hormonal activity 1.2.1.8 Other solid dosage forms: vaginal rings (Hormones or substances with hormonal activity);**

2021-03-30

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

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**Confidential**

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