

## ***Bulgarian Food Safety Agency***

CERTIFICATE NUMBER: **28/2013/GMP**

### **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER <sup>(1)</sup>**

#### **Part 1**

Issued following an inspection in accordance with :

Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Bulgaria confirms the following:

The manufacturer: ***Laboratorio Baldan***

Site address: ***Paso del Rey, Belaustegi, Buenos Aires, 1648, Argentina***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 80(4) of Directive 2001/82/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2013-07-18** , it is considered that it complies with :

- 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 EudraGMP. If it does not appear, please contact the issuing authority.

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*(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.*

*(3) These requirements fulfil the GMP recommendations of WHO.*

## Part 2

Veterinary Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.8 Other solid dosage forms
<b>1.6</b>	<b>Quality Control Testing</b>
	1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Clarifying remarks (for public users)

*This certificate covers the production of non-sterile pharmaceutical solid dosage forms intended for placement in beehives*

2013-08-19

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

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*Конфиденциално*  
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