

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

The competent authority of Iceland confirms the following:  
 The manufacturer: *Pharmartica ehf.*  
 Site address: *Lundsbrunn 2, Grenivik, IS-610, Iceland*

Has been inspected under the national inspection programme in connection with manufacturing  
 authorisation no. *038* in accordance with Art. 40 of Directive 2001/83/EC and Art. 44 of Directive  
 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on  
 2018-05-02, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>1</sup>
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC<sup>2</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



Human Medicinal Products
Veterinary Medicinal Products

**I MANUFACTURING OPERATIONS**

<b>1.2</b>	<b>Non-sterile products</b>	<p>1.2.1 Capsules, hard shell</p> <p>1.2.1.1 Capsules, hard shell</p> <p>1.2.1.5 Liquids for external use</p> <p>1.2.1.6 Liquids for internal use</p> <p>1.2.1.11 Semi-solids</p> <p>1.2.1.12 Suppositories</p> <p>1.2.1.13 Tablets</p>
<b>1.5</b>	<b>Packaging</b>	<p>1.5.1 Primary Packaging</p> <p>1.5.1.1 Capsules, hard shell</p> <p>1.5.1.5 Liquids for external use</p> <p>1.5.1.6 Liquids for internal use</p> <p>1.5.1.11 Semi-solids</p> <p>1.5.1.12 Suppositories</p> <p>1.5.1.13 Tablets</p>
	1.5.2 Secondary packaging	

Any restrictions related to the scope of this certificate :

*Pharmarcica ehf. license in point 1.2 in annex 1 is restricted to magistral formula products. All Pharmarcica ehf. magistral formula products are prescription medicines.*

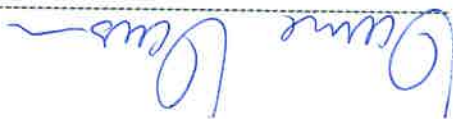
Claritying remarks (for public users)

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2018-06-01

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



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