



**OGYÉI**  
National Institute of  
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**Mr. Pranav Choksi**  
**Executive Director**  
**Gufic Lifesciences Private Limited**

**Ref: OGYÉI/26510-6/2019**  
**Subject: GMP Certificate**  
**Date: 16 September 2019**

Gufic Lifesciences Private Limited  
Block Survey, No.171  
National Grid, At & PO Kabilpore  
396424, Navsari  
Gujarat, India

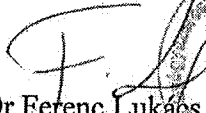
**Dear Mr. Pranav Choksi,**

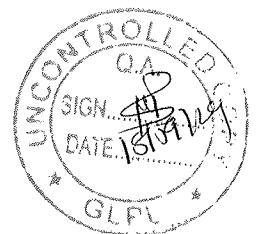
Please find attached the GMP certificate of your facility registered in EudraGMDP database.

**Gufic Lifesciences Private Limited**  
Block Survey, No.171  
National Grid, At & PO Kabilpore  
396424, Navsari  
Gujarat, India

Please consider that any event which affects the GMP compliance shall be reported in a timely manner, major changes related to the GMP system on a yearly basis.

Yours sincerely,

  
Dr Ferenc Lukács  
Inspectorate Head





*National Institute of Pharmacy and Nutrition*

CERTIFICATE NUMBER: *OGYÉI/26510-6/2019*

**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

The competent authority of Hungary confirms the following:

The manufacturer: *Gufic Lifesciences Private Limited*

Site address: *Block Survey No. 171, National grid, AT&PO Kabilpore, Navsari, Gujarat, 396 424, India*

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-06-29** , it is considered that it complies with :

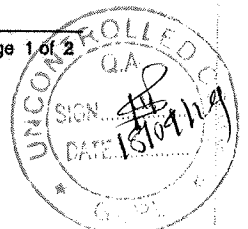
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC<sup>3</sup>

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

<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.1</b>	<b>Sterile products</b>
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> <i>1.1.1.2 Lyophilisates</i> <i>1.1.1.4 Small volume liquids</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.2 Secondary packing</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2019-09-16

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

  
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**Dr. Lukacs Ferenc**  
**National Institute of Pharmacy and Nutrition**  
Tel:  
Fax:

