

## Health Products Regulatory Authority

CERTIFICATE NUMBER: 33973\_M00589/00001

# 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 Ireland confirms the following:

The manufacturer: **Gilead Sciences Ireland Unlimited Company**

Site address: **Ida Business And Technology Park, Carrigtohill, T45 DP77, Ireland**

OMS Organisation Id. / OMS Location Id.: **ORG-100008368 / LOC-100013885**

Has been inspected under the national inspection programme in connection with manufacturing  
authorisation no. **M00589/00001** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted  
on **2023-09-08**, it is considered that it complies with::

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572  
and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in  
Part 2.<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. Updates to restrictions or  
clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>).  
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 Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup> Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

<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>1.1.3 Batch certification</i>
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.13 Tablets 1.2.1.17 Other: Powders(en)
	<i>1.2.2 Batch certification</i>
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Powders(en)
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>
<b>2 IMPORTATION OF MEDICINAL PRODUCTS</b>	
<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>
	<i>2.1.2 Microbiological: non-sterility</i> <i>2.1.3 Chemical/Physical</i> <i>2.1.4 Biological</i>
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared
	<i>2.2.2 Non-sterile products</i>
<b>2.3</b>	<b>Other importation activities</b>
	<i>2.3.1 Site of physical importation</i>

Clarifying remarks (for public users)

***Authorised operations include remote batch certification by a Qualified Person when operating within the EEA or Northern Ireland. The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.***

**2023-12-06**

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

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***Confidential***  
***Health Products Regulatory Authority***  
Tel: ***Confidential***  
Fax: ***Confidential***