

Health Products Regulatory Authority

CERTIFICATE NUMBER: 31532/M760

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1,2}

Part 1

Issued following an inspection in accordance with :

The competent authority of Ireland confirms the following:

The manufacturer: **Synergy Health Ireland Limited**

Site address: **IDA Business & Technology Park Tullamore Co Offaly, R35 X865, Ireland**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **M00760/00001** 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 **2021-11-18**, it is considered that it complies with:

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.

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.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS	
1.4	Other products or manufacturing activity
	<i>1.4.2 Sterilisation of active substance/ excipients/ finished product</i> 1.4.2.4 Chemical 1.4.2.6 Electron beam
1.6	Quality control testing
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

1.4.2.4 relates to sterilisation using Ethylene oxide. Reference to 1.6.2 and 1.6.3 refers to biological indicator testing and chemical residuals testing, respectively. The HPRA does not routinely issue hard copies of GMP certificates. The authenticity of GMP certification may be verified on the EudraGMDP database.

2021-12-09

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

Confidential
Health Products Regulatory Authority
Tel: Confidential
Fax: Confidential