HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: *23694/M641*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

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: ***Synergy Health Westport Ltd***
Site address: ***Lodge Road, Westport, Co. Mayo, Ireland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***641*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-01-10*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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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.*

[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.*

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Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.5 Gamma irradiation
	1.4.3 Other: Gamma Irradiation of Primary Packaging Components(en)

2019-03-22

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

Ms. Catherine Neary
Health Products Regulatory Authority
Tel: *+353 1 6764971*
Fax *+353 1 6764061*

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: *23694/V10834*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Ireland confirms the following:
The manufacturer: ***Synergy Health Westport Ltd***
Site address: ***Lodge Road, Westport, County Mayo, Ireland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. *10834* in accordance with Art. 44 of Directive 2001/82/EC transposed in the following national legislation:
European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No 786 of 2007), as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on *2019-01-10* , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC [3]

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.

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[3] *These requirements fulfil the GMP recommendations of WHO.*

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Part 2

Veterinary Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.5 Gamma irradiation
	1.4.3 Other: Gamma Irradiation of Primary Packaging Components(en)

2019-03-22

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

CERTIFIED HPRA

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HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Health Products Regulatory Authority

CERTIFICATE NUMBER: *23694/IMP11942*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 15 of Directive 2001/20/EC

The competent authority of Ireland confirms the following:
The manufacturer: ***Synergy Health Westport Limited***
Site address: ***Lodge Road, Westport, Co. Mayo, Ireland***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***IMP11942/00001*** in accordance with Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Medicinal Products (Control of Manufacture) Regulations 2007 to 2013.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-01-10*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.

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[3] *These requirements fulfil the GMP recommendations of WHO.*

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Part 2

Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.4	**Other products or manufacturing activity**
	1.4.2 Sterilisation of active substance/ excipients/ finished product 1.4.2.5 Gamma irradiation
	1.4.3 Other: Gamma Irradiation of Primary Packaging Components(en)

2019-03-22

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

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