HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Ms. Miriam Holohan
Qualified Person

Mr. Lee Keegan
Site Quality Manager

Synergy Health Westport Limited
Lodge Road
Westport
Co. Mayo
F28 AF54

Authorisation number: M00641/00001, V10834/00001, IMP11942/00001

22 March 2019

Inspection Reference: 23694

Dear Ms. Holohan and Mr. Keegan,

I refer to the GMP inspection performed at Synergy Health Westport Limited from the 8 – 10 January 2019 inclusive.

All correspondence relating to this inspection has been completed and implementation of corrective actions will be followed up at the next inspection.

Based on the outcome of this inspection, GMP Certificates were issued for manufacturing activities relating to human medicines, veterinary medicines and investigational medicinal products. The scope of these certificates indicate the areas of the site that are considered to operate in accordance with the principles and guidelines of Good Manufacturing Practice laid down in Directives 2003/94/EC and 91/412/EC.

Yours sincerely

C. Neary

Catherine Neary
Inspector

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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.*

An tÚdarás Rialála Táirgí Sláinte, Teach Kevin O'Malley, Ionad Phort an Iarla, Ardán Phort an Iarla, Baile Átha Cliath 2, Éire
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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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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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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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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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