*Health Products Regulatory Authority*

CERTIFICATE NUMBER: ***32540/QCLab12287_(V)_2***

# 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: ***Complete Laboratory Solutions***
Site address: ***Units 3a And 8 Ida Small Business Centre, Tuam Road, Galway, H91 H520, Ireland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100019628 / LOC-100053416***

Has been inspected under the national inspection programme in accordance with Art. 44 of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-07-20***, 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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[1] *The certificate referred to in paragraph Art. 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

| Veterinary Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.6** | **Quality control testing** |
| | *1.6.2 Microbiological: non-sterility* |
| | *1.6.3 Chemical/Physical* |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|---|---|
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.2 Microbiological: non-sterility* |
| | *2.1.3 Chemical/Physical* |

Clarifying remarks (for public users)

***The HPRA does not routinely issue hard copies of GMP certificates, Authenticity of GMP certification may be verified on the EudraGMDP database.***

***2022-08-29***

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***

*Health Products Regulatory Authority*

CERTIFICATE NUMBER: ***32540/QCLab12287***

# 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: ***Complete Laboratory Solutions***
Site address: ***Units 3a And 8 Ida Small Business Centre, Tuam Road, Galway, H91 H520, Ireland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100019628*** / ***LOC-100053416***

Has been inspected under the national inspection programme 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 ***2022-07-20***, 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 Art. 111(5) of Directive 2001/83/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

| Human Medicinal Products |
|---|

| 1 MANUFACTURING OPERATIONS | |
|---|---|
| **1.6** | **Quality control testing** |
| | *1.6.2 Microbiological: non-sterility* |
| | *1.6.3 Chemical/Physical* |

| 2 IMPORTATION OF MEDICINAL PRODUCTS | |
|---|---|
| **2.1** | **Quality control testing of imported medicinal products** |
| | *2.1.2 Microbiological: non-sterility* |
| | *2.1.3 Chemical/Physical* |

Clarifying remarks (for public users)

***The HPRA does not routinely issue hard copies of GMP certificates. Authenticity of GMP certification may be verified on the EudraGMDP database.***

***2022-08-29***

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

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