*Medicines And Healthcare Products Regulatory Agency*

CERTIFICATE NUMBER: ***UK GMP 20657 Insp GMP 20657/873857-0004***

# 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 United Kingdom confirms the following:
The manufacturer: ***CATALENT PHARMA SOLUTIONS LLC***
Site address: ***1100 ENTERPRISE DRIVE, WINCHESTER, 40391, United States***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 19(3) of Regulation 726/2004/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-03-13***, 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. 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.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

EudraGMP

**Part 2**

| Human Medicinal Products |
|---|

| **1 MANUFACTURING OPERATIONS** | |
|---|---|
| **1.2** | **Non-sterile products** |
| | *1.2.1 Non-sterile products (processing operations for the following dosage forms)*<br>1.2.1.1 Capsules, hard shell<br>1.2.1.8 Other solid dosage forms<br>1.2.1.13 Tablets<br>1.2.1.17 Other: coated beads, powders(en) |
| **1.6** | **Quality control testing** |
| | *1.6.2 Microbiological: non-sterility*<br>*1.6.3 Chemical/Physical* |

Any restrictions related to the scope of this certificate:

| Building | Room | Line/equipment | QC testing | Products |
|---|---|---|---|---|
| | | ***The site does not perform final primary packaging. All products are sent in bulk for packaging elsewhere.*** | | |

***2017-06-12***

Name and signature of the authorised person of the Competent Authority of United Kingdom

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***Medicines and Healthcare Products Regulatory Agency***
Tel:***Confidential***
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