Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 20656 Insp GMP/IMP 20656/430174-0009 [V]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of United Kingdom confirms the following :

The Manufacturer : CATALENT PHARMA SOLUTIONS LLC

Site address : CATALENT PHARMA SOLUTIONS LLC, 14 SCHOOLHOUSE ROAD, SOMERSET, NEW JERSEY 08873, UNITED STATES

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 5 of The current Veterinary Medicines Regulations

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 17/09/2013, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.2] Capsules, soft shell

MHRA-GMDP MHRA

[1.2.1.8] Other solid dosage forms

[1.2.1.13] Tablets

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

11/11/2015	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

MHRA-GMDP