Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 40699 Insp GMP 40699/7634946-0007 [H]

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

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : APTUIT (OXFORD) LIMITED

Site address : APTUIT (OXFORD) LIMITED, 110-111 AND 117 INNOVATION DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4RZ, UNITED KINGDOM
Other :
Is a contract laboratory that has been inspected in accordance with the Medicines Act as amended

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 14/11/2018, it is considered that it complies with

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

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

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.6] Quality control testing

[1.6.3] Chemical/Physical

2. IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

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Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
			Active Substances for Medicinal Products and Active Substances for use as Investigational Medicinal Products Includes analytical QC testing of active substances packaged in vials or similar closure for use as Medicinal Products or Investigational Medicinal Products.	

27/02/2019	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential

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