

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 22917 Insp GMP 22917/8721389-0002[I]

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

Part 1

Issued following an inspection in accordance with :

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following :

The Manufacturer : PHARMACEUTICS INTERNATIONAL INCORPORATED

Site address : PHARMACEUTICS INTERNATIONAL INCORPORATED, 103 BEAVER COURT, COCKEYSVILLE, 21030, UNITED STATES

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 22/02/2016, 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.

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- (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 Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

[1.1.2] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.3] Small volume liquids

[1.4] Other products or manufacturing activity

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.4.2.2] Dry heat

[1.4.2.3] Moist heat

[1.5] Packaging

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Restrictions or Remarks

The scope of manufacturing / testing covered this GMP certificate is limited to medicinal products confirmed by the relevant national competent authority as critical to public health, and with a valid marketing authorisation approved naming the site address. The GMP certificate may also not be used to support marketing authorisation applications made to a competent authority after the date of issuance. The certificate will not be considered valid after 30 June 2017.

15/06/2016 Name and signature of the authorised person of the Competent Authority of United Kingdom
Confidential
Medicines and Healthcare products Regulatory Agency
Tel : Confidential