Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 23031 Insp GMP 23031/9414256-0002[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 : GLAXOSMITHKLINE

Site address : GLAXOSMITHKLINE, GMS BIOPHARM, BUILDING 40, 893 RIVER ROAD, CONSHOHOCKEN, 19428, UNITED STATES

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 08/12/2014, 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

[1.1] Sterile Products

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

[1.1.1.6] Other aseptically prepared products
Bulk Biological API for filling elsewhere

[1.2] Non-sterile products

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

[1.2.1.17] Other non-sterile medicinal products
Bulk Biological API (low bioburden)

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products
Biological API from cell or microbiological fermentation

[1.4] Other products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.3] Other
Biological active starting materials

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

[1.4.2.1] Filtration

[1.4.3] Other
Biological API is filtered to remove bioburden

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.17] Other non-sterile medicinal products
Bulk biological API (low bioburden liquids) Isolation & Purification

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

[1.6.4] Biological

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
40 for manufacturing			Biotechnology tests, Chemical & Physical, Microbiology Non-sterile	Eperzan & Nucala Cell and microbiology fermentation manufacturing processes, isolation, purification, filtration & bulk filling of API

03/03/2015	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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