Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 20003 Insp GMP 20003/1275284-0003[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 : STRIDES ARCOLAB LIMITED - SPECIALTY FORMULATION FACILITY

Site address : STRIDES ARCOLAB LIMITED - SPECIALTY FORMULATION FACILITY, PLOT NO 284/B1, BOMMASANDRA JIGANI LINK ROAD INDUSTRIAL AREA, JIGANI HOBLI, ANEKAL TALUK, BANGALORE, IN-560105, INDIA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Part 16 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 03/09/2012, 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)

[1.1.1.2] Lyophilisates

[1.1.1.4] Small volume liquids

MHRA-GMDP MHRA

[1.1.1.6] Other aseptically prepared products

Sterile Dry Powder Injectables

[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

[1.4.2.3] Moist heat

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Speciality Formulation Facility Inspected not other buildings			QC and Microbiology laboratories were inspected	The sterile manufacturing facilities suites 1,2 and 3 were inspected. The primary focus of this inspection was Vancomycin Injection in vials. However, a general inspection of aseptic filling, lyophilisation but NOT dry powder filling was undertaken. Autoclaves were examined for suitability for liquid and porous load cycles.

09/05/2013	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 MHRA