Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 25315 Insp GMP 23158/39047-0009 [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 : LUPIN LIMITED

Site address : LUPIN LIMITED, 198-202 NEW INDUSTRIAL AREA NO. 2, MANDIDEEP, DISTRICT RAISEN, IN-462 046, 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 10/09/2012, 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)

[1.1.1.5] Solids and implants

[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

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

Dry syrups for oral administration after reconstitution

[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

Restrictions or Remarks

15-Aug-2016 In accordance with the Compilation of Community Procedures (EMA/572454/2014 Rev 17), the MHRA as the issuing authority confirm that this certificate based on the inspection conducted 2012-Sep-10 remains valid and can be utilised to support regulatory submissions until a subsequent inspection has been concluded.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
The inspection covered sterile APIs manufactured in 'Phase 3', sterile powder filling operations in 'Phase 2', and dosage form manufacture in the 'Orals Facility'.				The inspection covered the manufacture of non-sterile and sterile dosage forms referred to in preceding sections of the certificate. The manufacture of sterile APIs was also covered within the scope of this inspection. Sterile APIs for EU supply were covered by this inspection.

15/08/2016	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential