Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 5129 Insp GMP 5129/765573-0002[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 : KYOWA HAKKO KIRIN COMPANY LIMITED

Site address : KYOWA HAKKO KIRIN COMPANY LIMITED, FUJI PLANT, 1188 SHIMOTOGARI, NAGAIZUMI-CHO, SUNGO-GUN, JP-411-8731, JAPAN

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 05/12/2011, 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

[1.1.1.5] Solids and implants

[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

THE SCOPE OF THE INSPECTION WAS LIMITED TO MANUFACTURE AND PACKAGING OF STERILE PRODUCTS, SPECIFICALLY MITOMYCIN C ON #1 VIAL FILLLING LINE AND ASPARAGINASE ON #7 VIAL FILLING LINE. THESE ARE LOCATED ON THE 2ND FLOOR OF PHARMACEUTICAL PLANT NUMBER 1. PACKAGING ACTIVITIES ON 1V LINE AND 100V LINE IN PHARMACEUTICAL PLANT NUMBER 2 WERE ALSO INSPECTED. QC LABORATORIES AND RELEVANT WAREHOUSES WERE ALSO INCLUDED.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
THE SCOPE OF THE INSPECTION WAS LIMITED TO MANUFACTURE AND PACKAGING OF STERILE PRODUCTS, SPECIFICALLY MITOMYCIN C ON #1 VIAL FILLLING LINE AND ASPARAGINASE ON #7 VIAL FILLING LINE. THESE ARE LOCATED ON THE 2ND FLOOR OF PHARMACEUTICAL PLANT NUMBER 1. PACKAGING ACTIVITIES ON 1V LINE AND 100V LINE IN PHARMACEUTICAL PLANT NUMBER 2 WERE ALSO INSPECTED. QC LABORATORIES AND RELEVANT WAREHOUSES WERE ALSO INCLUDED.		FILLING: VIAL LINE 1 AND VIAL LINE 7 WERE INSPECTED. PACKAGING ACTIVITIES ON 1V LINE AND 100V LINE WERE INSPECTED.	QC LABORATORIES ASSOCIATED WITH THE TESTING OF MITOMYCIN C AND ASPARAGINASE PRODUCTS WERE INSPECTED.	MITOMYCIN C AND ASPARAGINASE WERE IN SCOPE OF INSPECTION

15/03/2012 Name and signature of the authorised person of the Competent Authority of United Kingdom

Confidential

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