Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 45282 Insp GMP 45282/13009579-0001[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 : FUJIFILM DIOSYNTH BIOTECHNOLOGIES U.S.A. INCORPORATED

Site address : FUJIFILM DIOSYNTH BIOTECHNOLOGIES U.S.A. INCORPORATED, 6051 GEORGE WATTS HILL DRIVE, RESEARCH TRIANGLE PARK, 27709, 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 10/08/2015, 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

[1.3] Biological medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.1.6] Human or animal extracted products

[1.3.1.8] Other biological medicinal products

Manufacture of recombinant proteins for use as intermediates, critical reagents or active pharmaceut

[1.6] Quality control testing

[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
				Kanuma, concentrate for solution for infusion

12/10/2015	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential