



Certificate No: UK API 25136 Insp GMP 25136/89532-0003

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	SAFC PHARMA
Site address	GUILDHALL CLOSE SYNERGY HOUSE MANCHESTER SCIENCE PARK MANCHESTER M15 6SY UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. API 25136 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Medicines Act 1968 as amended.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 31/03/2009, it is considered that it complies with the principles of GMP for active substances

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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

