



Mr Bharat Shah
SIGMA PHARMACEUTICALS PLC
UNITS 4
5
6 & 7
CLIVE WAY
WATFORD
WD24 4PX
UNITED KINGDOM

MHRA

151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Article 111 of Directive 2001/83/EC as amended.

The competent Authority of the United Kingdom confirms the following:

The Wholesale Distributor: SIGMA PHARMACEUTICALS PLC

Site Address in the United Kingdom:

UNITS 4
5
6 & 7
CLIVE WAY
WATFORD
WD24 4PX
UNITED KINGDOM

Has been inspected under the national inspection programme in connection with the authorisation required in accordance with Article 77 (1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 12/05/2016, it is considered that it complies with the principles of good distribution practice requirements referred to in Article 84 of Directive 2001/83/EC as amended.

This certificate reflects the status of the inspected site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is only valid when presented with all pages.

The authenticity of this certificate may be verified in the EUDRAGMDP database.

The authorisation of this wholesale distributor may be verified with the issuing authority.

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

**Name of the authorised person of the
Competent Authority of the United Kingdom**

Claire Glenister
GDP Inspector
Claire.Glenister@mhra.gsi.gov.uk

Date: 30/06/2016