



Certificate No: UK API 10336 Insp GMP/GDP 10336/1297-0011

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GDP COMPLIANCE OF A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

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 Active Substance Distributor: BASILDON CHEMICAL COMPANY LIMITED

Site Address in the United Kingdom:

KIMBER ROAD
ABINGDON
OX14 1RZ
UNITED KINGDOM

Has been inspected under the national inspection programme in accordance with Article 111 (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 active substance distributor, the latest of which was conducted on 18/02/2019, it is considered that it complies with the principles of good distribution practice for active substances referred to in Article 47 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 registration of this active substance distributor may be verified with the issuing authority.





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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**

Ana Boban
GDP Inspector
Ana.Boban@mhra.gov.uk

Date: 27/03/2019

