Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL
Mr. Ian Smith
BASILDON CHEMICAL COMPANY LIMITED
KIMBER ROAD
ABINGDON
OX14 1RZ
UNITED KINGDOM

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK API 10336 Insp GMP/GDP 10336/1297-0012

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)

The competent authority of the United Kingdom confirms the following:

The manufacturer	BASILDON CHEMICAL COMPANY LIMITED
Site address	KIMBER ROAD ABINGDON OX14 1RZ UNITED KINGDOM

Is an active substance manufacturer that has been inspected 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 04/04/2022, 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. 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 only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in MHRA-GMDP database. If it does not appear please contact the issuing authority.

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

Not Authorised

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

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SIMETHICONE EMULSION

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Unspecified

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

3.6.3 Microbiological testing (including sterility testing)

4 Other Activities

Not Authorised

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DIMETHICONE

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
3.5.1 Physical Processing Steps
Blending of Dimethicone fluids to achieve a specified viscosity
3.5.2 Primary Packaging

3.6 Quality Control Testing
3.6.1 Physical / Chemical testing
3.6.3 Microbiological testing (including sterility testing)

4 Other Activities
Not Authorised

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SIMETHICONE

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1 Manufacture Of Active Substance Intermediates

3.2 Processing Activities of Active Substance from Natural Sources

Not Authorised

3.3 Manufacture of Active Substance using Biological Processes

Not Authorised

3.4 Manufacture of sterile active substance

Not Authorised

3.5 General Finishing Steps

3.5.1 Physical Processing Steps

Unspecified

3.5.2 Primary Packaging

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

3.6.2 Microbiological testing (excluding sterility testing)

4 Other Activities

Not Authorised

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

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

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

Dr A J Gray
Head of Inspectorate
inspectionplanning@mhra.gov.uk

Date: 16/08/2022