



Medicines & Healthcare products  
Regulatory Agency



**MHRA**

10 South Colonnade  
Canary Wharf  
London  
E14 4PU  
United Kingdom

[gov.uk/mhra](https://www.gov.uk/mhra)

RESTRICTED – COMMERCIAL

Ms Louise Rose  
BASILDON CHEMICAL COMPANY LIMITED  
KIMBER ROAD  
ABINGDON  
OX14 1RZ  
UNITED KINGDOM



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

## 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 06/06/2025, 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.



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

## 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



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

## 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



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

## 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



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

### 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



Certificate No: UK API 10336 Insp GMP 10336/1297-0013

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

This certificate is issued based on a desk-based assessment of GMP compliance information provided by the manufacturer. This certificate should be used in combination with the relevant authorisation/registration. A risk-based site inspection programme remains in force.

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**

**Christine Atkins**  
**Head of Compliance Team 2 (GMP and GDP)**  
**inspectionplanning@mhra.gov.uk**

**Date: 06/06/2025**