



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  
Mr Emmet Tilley  
BROUGHTON LABORATORIES LIMITED  
COLEBY HOUSE  
THE WATER MILL PARK  
BROUGHTON  
SKIPTON  
BD23 3AG  
UNITED KINGDOM



Certificate No: UK GMP 29769 Insp GMP/IMP 29769/303305-0009

## 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	BROUGHTON LABORATORIES LIMITED
Site address	COLEBY HOUSE THE WATER MILL PARK BROUGHTON SKIPTON BD23 3AG UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with for human medicines Regulation 327 of 'The Human Medicines Regulations 2012 (SI 2012/1916)'; for veterinary medicines Regulation 5 of 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 17/09/2025, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended).

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.



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## 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

1.6.3 Chemical/physical

### 2. IMPORTATION OF MEDICINAL PRODUCTS

#### 2.1 Quality control testing of imported medicinal products

2.1.3 Chemical/physical

#### 2.2 Batch certification of imported medicinal products

Not Authorised

#### 2.3 Other importation activities

Not Authorised



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### **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**  
Not Authorised
  
- 3.6 Quality Control Testing**  
Not Authorised
  
- 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**

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

**Date: 18/11/2025**