



Medicines & Healthcare products
Regulatory Agency



MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

RESTRICTED – COMMERCIAL
Mr Erwan Jaffre
CEM ANALYTICAL SERVICES LIMITED
IMPERIAL HOUSE
8 OAKLANDS BUSINESS CENTRE
OAKLANDS PARK
WOKINGHAM
RG41 2FD
UNITED KINGDOM



Certificate No: UK GMP 16699 Insp GMP 16699/9507560-0012

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	CEM ANALYTICAL SERVICES LIMITED
Site address	IMPERIAL HOUSE 8 OAKLANDS BUSINESS CENTRE OAKLANDS PARK WOKINGHAM RG41 2FD 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 25/06/2025, 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:

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: 26/06/2025