Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 4 Insp GMP 4/15697-0023

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

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

The competent authority of United Kingdom confirms the following :

The Manufacturer : GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS

Site address : GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, 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 13/01/2025 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

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 valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

- [2000008117] CEFUROXIME AXETIL

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

CEFUROXIME AXETIL

3.1 Manufacture of Active Substance by Chemical Synthesis

	3.1.4 Other
	Physical form conversion from crystalline to amorphous form via spray drying
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps
	Spray drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Restrictions or Remarks

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.

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC Testing	Products
Manufacturing in the Building B12				

23/01/2025	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential