

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 10592 Insp GMP 10592/1524-0022

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 : SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS

Site address : SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, 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 20/12/2024 , 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 :

- [4000012986] POTASSIUM CLAVULANATE DILUTED

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

POTASSIUM CLAVULANATE DILUTED

3.2 Processing Activities of Active Substance from Natural Sources

- 3.2.7 Other
classical fermentation
- 3.5 General Finishing Steps
- 3.5.1 Physical Processing Steps
Extraction, crystallisation, blending
- 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
		Intermediate tBA Potassium Clavulanate (Neat) Potassium Clavulanate / Silicon Dioxide blend Potassium Clavulanate / Microcrystalline Cellulose blend Potassium Clavulanate / Amoxicillin blend The manufacture of 6-APA was not included in the scope of the inspection.

20/12/2024 Name and signature of the authorised person of the Competent Authority of United Kingdom
Confidential
Medicines and Healthcare products Regulatory Agency
Tel : Confidential