

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 10592

2: Name of authorisation holder SMITHKLINE BEECHAM LIMITED

3: Address(es) of manufacturing site(s) SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED KINGDOM

4: Legally registered address of authorisation holder SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

6: Legal Basis of authorisation Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Confidential

8: Authorisation Date 11/06/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.8] Other solid dosage forms [1.2.1.13] Tablets

- [1.2.1.17] Other non-sterile medicinal products
Including tablets (penicillin), Potassium Clavulanate/Amoxicillin Trihydrate

- [1.2.2] Batch certification

[1.5] Packaging

- [1.5.1] Primary packaging
 - [1.5.1.8] Other solid dosage forms
 - [1.5.1.13] Tablets
 - [1.5.1.17] Other non-sterile medicinal products
Tablets (penicillin), Potassium Clavulanate/Amoxicillin Trihydrate
- [1.5.2] Secondary packaging

[1.6] Quality control testing

- [1.6.2] Microbiological: non-sterility
- [1.6.3] Chemical/Physical

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP,
UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

- [1.2.1] Non-Sterile Products (processing operations for the following dosage forms)
 - [1.2.1.17] Other non-sterile medicinal products
Active intermediate Potassium Clavulanate/ Amoxicillin Trihydrate 1:1 non sterile mix, Blending of APIs.

[1.6] Quality control testing

- [1.6.3] Chemical/Physical