

# 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, CLARENDRON 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**

SMITHKLINE BEECHAM LIMITED, 79 NEW OXFORD STREET,  
LONDON, WC1A 1DG, UNITED KINGDOM

**6: Legal Basis of authorisation**

ANNEX 1 and/ or ANNEX 2

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**

28/01/2026

**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, CLARENDRON 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