

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 10592
<b>2: Name of authorisation holder</b>	SMITHKLINE BEECHAM LIMITED SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, SHEWALTON ROAD, IRVINE, KA11 5AP, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	SMITHKLINE BEECHAM LTD T/A SMITHKLINE BEECHAM PHARMACEUTICALS, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	SMITHKLINE BEECHAM LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	24/01/2025
<b>9: Annexes attached</b>	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, SHEWALTON ROAD, IRVINE, KA11 5AP,  
UNITED KINGDOM**

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile products</b> [ 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

**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