

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 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 LIMITED, CLARENDON ROAD, WORTHING, BN14 8QH, UNITED KINGDOM

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

6: Legal Basis of authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 18/09/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile investigational medicinal products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.13] Tablets Special Requirements B-lactam Antibiotics [1.2.1.15] 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

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Including 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