

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 28278

2: Name of authorisation holder IPCA LABORATORIES UK LIMITED

3: Address(es) of manufacturing site(s) IPCA LABORATORIES UK LIMITED, UNITS 97-98, SILVERBRIAR, SUNDERLAND ENTERPRISE PARK EAST, SUNDERLAND, SR5 2TQ, UNITED KINGDOM

4: Legally registered address of authorisation holder IPCA LABORATORIES UK LIMITED, UNITS 97-98, SILVERBRIAR, SUNDERLAND ENTERPRISE PARK EAST, SUNDERLAND, SR5 2TQ, 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 17/03/2026

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

IPCA LABORATORIES UK LIMITED, UNITS 97-98, SILVERBRIAR, SUNDERLAND ENTERPRISE PARK EAST, SUNDERLAND, SR5 2TQ, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
Part 1 - MANUFACTURING OPERATIONS [1.2] Non-sterile products [1.2.1] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell Special Requirements B-lactam Antibiotics

[1.2.1.13] Tablets

Special Requirements

B-lactam Antibiotics

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products