

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 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 | 21/11/2024 |
| 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

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| Human Medicinal Products |
| Authorised Operations |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.2] Batch certification of imported medicinal products [2.2.2] Non-sterile products |