

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 4102  |
| <b>2: Name of authorisation holder</b>  | CUSTOM PHARMACEUTICALS LIMITED   |
| <b>3: Address(es) of manufacturing site(s)</b>  | CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, UNITED KINGDOM                                       |
| <b>4: Legally registered address of authorisation holder</b>  | CUSTOM PHARMACEUTICALS LIMITED, UNIT 2, FAIRWAY TRADING ESTATE, MOULSECOOMB WAY, BRIGHTON, BN2 4QL, 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>  | 23/04/2024   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, UNITED KINGDOM**

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| Human Medicinal Products   |
| Authorised Operations  |
| MANUFACTURING OPERATIONS (according to part 1)   |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.1 ] Capsules, hard shell<br>[ 1.2.1.8 ] Other solid dosage forms<br>[ 1.2.1.13 ] Tablets<br>[ 1.2.1.17 ] Other non-sterile medicinal products<br>Granules and Powders. |

- [ 1.2.2 ] Batch certification
- [ 1.5 ] Packaging**
  - [ 1.5.1 ] Primary packaging
    - [ 1.5.1.17 ] Other non-sterile medicinal products
      - Granules and powders
- [ 1.6 ] Quality control testing**
  - [ 1.6.3 ] Chemical/Physical

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**CUSTOM PHARMACEUTICALS LIMITED**, UNIT 2, FAIRWAY TRADING ESTATE, MOULSECOOMB WAY, BRIGHTON, BN2 4QL,  
UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

- [ 1.2 ] Non-sterile products**
  - [ 1.2.2 ] Batch certification
- [ 1.5 ] Packaging**
  - [ 1.5.1 ] Primary packaging
    - [ 1.5.1.1 ] Capsules, hard shell
    - [ 1.5.1.8 ] Other solid dosage forms
    - [ 1.5.1.13 ] Tablets
    - [ 1.5.1.17 ] Other non-sterile medicinal products
      - Granules and Powders
  - [ 1.5.2 ] Secondary packaging
- [ 1.6 ] Quality control testing**
  - [ 1.6.2 ] Microbiological: non-sterility
  - [ 1.6.3 ] Chemical/Physical