

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 4102
2: Name of authorisation holder	CUSTOM PHARMACEUTICALS LIMITED
3: Address(es) of manufacturing site(s)	CUSTOM PHARMACEUTICALS LIMITED, UNIT 2, FAIRWAY TRADING ESTATE, MOULSECOOMB WAY, BRIGHTON, BN2 4QL, UNITED KINGDOM
4: Legally registered address of authorisation holder	CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, 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	19/01/2024
9: Annexes attached	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 1.2.2 ] Batch certification <b>[ 1.5 ] Packaging</b> [ 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
- [ 1.5.1.15 ] 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

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET, HOVE, BN3 3LW, 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)
  - [ 1.2.1.1 ] Capsules, hard shell
  - [ 1.2.1.8 ] Other solid dosage forms
  - [ 1.2.1.13 ] Tablets
  - [ 1.2.1.15 ] Other non-sterile medicinal products
    - Granules and Powders

**[ 1.6 ] Quality control testing**

- [ 1.6.3 ] Chemical/Physical