# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 4102

2: Name of authorisation holder CUSTOM PHARMACEUTICALS LIMITED

CUSTOM PHARMACEUTICALS LIMITED, CONWAY STREET,

HOVE, BN3 3LW, UNITED KINGDOM

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

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]

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

8: Authorisation Date 10/10/2024

9: Annexes attached Annex 1 and/or Annex 2

#### 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

Issue Date: 10 Oct 2024

[ 1.2.1.15 ] Other non-sterile medicinal products Granules and Powders

# [ 1.6 ] Quality control testing

[1.6.3] Chemical/Physical

### 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)

### Part 1 - MANUFACTURING OPERATIONS

# [ 1.2 ] Non-sterile investigational medicinal 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

[ 1.5.1.15 ] 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



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