# Medicines and Healthcare products Regulatory Agency

# MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 47794

2: Name of authorisation holder PHARMARON UK LIMITED

PHARMARON UK LIMITED, PEGASUS WAY, CROWN BUSINESS PARK, RUSHDEN, NN10 6ER, UNITED KINGDOM

3: Address(es) of manufacturing site(s)

PHARMARON UK LIMITED, WEST HILL INNOVATION PARK,

HERTFORD ROAD, HODDESDON, EN11 9FH, UNITED

KINGDOM

Confidential

4: Legally registered address of authorisation holder

PHARMARON UK LIMITED, PEGASUS WAY, CROWN

BUSINESS PARK, RUSHDEN, NN10 6ER, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

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

8: Authorisation Date 24/09/2025

9: Annexes attached Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

6: Legal Basis of authorisation

#### Annex 2

Name and address of the site:

PHARMARON UK LIMITED, PEGASUS WAY, CROWN BUSINESS PARK, RUSHDEN, NN10 6ER, 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

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[1.2.1.8] Other solid dosage forms

Issue Date: 24 Sep 2025

# [ 1.4 ] Other investigational medicinal products or manufacturing activity [ 1.4.1 ] Manufacture of: [ 1.4.1.3 ] Other Radioactive (API) drug product for phase I/II AME Studies. Drug product (API) for clinical studies [ 1.5 ] Packaging [ 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:

PHARMARON UK LIMITED, WEST HILL INNOVATION PARK, HERTFORD ROAD, HODDESDON, EN11 9FH, UNITED KINGDOM

Human Investigational Medicinal Products

#### **Authorised Operations**

MANUFACTURING OPERATIONS (according to part 1)
IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)

#### Part 1 - MANUFACTURING OPERATIONS

#### [ 1.1 ] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

#### [ 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

## Special Requirements

Powders and granules

[ 1.2.1.13 ] Tablets

[ 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

#### **Special Requirements**

Powders and granules

[ 1.5.1.13 ] Tablets

#### [ 1.6 ] Quality control testing

[ 1.6.3 ] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[ 2.1 ] Quality control testing of imported medicinal products

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[2.1.3] Chemical/Physical

# [ 2.2 ] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[ 2.2.1.2 ] Terminally sterilised

[2.2.2] Non-sterile products

# [ 2.3 ] Other Importation Activities

[2.3.1] Site of Physical Importation

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

[ 2.3.4 ] Other

Importation of QP certified IMPs from a country on the 'approved country for import list'



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