

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA 11724
<b>2: Name of authorisation holder</b>	ANDERSONBRECON (UK) LIMITED ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	ANDERSONBRECON (UK) LIMITED, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM ANDERSONBRECON (UK) LIMITED, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	ANDERSONBRECON (UK) LIMITED, PHAROS HOUSE, WYE VALLEY BUSINESS PARK, BRECON PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, 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>	12/02/2024
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**ANDERSONBRECON (UK) LIMITED**, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.5 ] Packaging</b>

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

**ANDERSONBRECON (UK) LIMITED**, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM

Human 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 Products

- [ 1.1.3 ] Batch certification

#### [ 1.2 ] Non-sterile products

- [ 1.2.2 ] Batch certification

#### [ 1.3 ] Biological medicinal products

- [ 1.3.2 ] Batch certification
  - [ 1.3.2.2 ] Immunological products
  - [ 1.3.2.5 ] Biotechnology products

#### [ 1.5 ] Packaging

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging

#### [ 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

- [ 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
- [ 2.2.3 ] Biological medicinal products
  - [ 2.2.3.2 ] Immunological products
  - [ 2.2.3.5 ] Biotechnology products
- [ 2.3 ] Other Importation Activities**
  - [ 2.3.1 ] Site of Physical Importation

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**ANDERSONBRECON (UK) LIMITED**, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM

Human Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

**Part 1 - MANUFACTURING OPERATIONS**

**[ 1.5 ] Packaging**

- [ 1.5.1 ] Primary packaging
  - [ 1.5.1.1 ] Capsules, hard shell
  - [ 1.5.1.2 ] Capsules, soft shell
  - [ 1.5.1.8 ] Other solid dosage forms
  - [ 1.5.1.13 ] Tablets
- [ 1.5.2 ] Secondary packaging