# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

| | |
|---|---|
| **1: Authorisation Number** | UK MIA(IMP) 11724 |
| **2: Name of authorisation holder** | ANDERSONBRECON (UK) LIMITED |
| | ANDERSONBRECON (UK) LIMITED, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM |
| **3: Address(es) of manufacturing site(s)** | ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, UNITED KINGDOM |
| | ANDERSONBRECON (UK) LIMITED, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM |
| **4: Legally registered address of authorisation holder** | ANDERSONBRECON (UK) LIMITED, PHAROS HOUSE, WYE VALLEY BUSINESS PARK, BRECON PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, 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** | 16/02/2026 |
| **9: Annexes attached** | Annex 1 and/or Annex 2 |

### SCOPE OF AUTHORISATION

**Annex 2**

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 Investigational Medicinal Products |
|---|

| Authorised Operations |
|---|
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2) |

MHRA-GMDP MHRA

**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)

[ 1.2.1.15 ] Other non-sterile medicinal products

Overencapsulation

[ 1.2.2 ] Batch certification

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.2 ] Batch certification

[ 1.3.2.2 ] Immunological products

[ 1.3.2.5 ] Biotechnology products

**[ 1.4 ] Other investigational medicinal products or manufacturing activitiy**

[ 1.4.1 ] Manufacture of:

[ 1.4.1.3 ] Other

Packaging of Tyvek lidded syringe tray for Nitrogen Dioxide sanitisation

**[ 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

[ 2.2.3.1 ] Blood 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

[ 2.3.2 ] Importation of Intermediate which undergoes further processing

**SCOPE OF AUTHORISATION**

**Annex 2**

MHRA-GMDP MHRA

Name and address of the site:

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

[ 1.2.1.15 ] Other non-sterile medicinal products

Overencapsulation

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

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[ 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 2**

Name and address of the site:

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

| Human Investigational Medicinal Products |
|---|

| Authorised Operations |
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| MANUFACTURING OPERATIONS (according to part 1) |

**Part 1 - MANUFACTURING OPERATIONS**

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MHRA-GMDP MHRA

[ 1.5.2 ] Secondary packaging

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