

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA(IMP) 11724 |
| 2: Name of authorisation holder | ANDERSONBRECON (UK) LIMITED ANDERSONBRECON (UK) LIMITED, FOREST ROAD, HAY-ON-WYE, HEREFORD, HR3 5EH, UNITED KINGDOM |
| 3: Address(es) of manufacturing site(s) | ANDERSONBRECON (UK) LIMITED, UNITS 2-7, WYE VALLEY BUSINESS PARK, BRECON ROAD, HAY-ON-WYE, HEREFORD, HR3 5PG, UNITED KINGDOM ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, 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 | 22/01/2024 |
| 9: Annexes attached | Annex 1 and/or Annex 2 |

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

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

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| 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

[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 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)

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)

[1.2.1.15] 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 activity

[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

Name and address of the site:

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

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| 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 [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 |