

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

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| 1: Authorisation Number | UK MIA 11724 |
| 2: Name of authorisation holder | ANDERSONBRECON (UK) LIMITED ANDERSONBRECON (UK) LIMITED, UNIT 1, TALGARTH BUSINESS PARK, TREFECCA ROAD, TALGARTH, BRECON, LD3 0PQ, 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, 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 | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation | Confidential |
| 8: Authorisation Date | 12/02/2024 |
| 9: Annexes attached | 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

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| 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

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

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| Human Medicinal Products |
| Authorised Operations |
| MANUFACTURING OPERATIONS (according to part 1) |
| Part 1 - MANUFACTURING OPERATIONS [1.5] Packaging <ul style="list-style-type: none">[1.5.1] Primary packaging<ul style="list-style-type: none">[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 |