

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

|                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1: Authorisation Number</b>                                                                                                    | UK MIA 17907                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>2: Name of authorisation holder</b>                                                                                            | BRISTOL LABORATORIES LIMITED<br><br>BRISTOL LABORATORIES LIMITED, UNIT 9A AND 9B,<br>PREMIER BUSINESS PARK, DENCORA WAY, LUTON, LU3 3HP,<br>UNITED KINGDOM<br><br>BRISTOL LABORATORIES LIMITED, UNIT 5, PREMIER<br>BUSINESS PARK, DENCORA WAY, LUTON, LU3 3HP, UNITED<br>KINGDOM<br><br>BRISTOL LABORATORIES LIMITED, LAPORTE WAY, LUTON,<br>LU4 8WL, UNITED KINGDOM                                                                                                       |
| <b>3: Address(es) of manufacturing site(s)</b>                                                                                    | BRISTOL LABORATORIES LIMITED, UNIT 3, CANALSIDE,<br>NORTHBRIDGE ROAD, BERKHAMSTED, HP4 1EG, UNITED<br>KINGDOM<br><br>BRISTOL LABORATORIES LIMITED, UNIT 6, SOVEREIGN<br>PARK, LAPORTE WAY, LUTON, LU4 8EL, UNITED KINGDOM<br><br>BRISTOL LABORATORIES LIMITED, UNIT 5, TRAYNOR WAY,<br>WHITEHOUSE BUSINESS PARK, PETERLEE, SR8 2RU,<br>UNITED KINGDOM<br><br>BRISTOL LABORATORIES LIMITED, UNIT 3, CANALSIDE,<br>NORTHBRIDGE ROAD, BERKHAMSTED, HP4 1EG, UNITED<br>KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <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<br>2012/1916)                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>7: Name of responsible officer of the competent authority of<br/>the member state granting the manufacturing authorisation</b> | Confidential                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>8: Authorisation Date</b>                                                                                                      | 15/09/2025                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>9: Annexes attached</b>                                                                                                        | Annex 1 and/or Annex 2                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, UNIT 9A AND 9B, PREMIER BUSINESS PARK, DENCORA WAY, LUTON, LU3 3HP, UNITED KINGDOM

|                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                     |
| Authorised Operations                                                                                                        |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                      |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br>[ 2.3 ] Other Importation Activities<br>[ 2.3.1 ] Site of Physical Importation |

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, UNIT 5, PREMIER BUSINESS PARK, DENCORA WAY, LUTON, LU3 3HP, UNITED KINGDOM

|                                                                                                                              |
|------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                     |
| Authorised Operations                                                                                                        |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                      |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br>[ 2.3 ] Other Importation Activities<br>[ 2.3.1 ] Site of Physical Importation |

**SCOPE OF AUTHORISATION**

**Annex 1**

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, LAPORTE WAY, LUTON, LU4 8WL, UNITED KINGDOM

|                                                                                                                                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                   |
| Authorised Operations                                                                                                                                      |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                  |
| Part 1 - MANUFACTURING OPERATIONS<br>[ 1.2 ] Non-sterile products<br>[ 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
- [ 1.2.1.13 ] Tablets
- [ 1.2.1.17 ] Other non-sterile medicinal products
  - Powders for sachets
- [ 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
  - [ 1.5.1.13 ] Tablets
  - [ 1.5.1.17 ] Other non-sterile medicinal products
    - Powders for sachets
- [ 1.5.2 ] Secondary packaging

#### [ 1.6 ] Quality control testing

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical

### Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

#### [ 2.1 ] Quality control testing of imported medicinal products

- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical

#### [ 2.2 ] Batch certification of imported medicinal products

- [ 2.2.2 ] Non-sterile products

#### [ 2.3 ] Other Importation Activities

- [ 2.3.1 ] Site of Physical Importation

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, UNIT 3, CANALSIDE, NORTHBRIDGE ROAD, BERKHAMSTED, HP4 1EG, UNITED KINGDOM

|                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                                                                                                   |
| Authorised Operations                                                                                                                                                                                                                      |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                    |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.2 ] Batch certification of imported medicinal products</b><br>[ 2.2.2 ] Non-sterile products<br><b>[ 2.3 ] Other Importation Activities</b><br>[ 2.3.1 ] Site of Physical Importation |

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, UNIT 6, SOVEREIGN PARK, LAPORTE WAY, LUTON, LU4 8EL, UNITED KINGDOM

|                                                                                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                            |
| Authorised Operations                                                                                                               |
| IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                             |
| Part 2 - IMPORTATION OF MEDICINAL PRODUCTS<br><b>[ 2.3 ] Other Importation Activities</b><br>[ 2.3.1 ] Site of Physical Importation |

## SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

**BRISTOL LABORATORIES LIMITED**, UNIT 5, TRAYNOR WAY, WHITEHOUSE BUSINESS PARK, PETERLEE, SR8 2RU, UNITED KINGDOM

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Medicinal Products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Authorised Operations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| MANUFACTURING OPERATIONS (according to part 1)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Part 1 - MANUFACTURING OPERATIONS<br><b>[ 1.2 ] Non-sterile products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.1 ] Capsules, hard shell<br>[ 1.2.1.13 ] Tablets<br>[ 1.2.2 ] Batch certification<br><b>[ 1.5 ] Packaging</b><br>[ 1.5.1 ] Primary packaging<br>[ 1.5.1.1 ] Capsules, hard shell<br>[ 1.5.1.13 ] Tablets<br>[ 1.5.2 ] Secondary packaging<br><b>[ 1.6 ] Quality control testing</b><br>[ 1.6.2 ] Microbiological: non-sterility<br>[ 1.6.3 ] Chemical/Physical |

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

**[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.2 ] Microbiological: non-sterility

[ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

[ 2.3.1 ] Site of Physical Importation