Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 17907
2: Name of authorisation holder	BRISTOL LABORATORIES LIMITED
3: Address(es) of manufacturing site(s)	BRISTOL LABORATORIES LIMITED, UNIT 3, CANALSIDE, NORTHBRIDGE ROAD, BERKHAMSTED, HP4 1EG, UNITED KINGDOM BRISTOL LABORATORIES LIMITED, UNIT 5, TRAYNOR WAY, WHITEHOUSE BUSINESS PARK, PETERLEE, SR8 2RU, UNITED KINGDOM BRISTOL LABORATORIES LIMITED, LAPORTE WAY, LUTON, LU4 8WL, UNITED KINGDOM
4: Legally registered address of authorisation holder	BRISTOL LABORATORIES LIMITED, UNIT 3, CANALSIDE, NORTHBRIDGE ROAD, BERKHAMSTED, HP4 1EG, 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	20/11/2023
9: Annexes attached	Annex 1 and/or Annex 2

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 **[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 5, TRAYNOR WAY, WHITEHOUSE BUSINESS PARK, PETERLEE, SR8 2RU, 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

[1.2] Non-sterile products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.1] Capsules, hard shell

[1.2.1.13] Tablets

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.13] Tablets

[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, LAPORTE WAY, LUTON, LU4 8WL, 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

[1.2] Non-sterile products

[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