# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 4483

2: Name of authorisation holder BRITANNIA PHARMACEUTICALS LIMITED

3: Address(es) of manufacturing site(s)

BRITANNIA PHARMACEUTICALS LIMITED, 200 LONGWATER

AVENUE, GREEN PARK, READING, RG2 6GP, UNITED KINGDOM

4: Legally registered address of authorisation holder

BRITANNIA PHARMACEUTICALS LIMITED, 200 LONGWATER

AVENUE, GREEN PARK, READING, RG2 6GP, 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 10/09/2024

9: Annexes attached Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

### Annex 1

Name and address of the site:

BRITANNIA PHARMACEUTICALS LIMITED, 200 LONGWATER AVENUE, GREEN PARK, READING, RG2 6GP, 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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[ 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

Issue Date: 10 Sep 2024

