Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA 4483

2: Name of authorisation holder BRITANNIA PHARMACEUTICALS LIMITED

BRITANNIA PHARMACEUTICALS LIMITED, 200 LONGWATER

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

KINGDOM

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)

Confidential

7: Name of responsible officer of the competent authority of

the member state granting the manufacturing authorisation

4: Legally registered address of authorisation holder

8: Authorisation Date 10/09/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

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

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

Issue Date: 10 Sep 2024

[2.2.2] Non-sterile products

