# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 35929

2: Name of authorisation holder CARDIFF AND VALE UNIVERSITY LOCAL HEALTH BOARD

CARDIFF AND VALE UNIVERSITY LOCAL HEALTH BOARD, ST 3: Address(es) of manufacturing site(s)

MARY'S PHARMACEUTICAL UNIT, 20 FIELD WAY, CARDIFF, CF14

4HY, UNITED KINGDOM

CARDIFF AND VALE UNIVERSITY LOCAL HEALTH BOARD,

4: Legally registered address of authorisation holder UNIVERSITY HOSPITAL OF WALES, HEATH PARK, CARDIFF, CF14

4XW, UNITED KINGDOM

5: Scope of authorisation and dosage forms ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 6: Legal Basis of authorisation

2004 [SI 2004/1031]

7: Name of responsible officer of the competent authority

of the member state granting the manufacturing

authorisation

Confidential

8: Authorisation Date 11/11/2024

9: Annexes attached Annex 1 and/or Annex 2

## SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

CARDIFF AND VALE UNIVERSITY LOCAL HEALTH BOARD, ST MARY'S PHARMACEUTICAL UNIT, 20 FIELD WAY, CARDIFF, CF14 4HY, UNITED KINGDOM

**Human Investigational 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 Investigational Medicinal Products

[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)

[1.1.2.1] Large volume liquids

[1.1.2.3] Small volume liquids

[1.1.3] Batch certification

Issue Date: 11 Nov 2024

## [ 1.2 ] Non-sterile investigational medicinal products [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [1.2.1.1] Capsules, hard shell [ 1.2.1.5 ] Liquids for external use [ 1.2.1.6 ] Liquids for internal use [ 1.2.1.8 ] Other solid dosage forms [1.2.1.11] Semi-solids [1.2.1.12] Suppositories [1.2.2] Batch certification [ 1.3 ] Biological investigational medicinal products [ 1.3.1 ] Biological medicinal products [ 1.3.1.8 ] Other biological medicinal products Labelling and packaging of sterile biological products supplied by other [ 1.4 ] Other investigational medicinal products or manufacturing activitiy [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.3 ] Moist heat [ 1.5 ] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.4] Impregnated matrices [1.5.1.5] Liquids for external use [ 1.5.1.6 ] Liquids for internal use [1.5.1.11] Semi-solids [1.5.1.12] Suppositories [ 1.5.1.13 ] Tablets [ 1.5.1.15 ] Other non-sterile medicinal products Labelling of non-sterile product [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 [2.1.3] 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 [ 2.3 ] Other Importation Activities [ 2.3.2 ] Importation of Intermediate which undergoes further processing [ 2.3.4 ] Other

Issue Date: 11 Nov 2024 Page 2 of 2

Importation of QP certified IMPs from a country on the approved country for import list

Manufacturer's Authorisation: UK MIA(IMP) 35929