# Medicines and Healthcare products Regulatory Agency

### MANUFACTURER'S AUTHORISATION

UK MIA(IMP) 34874 1: Authorisation Number

2: Name of authorisation holder CANCER RESEARCH UK FORMULATION UNIT

CANCER RESEARCH UK FORMULATION UNIT, UNIVERSITY OF

STRATHCLYDE, 161 CATHEDRAL STREET, GLASGOW, G4 ORE,

UNITED KINGDOM

CANCER RESEARCH UK FORMULATION UNIT, UNIVERSITY OF

STRATHCLYDE, 161 CATHEDRAL STREET, GLASGOW, G4 ORE,

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

4: Legally registered address of authorisation holder

the member state granting the manufacturing authorisation

27/02/2025

Confidential

8: Authorisation Date

9: Annexes attached Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

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

#### Annex 2

Name and address of the site:

CANCER RESEARCH UK FORMULATION UNIT, UNIVERSITY OF STRATHCLYDE, 161 CATHEDRAL STREET, GLASGOW, G4 ORE, 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

[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.1] Large volume liquids

[1.1.1.2] Lyophilisates

[ 1.1.1.4 ] Small volume liquids

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

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[1.1.2.1] Large volume liquids [1.1.2.3] Small volume liquids [1.1.3] Batch certification [ 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 [1.2.1.11] Semi-solids [ 1.2.2 ] Batch certification [ 1.3 ] Biological investigational medicinal products [ 1.3.1 ] Biological medicinal products [ 1.3.1.2 ] Immunological products **Special Requirements** Vaccine [ 1.3.1.5 ] Biotechnology products [1.3.2] Batch certification [ 1.3.2.2 ] Immunological products Special Requirements Vaccine [ 1.3.2.5 ] Biotechnology products [ 1.4 ] Other investigational medicinal products or manufacturing activitiy [ 1.4.2 ] Sterilisation of active substances/excipients/finished products: [ 1.4.2.1 ] Filtration [ 1.4.2.2 ] Dry heat [ 1.4.2.3 ] Moist heat [ 1.5 ] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.2] Secondary packaging [ 1.6 ] Quality control testing [ 1.6.1 ] Microbiological: sterility [ 1.6.2 ] Microbiological: non-sterility [1.6.3] Chemical/Physical [1.6.4] Biological Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [ 2.1 ] Quality control testing of imported medicinal products [2.1.1] Microbiological: sterility [2.1.2] Microbiological: non-sterility [2.1.3] Chemical/Physical [2.1.4] Biological [ 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 [2.2.3] Biological medicinal products [ 2.2.3.5 ] Biotechnology products

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## [ 2.3 ] Other Importation Activities

[ 2.3.1 ] Site of Physical Importation

[2.3.3] Biological Active Substance

[ 2.3.4 ] Other

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

