# Medicines and Healthcare products Regulatory Agency

### MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 34874

2: Name of authorisation holder CANCER RESEARCH UK FORMULATION UNIT

CANCER RESEARCH UK FORMULATION UNIT, UNIVERSITY OF 3: Address(es) of manufacturing site(s)

STRATHCLYDE, 161 CATHEDRAL STREET, GLASGOW, G4 0RE,

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

6: Legal Basis of authorisation

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004

[SI 2004/1031]

7: Name of responsible officer of the competent

4: Legally registered address of authorisation holder

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 23/03/2022

9: Annexes attached Annex 1 and/or Annex 2

#### SCOPE OF AUTHORISATION

#### 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 [ 1.2 ] 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 [ 1.3 ] 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 [ 1.4 ] 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 [1.5.2] Secondary packaging [ 1.6 ] Quality control testing [ 1.6.1 ] Microbiological: sterility [ 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

[ 2.2.3 ] Biological medicinal products

[ 2.2.3.5 ] Biotechnology products

## [ 2.3 ] Other Importation Activities

[ 2.3.4 ] Other

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

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