Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 15140
2: Name of authorisation holder	HAMMERSMITH MEDICINES RESEARCH LIMITED
3: Address(es) of manufacturing site(s)	HAMMERSMITH MEDICINES RESEARCH LIMITED, CUMBERLAND AVENUE, LONDON, NW10 7EW, UNITED KINGDOM
4: Legally registered address of authorisation holder	HAMMERSMITH MEDICINES RESEARCH LIMITED, CUMBERLAND AVENUE, LONDON, NW10 7EW, 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 authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	06/12/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

HAMMERSMITH MEDICINES RESEARCH LIMITED, CUMBERLAND AVENUE, LONDON, NW10 7EW, 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

[1.1.1.3] Semi-solids

[1.1.1.4] Small volume liquids

[1.1.1.6] Other aseptically prepared products

Radiopharmaceuticals; Site of physical importation; Importation of intermediate for further processing

[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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[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

[1.3.1.5] Biotechnology products

[1.3.1.6] Human or animal extracted products

[1.3.2] Batch certification

[1.3.2.2] Immunological products

[1.3.2.5] Biotechnology products

[1.3.2.6] Human or animal extracted products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.4.1.2] Homoeopathic products

[1.4.1.3] Other

Importation of QP certified IMPs from a country on the approved country for import list/Radiopharmaceuticals; Site of physical importation of intermediate for further processing

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.2] Secondary packaging

[1.6] Quality control testing

[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

[2.2.3.1] Blood products

[2.2.3.2] Immunological products

[2.2.3.4] Gene therapy products

[2.2.3.5] Biotechnology products

[2.2.3.6] Human or animal extracted products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP certified IMPs from a country on the approved country for import list/Radiopharmaceuticals; Site of physical importation of intermediate for further processing