Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 12689
2: Name of authorisation holder	PAREXEL INTERNATIONAL LIMITED
3: Address(es) of manufacturing site(s)	PAREXEL INTERNATIONAL LIMITED, CLINICAL PHARMACOLOGY RESEARCH UNIT, LEVEL 7, NORTHWICK PARK HOSPITAL, WATFORD ROAD, HARROW, HA1 3UJ, UNITED KINGDOM
4: Legally registered address of authorisation holder	PAREXEL INTERNATIONAL LIMITED, C/O LAWRENCE YOUNG LIMITED, HART HOUSE, PRIESTLEY ROAD, BASINGSTOKE, RG24 9PU, 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:

PAREXEL INTERNATIONAL LIMITED, CLINICAL PHARMACOLOGY RESEARCH UNIT, LEVEL 7, NORTHWICK PARK HOSPITAL, WATFORD ROAD, HARROW, HA1 3UJ, 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

[1.1.3] 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

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.3] Other

Assemble and Import closed containers of cytostatics/cytotoxics, where there will be minimal risk of exposure/ Importation of QP certified IMPs from a country on the approved country for import list

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.3] Chewing gums

[1.5.1.5] Liquids for external use

[1.5.1.6] Liquids for internal use

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[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

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Assemble and Import closed containers of cytostatics/cytotoxics, where there will be minimal risk of exposure/ Importation of QP certified IMPs from a country on the approved country for import list