

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 17857
<b>2: Name of authorisation holder</b>	PATHEON UK LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	PATHEON UK LIMITED, 151 BROOK DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4SD, UNITED KINGDOM PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	08/06/2023
<b>9: Annexes attached</b>	Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**PATHEON UK LIMITED**, 151 BROOK DRIVE, MILTON PARK, MILTON, ABINGDON, OX14 4SD, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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 [ 1.2.1.12 ] Suppositories [ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Sachets, powder, Cytostatics.

**[ 1.3 ] Biological investigational medicinal products**

[ 1.3.1 ] Biological medicinal products

[ 1.3.1.5 ] Biotechnology products

[ 1.3.1.8 ] Other biological medicinal products

Pharmaceutical dosage forms containing peptides, proteins, enzymes or other materials from human, animal or microbiological sources

**[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 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

Sachets, powder, cytostatics

**[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

[ 1.6.4 ] Biological

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**PATHEON UK LIMITED**, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, 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)

[ 1.1.1.2 ] Lyophilisates

[ 1.1.1.4 ] Small volume liquids

[ 1.1.1.6 ] Other aseptically prepared products

Powder, Cephalosporins, Cytostatics, and Tazobactam Sodium

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

[ 1.1.2.3 ] Small volume liquids

[ 1.1.2.5 ] Other terminally sterilised prepared products

Terminally sterilised microspheres of TCA and PLGA presented in vial

**[ 1.4 ] Other investigational medicinal products or manufacturing activity**

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

[ 1.4.2.1 ] Filtration

[ 1.4.2.3 ] Moist heat

**[ 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

**[ 2.2 ] 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**

[ 2.3.3 ] Biological Active Substance

[ 2.3.4 ] Other

Biological active substances