Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 17857
2: Name of authorisation holder	PATHEON UK LIMITED
3: Address(es) of manufacturing site(s)	PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM
4: Legally registered address of authorisation holder	PATHEON UK LIMITED, KINGFISHER DRIVE, COVINGHAM, SWINDON, SN3 5BZ, 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	13/02/2026
9: Annexes attached	Annex 1 and/or Annex 2

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, Cephalsporins, Cytostatics, and Tazobactam Sodium

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

[1.1.2.3] Small volume liquids

MHRA-GMDP MHRA

[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 activitiy

[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

MHRA-GMDP MHRA