

# 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,<br>COVINGHAM, SWINDON, SN3 5BZ, UNITED KINGDOM       |
| 4: Legally registered address of authorisation holder                                                                  | PATHEON UK LIMITED, KINGFISHER DRIVE,<br>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)<br>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)<br>IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.1 ] Aseptically prepared (processing operations for the following dosage forms)<br>[ 1.1.1.2 ] Lyophilisates<br>[ 1.1.1.4 ] Small volume liquids<br>[ 1.1.1.6 ] Other aseptically prepared products<br>Powder, Cephalosporins, Cytostatics, and Tazobactam Sodium<br>[ 1.1.2 ] Terminally Sterilised (processing operations for the following dosage forms)<br>[ 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