# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

| | |
|---|---|
| **1: Authorisation Number** | UK MIA(IMP) 14076 |
| **2: Name of authorisation holder** | TAYSIDE HEALTH BOARD |
| **3: Address(es) of manufacturing site(s)** | NHS SCOTLAND PHARMACEUTICAL SPECIALS SERVICE, 1 JAMES ARROTT DRIVE, NINEWELLS HOSPITAL, DUNDEE, DD2 1FE, UNITED KINGDOM |
| **4: Legally registered address of authorisation holder** | TAYSIDE HEALTH BOARD, NHS SCOTLAND PHARMACEUTICAL SPECIALS SERVICE, NINEWELLS HOSPITAL, DUNDEE, DD1 9SY, 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** | 01/06/2026 |
| **9: Annexes attached** | Annex 1 and/or Annex 2 |

**SCOPE OF AUTHORISATION**

**Annex 2**

Name and address of the site:

**NHS SCOTLAND PHARMACEUTICAL SPECIALS SERVICE**, 1 JAMES ARROTT DRIVE, NINEWELLS HOSPITAL, DUNDEE, DD2 1FE, UNITED KINGDOM

| Human Investigational Medicinal Products |
|---|

| Authorised Operations |
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| MANUFACTURING OPERATIONS (according to part 1)<br>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

[ 1.1.1.4 ] Small volume liquids

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

[ 1.1.2.1 ] Large volume liquids

[ 1.1.2.3 ] 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

[ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.12 ] Suppositories

[ 1.2.2 ] Batch certification

**[ 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

**[ 1.5 ] 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

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.12 ] Suppositories

[ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

[ 1.6.1 ] Microbiological: sterility

[ 1.6.2 ] Microbiological: non-sterility

[ 1.6.3 ] Chemical/Physical

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