

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|--|---|
| 1: Authorisation Number  | UK MIA(IMP) 45848   |
| 2: Name of authorisation holder  | QUOTIENT SCIENCES (ALNWICK) LIMITED   |
| 3: Address(es) of manufacturing site(s)  | QUOTIENT SCIENCES (ALNWICK) LIMITED, TAYLOR DRIVE,<br>ALNWICK, NE66 2DH, UNITED KINGDOM   |
| 4: Legally registered address of authorisation holder  | QUOTIENT SCIENCES (ALNWICK) LIMITED, TRENT HOUSE, MERE<br>WAY, RUDDINGTON FIELDS BUSINESS PARK, RUDDINGTON,<br>NOTTINGHAM, NG11 6JS, 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<br>2004 [SI 2004/1031]  |
| 7: Name of responsible officer of the competent<br>authority of the member state granting the<br>manufacturing authorisation | Confidential  |
| 8: Authorisation Date  | 23/02/2026  |
| 9: Annexes attached  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**QUOTIENT SCIENCES (ALNWICK) LIMITED**, TAYLOR DRIVE, ALNWICK, NE66 2DH, UNITED KINGDOM

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| 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>[ 1.1.1.4 ] Small volume liquids<br>[ 1.1.1.6 ] Other aseptically prepared products<br>Radiolabelled Products & Cytotoxic Products<br>[ 1.1.3 ] Batch certification<br><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

[ 1.2.1.2 ] Capsules, soft 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

[ 1.2.1.15 ] Other non-sterile medicinal products

Radiolabelled Products & Cytotoxic Products, Moulded Tablets, Drug in a Vial, Over encapsulated product.

[ 1.2.2 ] Batch certification

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

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

[ 1.4.2.1 ] Filtration

**[ 1.6 ] 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