

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA(IMP) 60218

**2: Name of authorisation holder** FQS PHARMA UK LTD

**3: Address(es) of manufacturing site(s)** FQS PHARMA UK LTD, THE MOUNT BUSINESS CENTRE, 2 WOODSTOCK LINK, BELFAST, BT6 8DD, UNITED KINGDOM

**4: Legally registered address of authorisation holder** FQS PHARMA UK LTD, THE MOUNT BUSINESS CENTRE, 2 WOODSTOCK LINK, BELFAST, BT6 8DD, 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** 05/12/2025

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**FQS PHARMA UK LTD**, THE MOUNT BUSINESS CENTRE, 2 WOODSTOCK LINK, BELFAST, BT6 8DD, UNITED KINGDOM

|                                                                                                                                                                                                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Human Investigational Medicinal Products                                                                                                                                                                                                 |
| Authorised Operations                                                                                                                                                                                                                    |
| MANUFACTURING OPERATIONS (according to part 1)                                                                                                                                                                                           |
| <b>Part 1 - MANUFACTURING OPERATIONS</b><br><b>[ 1.1 ] Sterile Investigational Medicinal Products</b><br>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.2 ] Batch certification |