

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|--|---|
| 1: Authorisation Number  | UK MIA(IMP) 20300   |
| 2: Name of authorisation holder  | SGS QUAY PHARMACEUTICALS LIMITED  |
| 3: Address(es) of manufacturing site(s)  | SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, UNITED KINGDOM |
| 4: Legally registered address of authorisation holder  | SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, 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  | 28/04/2025  |
| 9: Annexes attached  | Annex 1 and/or Annex 2  |

### SCOPE OF AUTHORISATION

#### Annex 2

Name and address of the site:

**SGS QUAY PHARMACEUTICALS LIMITED**, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, 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>[ 1.1.3 ] Batch certification<br><b>[ 1.2 ] Non-sterile investigational medicinal products</b><br>[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)<br>[ 1.2.1.1 ] Capsules, hard shell |

[ 1.2.1.3 ] Chewing gums

[ 1.2.1.5 ] Liquids for external use

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.12 ] Suppositories

[ 1.2.1.13 ] Tablets

[ 1.2.1.15 ] Other non-sterile medicinal products

Cytotoxic materials, steroids and sachets. Final formulation, filling, manufacture packing of biological/organic finished products for non-sterile applications.

[ 1.2.2 ] Batch certification

## **[ 1.5 ] Packaging**

[ 1.5.1 ] Primary packaging

[ 1.5.1.1 ] Capsules, hard shell

[ 1.5.1.3 ] Chewing gums

[ 1.5.1.5 ] Liquids for external use

[ 1.5.1.6 ] Liquids for internal use

[ 1.5.1.11 ] Semi-solids

[ 1.5.1.12 ] Suppositories

[ 1.5.1.13 ] Tablets

[ 1.5.1.15 ] Other non-sterile medicinal products

Non-sterile medical products - Cytotoxic materials, Steroids and sachets. Final formulation, filling, manufacture, packing of biological/organic finished products for non-sterile applications.

[ 1.5.2 ] Secondary packaging

## **[ 1.6 ] Quality control testing**

[ 1.6.3 ] Chemical/Physical

## **Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

### **[ 2.1 ] Quality control testing of imported medicinal products**

[ 2.1.3 ] Chemical/Physical

### **[ 2.2 ] Batch certification of imported medicinal products**

[ 2.2.2 ] Non-sterile products