

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 20300
<b>2: Name of authorisation holder</b>	SGS QUAY PHARMACEUTICALS LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	10/11/2023
<b>9: Annexes attached</b>	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

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1) IMPORTATION OF MEDICINAL PRODUCTS (according to part 2)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <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 [ 1.2.1.3 ] 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