

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA 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	Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)
7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation	Confidential
8: Authorisation Date	10/11/2023
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28, PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, UNITED KINGDOM

Human Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
Part 1 - MANUFACTURING OPERATIONS [1.1] Sterile Products [1.1.3] Batch certification [1.2] Non-sterile 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

[1.2.1.11] Semi-solids

[1.2.1.12] Suppositories

[1.2.1.13] Tablets

[1.2.1.17] Other non-sterile medicinal products

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

Special Requirements

Cytotoxics

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[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

[1.5.1.17] 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