Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

- 1: Authorisation Number
- 2: Name of authorisation holder
- 3: Address(es) of manufacturing site(s)

UK MIA(IMP) 20300 SGS QUAY PHARMACEUTICALS LIMITED

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

PARKWAY, DEESIDE INDUSTRIAL PARK, DEESIDE, CH5 2NS, UNITED

Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004

SGS QUAY PHARMACEUTICALS LIMITED, QUAY HOUSE, UNIT 28,

- 4: Legally registered address of authorisation holder
- 5: Scope of authorisation and dosage forms
- 6: Legal Basis of authorisation

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation

- 8: Authorisation Date
- 9: Annexes attached

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)

Part 1 - MANUFACTURING OPERATIONS

[1.1] Sterile Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

[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

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10/11/2023

KINGDOM

Annex 1 and/or Annex 2

ANNEX 1 and/ or ANNEX 2

[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, steriods 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