Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 35718
2: Name of authorisation holder	QUOTIENT SCIENCES LIMITED
3: Address(es) of manufacturing site(s)	QUOTIENT SCIENCES LIMITED, TRENT HOUSE/SHERWOOD HOUSE/LIME HOUSE, MERE WAY, RUDDINGTON FIELDS, RUDDINGTON, NOTTINGHAM, NG11 6JS, UNITED KINGDOM QUOTIENT SCIENCES LIMITED, 5 BOULTON ROAD, READING, RG2 0NH, UNITED KINGDOM
4: Legally registered address of authorisation holder	QUOTIENT SCIENCES LIMITED, TRENT HOUSE, MERE WAY, RUDDINGTON FIELDS BUSINESS PARK, RUDDINGTON, NOTTINGHAM, NG11 6JS, 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	09/05/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

QUOTIENT SCIENCES LIMITED, TRENT HOUSE/SHERWOOD HOUSE/LIME HOUSE, MERE WAY, RUDDINGTON FIELDS, RUDDINGTON, NOTTINGHAM, NG11 6JS, 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

[1.1.1] Aseptically prepared (processing operations for the following dosage forms)

[1.1.1.6] Other aseptically prepared products

Clinical labelling and/or randomisation & blinding and batch certification of sterile IMPs manufactured at other authorised manufacturing sites

[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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[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

Any products listed in 1.2 may be radiolabelled and contain antibiotics, cytotoxics, biotechnology, human or animal derived products.

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.1.8] Other biological medicinal products

Radiolabelling and/or aseptic assembly of pre-formulated biologicals. Any of the products listed in section 1.3 may contain Antibiotics, Cytototoxics, Biotechnology and Human or Animal derived products.

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.2] Sterilisation of active substances/excipients/finished products:

[1.4.2.1] Filtration

[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

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.1] Quality control testing of imported medicinal products

[2.1.2] Microbiological: non-sterility

[2.1.3] Chemical/Physical

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.8] Other biological medicinal products

Radiolabelling and/or aseptic assembly of pre-formulated biologicals. Any of the products listed in section 1.3 may contain Antibiotics, Cytototoxics, Biotechnology and Human or Animal derived products.

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.2] Importation of Intermediate which undergoes further processing

[2.3.4] Other

Importation of QP-certified IMPs from a country on the approved country for import list

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

QUOTIENT SCIENCES LIMITED, 5 BOULTON ROAD, READING, RG2 0NH, 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

[1.2] 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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

[1.2.1.9] Pressurised preparations

[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

Blister/Multidose Resovoir Dry Powder Inhaler,DPI/PMDI

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.3.2] Batch certification

[1.3.2.5] Biotechnology products

[1.4] Other investigational medicinal products or manufacturing activitiy

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[1.4.1.3] Other

Traditional Herbal Medicines/Importation of QP-certified IMPs from a country on the approved country for import list

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.2] Capsules, soft shell

[1.5.1.8] Other solid dosage forms

[1.5.1.9] Pressurised preparations

[1.5.1.11] Semi-solids

[1.5.1.12] Suppositories

[1.5.1.13] Tablets

[1.5.1.14] Transdermal patches

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.1] Sterile Products

[2.2.1.1] Aseptically prepared

[2.2.1.2] Terminally sterilised

[2.2.2] Non-sterile products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation

[2.3.4] Other

Traditional Herbal Medicines/Importation of QP-certified IMPs from a country on the approved country for import list