

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number	UK MIA(IMP) 49934
2: Name of authorisation holder	UPPERTON LIMITED UPPERTON LIMITED, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, UNITED KINGDOM
3: Address(es) of manufacturing site(s)	UPPERTON LIMITED, UNIT 3, 5 & 11 BEESTON BUSINESS PARK, TRENT GATEWAY, TECHNOLOGY DRIVE, BEESTON, NOTTINGHAM, NG9 1LA, UNITED KINGDOM
4: Legally registered address of authorisation holder	UPPERTON LIMITED, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, 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	13/11/2024
9: Annexes attached	Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UPPERTON LIMITED, ALBERT EINSTEIN CENTRE, NOTTINGHAM SCIENCE AND TECHNOLOGY PARK, NOTTINGHAM, NG7 2TN, UNITED KINGDOM

Human Investigational Medicinal Products
Authorised Operations
MANUFACTURING OPERATIONS (according to part 1)
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

[1.2.1.6] Liquids for internal use

Special Requirements

Substance with hormonal activity

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Spray dried bulk intermediate pharmaceutical products for Oral, nasal and pulmonary administration.

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources.

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

Special Requirements

GWP4202541 (API) in Acetone Solution

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Herbal

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

UPPERTON LIMITED, UNIT 3, 5 & 11 BEESTON BUSINESS PARK, TRENT GATEWAY, TECHNOLOGY DRIVE, BEESTON,
NOTTINGHAM, NG9 1LA, UNITED KINGDOM

Human Investigational Medicinal Products

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

[1.2.1.6] Liquids for internal use

Special Requirements

Substance with hormonal activity

[1.2.1.8] Other solid dosage forms

[1.2.1.11] Semi-solids

[1.2.1.13] Tablets

[1.2.1.15] Other non-sterile medicinal products

Spray dried bulk intermediate pharmaceutical products for oral, nasal and pulmonary administration

[1.2.2] Batch certification

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources

[1.3.2] Batch certification

[1.3.2.8] Other biological medicinal products

Spray dried bulk intermediate and finished products from recombinant sources

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

Special Requirements

GWP4202541 (API) in Acetone solution

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.6] Liquids for internal use

[1.5.1.8] Other solid dosage forms

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.15] Other non-sterile medicinal products

Herbal

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.3] Chemical/Physical

[1.6.4] Biological