

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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

[ 1.2.1.6 ] 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

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GWP4202541 (API) in Acetone solution

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Herbal

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

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