

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 14988

2: Name of authorisation holder MELBOURN SCIENTIFIC LIMITED

3: Address(es) of manufacturing site(s) MELBOURN SCIENTIFIC LIMITED, SAXON WAY,
MELBOURN, ROYSTON, SG8 6DN, UNITED KINGDOM

4: Legally registered address of authorisation holder MELBOURN SCIENTIFIC LIMITED, SAXON WAY,
MELBOURN, ROYSTON, SG8 6DN, 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 20/11/2024

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

MELBOURN SCIENTIFIC LIMITED, SAXON WAY, MELBOURN, ROYSTON, SG8 6DN, 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 Special Requirements Epinephrine bitartrate capsules for inhalation [1.2.1.5] Liquids for external use [1.2.1.6] Liquids for internal use

[1.2.1.11] Semi-solids

[1.2.1.15] Other non-sterile medicinal products

Suspension nasal spray, Powder for Reconstitution, Pancreatin Powder Blend, Pre-metered cartridge for vaporisation (Inhalation), Nasal spray emulsion, Soft mist for inhalation

[1.2.2] Batch certification

[1.4] Other investigational medicinal products or manufacturing activity

[1.4.1] Manufacture of:

[1.4.1.1] Herbal products

[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

[1.5.1.15] Other non-sterile medicinal products

Manual filling into sachets

[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

[2.1] Quality control testing of imported medicinal products

[2.1.3] Chemical/Physical

[2.1.4] Biological

[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

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

[2.3] Other Importation Activities

[2.3.1] Site of Physical Importation