

Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 33496

2: Name of authorisation holder VECTURA LIMITED

3: Address(es) of manufacturing site(s) VECTURA LIMITED, 1-6 PROSPECT WEST, CHIPPENHAM, SN14 6FH, UNITED KINGDOM

4: Legally registered address of authorisation holder VECTURA LIMITED, VECTURA HOUSE, BUMPERS WAY, BUMPERS FARM, CHIPPENHAM, SN14 6LH, UNITED KINGDOM

5: Scope of authorisation and dosage forms VECTURA LIMITED, UNIT 1-6, PROSPECT WEST, BUMPERS WAY, BUMPERS FARM, CHIPPENHAM, SN14 6FH, UNITED KINGDOM

6: Legal Basis of authorisation ANNEX 1 and/ or ANNEX 2

7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]

8: Authorisation Date Confidential

9: Annexes attached 13/05/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

VECTURA LIMITED, 1-6 PROSPECT WEST, CHIPPENHAM, SN14 6FH, 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 Special Requirements Substance with Hormonal Activity and Controlled Drugs

[1.2.1.15] Other non-sterile medicinal products

DPI and Aerosols (Including filling primary container and Substance with Hormonal Activity and Controlled Drugs)

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.15] Other non-sterile medicinal products

DPI and Aerosols (Including filling primary container and Substance with Hormonal Activity and Controlled Drugs)

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[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

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

[2.2.3] Biological medicinal products

[2.2.3.5] Biotechnology products

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

VECTURA LIMITED, VECTURA HOUSE, BUMPERS WAY, BUMPERS FARM, CHIPPENHAM, SN14 6LH, 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

Special Requirements

Substances with Hormonal Activity

[1.2.1.15] Other non-sterile medicinal products

DPI and Aerosols (including primary container and Substance with Hormonal Activity)

[1.3] Biological investigational medicinal products

[1.3.1] Biological medicinal products

[1.3.1.5] Biotechnology products

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

[1.5.1.8] Other solid dosage forms

[1.5.1.15] Other non-sterile medicinal products

DPI and aerosols (including filling primary container and handling Substance with Hormonal Activity)

[1.5.2] Secondary packaging