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, VECTURA HOUSE, BUMPERS WAY, BUMPERS FARM, CHIPPENHAM, SN14 6LH, UNITED KINGDOM VECTURA LIMITED, 1-6 PROSPECT WEST, CHIPPENHAM, SN14 6FH, UNITED KINGDOM
4: Legally registered address of authorisation holder	VECTURA LIMITED, UNIT 1-6, PROSPECT WEST, BUMPERS WAY, BUMPERS FARM, CHIPPENHAM, SN14 6FH, 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	24/06/2025
9: Annexes attached	Annex 1 and/or Annex 2

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) 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

Substances with Hormonal Activity

MHRA-GMDP

[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

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

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

MHRA-GMDP MHRA

[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

[2.3] Other Importation Activities

[2.3.2] Importation of Intermediate which undergoes further processing

MHRA-GMDP MHRA MHRA-GMDP MHRA