

# 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, 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** 04/11/2021

**9: Annexes attached** 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)
<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 <b>Special Requirements</b> 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 Contr <b>[ 1.3 ] Biological investigational medicinal products</b> [ 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 Contr

[ 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