

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

**1: Authorisation Number** UK MIA 12063

**2: Name of authorisation holder** WRAFTON LABORATORIES LIMITED

**3: Address(es) of manufacturing site(s)** WRAFTON LABORATORIES LIMITED, EXETER ROAD,  
WRAFTON, BRAUNTON, EX33 2DL, UNITED KINGDOM

**4: Legally registered address of authorisation holder** WRAFTON LABORATORIES LIMITED, EXETER ROAD,  
WRAFTON, BRAUNTON, EX33 2DL, UNITED KINGDOM

**5: Scope of authorisation and dosage forms** ANNEX 1 and/ or ANNEX 2

**6: Legal Basis of authorisation** Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)

**7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation** Confidential

**8: Authorisation Date** 22/03/2024

**9: Annexes attached** Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**WRAFTON LABORATORIES LIMITED, EXETER ROAD, WRAFTON, BRAUNTON, EX33 2DL, UNITED KINGDOM**

Human 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 products</b> [ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms) [ 1.2.1.1 ] Capsules, hard shell [ 1.2.1.8 ] Other solid dosage forms [ 1.2.1.13 ] Tablets [ 1.2.1.17 ] Other non-sterile medicinal products Chewable Tablets, Effervescent powder, Powder for oral solution, Compressed lozenges, Powder for Oral Suspension [ 1.2.2 ] Batch certification <b>[ 1.5 ] Packaging</b> [ 1.5.1 ] Primary packaging

- [ 1.5.1.1 ] Capsules, hard shell
- [ 1.5.1.2 ] Capsules, soft shell
- [ 1.5.1.8 ] Other solid dosage forms
- [ 1.5.1.13 ] Tablets

[ 1.5.2 ] Secondary packaging

**[ 1.6 ] Quality control testing**

- [ 1.6.2 ] Microbiological: non-sterility
- [ 1.6.3 ] Chemical/Physical

**Part 2 - IMPORTATION OF MEDICINAL PRODUCTS**

**[ 2.1 ] Quality control testing of imported medicinal products**

- [ 2.1.2 ] Microbiological: non-sterility
- [ 2.1.3 ] Chemical/Physical

**[ 2.2 ] Batch certification of imported medicinal products**

- [ 2.2.2 ] Non-sterile products

**[ 2.3 ] Other Importation Activities**

- [ 2.3.2 ] Importation of Intermediate which undergoes further processing