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	25/02/2026
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)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile products

[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

[1.5] Packaging

MHRA-GMDP MHRA-GMDP MHRA

[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

MHRA-GMDP MHRA