Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number

2: Name of authorisation holder

3: Address(es) of manufacturing site(s)

4: Legally registered address of authorisation holder

5: Scope of authorisation and dosage forms

6: Legal Basis of authorisation

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

8: Authorisation Date

9: Annexes attached

UK MIA 12063

WRAFTON LABORATORIES LIMITED

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

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

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

24/10/2025

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

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[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

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