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 15513

MCNEIL PRODUCTS LIMITED

MCNEIL PRODUCTS LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

MCNEIL PRODUCTS LIMITED, 1 STATION HILL SQUARE, READING, RG1 1LN, UNITED KINGDOM

MCNEIL PRODUCTS LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, UNITED KINGDOM

ANNEX 1 and/ or ANNEX 2

Regulation 17 of The Human Medicines Regulations 2012

(SI 2012/1916)

Confidential

13/10/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MCNEIL PRODUCTS LIMITED, 50-100 HOLMERS FARM WAY, HIGH WYCOMBE, HP12 4EG, 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

[1.2.2] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

Issue Date: 13 Oct 2025

SCOPE OF AUTHORISATION

Annex 1

Name and address of the site:

MCNEIL PRODUCTS LIMITED, 1 STATION HILL SQUARE, READING, RG1 1LN, 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

[1.1] Sterile Products

[1.1.3] Batch certification

Part 2 - IMPORTATION OF MEDICINAL PRODUCTS

[2.2] Batch certification of imported medicinal products

[2.2.2] Non-sterile products

MHRA: GMDY MHRA

Manufacturer's Authorisation: UK MIA 15513

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