Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 12470

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

> DERMAL LABORATORIES LIMITED, TATMORE PLACE, PRESTON ROAD, GOSMORE, HITCHIN, SG4 7QR, UNITED

KINGDOM

3: Address(es) of manufacturing site(s) DERMAL LABORATORIES LIMITED, POSTLEY ROAD, WOBURN

ROAD INDUSTRIAL ESTATE, KEMPSTON, MK42 7BU, UNITED

KINGDOM

Confidential

DERMAL LABORATORIES LIMITED, TATMORE PLACE, 4: Legally registered address of authorisation holder

GOSMORE, HITCHIN, SG4 7QR, UNITED KINGDOM

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

Part 6 of The Medicines for Human Use (Clinical Trials) 6: Legal Basis of authorisation

Regulations 2004 [SI 2004/1031]

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

8: Authorisation Date 12/02/2025

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

DERMAL LABORATORIES LIMITED, TATMORE PLACE, PRESTON ROAD, GOSMORE, HITCHIN, SG4 7QR, UNITED KINGDOM

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.6] Quality control testing

[1.6.3] Chemical/Physical

Issue Date: 12 Feb 2025

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

DERMAL LABORATORIES LIMITED, POSTLEY ROAD, WOBURN ROAD INDUSTRIAL ESTATE, KEMPSTON, MK42 7BU, UNITED **KINGDOM**

Human Investigational Medicinal Products

Authorised Operations

MANUFACTURING OPERATIONS (according to part 1)

Part 1 - MANUFACTURING OPERATIONS

[1.2] Non-sterile investigational medicinal products

[1.2.1] Non-Sterile Products (processing operations for the following dosage forms)

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.11] Semi-solids

[1.2.1.15] Other non-sterile medicinal products

Unit and multi-dose non-sterile gels, collodions etc. unit and multi-dose nonsterile dosage forms for external use

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.13] Tablets

[1.5.2] Secondary packaging



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