

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 12470
<b>2: Name of authorisation holder</b>	DERMAL LABORATORIES LIMITED DERMAL LABORATORIES LIMITED, TATMORE PLACE, PRESTON ROAD, GOSMORE, HITCHIN, SG4 7QR, UNITED KINGDOM
<b>3: Address(es) of manufacturing site(s)</b>	DERMAL LABORATORIES LIMITED, POSTLEY ROAD, WOBURN ROAD INDUSTRIAL ESTATE, KEMPSTON, MK42 7BU, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	DERMAL LABORATORIES LIMITED, TATMORE PLACE, GOSMORE, HITCHIN, SG4 7QR, UNITED KINGDOM
<b>5: Scope of authorisation and dosage forms</b>	ANNEX 1 and/ or ANNEX 2
<b>6: Legal Basis of authorisation</b>	Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]
<b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b>	Confidential
<b>8: Authorisation Date</b>	12/03/2024
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> [ 1.6 ] <b>Quality control testing</b> [ 1.6.3 ] Chemical/Physical

### 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