Medicines and Healthcare products Regulatory Agency

MANUFACTURER'S AUTHORISATION

1: Authorisation Number UK MIA(IMP) 189

THE MENTHOLATUM COMPANY LIMITED 2: Name of authorisation holder

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE, 3: Address(es) of manufacturing site(s)

PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE,

UNITED KINGDOM

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE,

PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE,

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) Regulations 6: Legal Basis of authorisation

2004 [SI 2004/1031]

7: Name of responsible officer of the competent

4: Legally registered address of authorisation holder

authority of the member state granting the

manufacturing authorisation

Confidential

8: Authorisation Date 20/12/2023

9: Annexes attached Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

THE MENTHOLATUM COMPANY LIMITED, 1 REDWOOD AVENUE, PEEL PARK CAMPUS, EAST KILBRIDE, GLASGOW, G74 5PE, 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)

[1.2.1.11] Semi-solids

[1.2.2] Batch certification

[1.5] Packaging

[1.5.1] Primary packaging

[1.5.1.11] Semi-solids

Issue Date: 20 Dec 2023

[1.5.2] Secondary packaging

[1.6] Quality control testing

[1.6.2] Microbiological: non-sterility

[1.6.3] Chemical/Physical

