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(IMP) 322 NORGINE LIMITED

NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM

NORGINE LIMITED, ARC UXBRIDGE, BUILDING 01, SANDERSON ROAD, UXBRIDGE, UB8 1DH, UNITED

KINGDOM

ANNEX 1 and/ or ANNEX 2

Part 6 of The Medicines for Human Use (Clinical Trials)

Regulations 2004 [SI 2004/1031]

Confidential

07/03/2025

Annex 1 and/or Annex 2

SCOPE OF AUTHORISATION

Annex 2

Name and address of the site:

NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM

Human Investigational 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 Investigational Medicinal Products

[1.1.3] Batch certification

[1.2] Non-sterile investigational medicinal products

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

[1.2.1.1] Capsules, hard shell

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

Issue Date: 07 Mar 2025

[1.2.1.12] Suppositories [1.5] Packaging [1.5.1] Primary packaging [1.5.1.1] Capsules, hard shell [1.5.1.2] Capsules, soft shell [1.5.1.5] Liquids for external use [1.5.1.6] Liquids for internal use [1.5.1.8] Other solid dosage forms [1.5.1.11] Semi-solids [1.5.1.13] Tablets [1.5.1.15] Other non-sterile medicinal products Pessaries, Powders [1.5.2] Secondary packaging [1.6] Quality control testing [1.6.3] Chemical/Physical Part 2 - IMPORTATION OF MEDICINAL PRODUCTS [2.1] Quality control testing of imported medicinal products [2.1.3] Chemical/Physical [2.2] Batch certification of imported medicinal products [2.2.1] Sterile Products [2.2.1.1] Aseptically prepared [2.2.1.2] Terminally sterilised [2.2.2] Non-sterile products



Importation of QP-certified IMPs from a country on the approved country for import list

Page 2 of 2 Issue Date: 07 Mar 2025

[2.3] Other Importation Activities

[2.3.4] Other