# 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 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

Regulation 17 of The Human Medicines Regulations 2012 (SI

2012/1916)

Confidential

07/03/2025

Annex 1 and/or Annex 2

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

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

**Human Medicinal Products** 

**Authorised Operations** 

MANUFACTURING OPERATIONS (according to part 1)

## Part 1 - MANUFACTURING OPERATIONS

## [ 1.2 ] Non-sterile products

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

[1.2.1.1] Capsules, hard shell

[ 1.2.1.8 ] Other solid dosage forms

[ 1.2.1.13 ] Tablets

[ 1.2.2 ] Batch certification

## [ 1.5 ] Packaging

[1.5.1] Primary packaging

[1.5.1.1] Capsules, hard shell

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[ 1.5.1.8 ] Other solid dosage forms

[ 1.5.1.13 ] Tablets

[ 1.5.1.17 ] Other non-sterile medicinal products

Including Powders, Labelling of Primary containers & secondary packaging of primary containers.

[ 1.5.2 ] Secondary packaging

[ 1.6 ] Quality control testing

[ 1.6.3 ] Chemical/Physical

