

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

<b>1: Authorisation Number</b>	UK MIA(IMP) 322
<b>2: Name of authorisation holder</b>	NORGINE LIMITED
<b>3: Address(es) of manufacturing site(s)</b>	NORGINE LIMITED, NEW ROAD, TIR-Y-BERTH, HENGOED, CF82 8SJ, UNITED KINGDOM
<b>4: Legally registered address of authorisation holder</b>	NORGINE LIMITED, NORGINE HOUSE, WIDEWATER PLACE, MOORHALL ROAD, HAREFIELD, UXBRIDGE, UB9 6NS, 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>	18/09/2023
<b>9: Annexes attached</b>	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)
<b>Part 1 - MANUFACTURING OPERATIONS</b> <b>[ 1.1 ] Sterile Investigational Medicinal Products</b> [ 1.1.3 ] Batch certification <b>[ 1.2 ] Non-sterile investigational medicinal products</b> [ 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 [ 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

**[ 2.3 ] Other Importation Activities**

[ 2.3.4 ] Other

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