

Medicines and Healthcare products Regulatory Agency

Report No : Insp GMP/GDP/IMP 322/14798-0032[I]

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Part 6 of The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)

The competent authority of United Kingdom confirms the following:

The Manufacturer: NORGINE LIMITED

Site address:

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **08/05/2026** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17(3) of the Human Medicines Regulations 2012 (as amended)

Part 2

Human Investigational Medicinal Products

1. MANUFACTURING OPERATIONS

[1.1] Sterile Products

[1.1.3] Batch certification

[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

[1.2.1.5] Liquids for external use

[1.2.1.6] Liquids for internal use

[1.2.1.8] Other solid dosage forms

All other solid dosage forms not otherwise specified

[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

All other solid dosage forms not otherwise specified

[1.5.1.11] Semi-solids

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Pessaries, Powders

[1.5.2] Secondary packing

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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

[2.2.4] Other Importation Activities

[2.2.4.6] Other

Importation of QP-certified IMPs from country on approved list

Part 3

Nature of non-compliance :

An inspection of the site was conducted from 05 to 08 May 2026. Two critical deficiencies and three major deficiencies from GMP were raised. The critical deficiencies concerned the failure to implement a comprehensively designed and correctly implemented PQS incorporating GMP and QRM, evidenced by the failure to ensure that robust and reliable batch control procedures were in place, as

well as the failure of the Qualified Persons to ensure that each individual batch had been manufactured and checked in compliance the requirements of GMP.

Action taken/proposed:

suspension
in full

Withdrawal of current valid GMP certificates:

UK MIA(IMP) 322 INSP IMP 322/14798-0031[I]

03/08/2026

Name and signature of the authorised person of the Competent Authority of United Kingdom

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Medicines and Healthcare products Regulatory Agency

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