Medicines and Healthcare products Regulatory Agency

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

STATEMENT OF NON-COMPLIANCE WITH GMP

Part 1

Issued following an inspection in accordance with :

- Regulation 331 of The Human Medicines Regulations 2012 (SI 2012/1916)

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 Medicinal Products
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 All other solid dosage forms not otherwise specified [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

[1.5.1.8] Other solid dosage forms

All other solid dosage forms not otherwise specified

[1.5.1.13] Tablets

[1.5.1.17] Other non-sterile medicinal products

Including powders and labelling of primary containers

[1.5.2] Secondary packing

[1.6] Quality control testing

[1.6.3] Chemical/Physical

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 the MA and GMP. This Statement of Non Compliance does not include the manufacture of critical products. Such products should be agreed in writing with individual National Competent Authorities.

Action taken/proposed:

suspension

In part

Withdrawal of current valid GMP certificates:

UK MIA 322 INSP GMP 322/14798-0030[H]

Prohibition of supply:

Only batches of critical products can be supplied to UK markets while this statement of non-compliance remains in force.

03/08/2026	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Tel : Confidential