

Norwegian Medical Products Agency

Report No: 24/03997

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer¹

Part 1

Issued following an inspection in accordance with
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Norway confirms the following:

The manufacturer: **Everest Organics Limited**

Site address: **Aroor Village, Sangareddy District, Sadasivpet, 502291**

OMS Organisation Id. / OMS Location Id.: **ORG-100033981 / LOC-100053625**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2024-02-07**, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC.

Note to receiving authorities: Please contact the issuing authority within 20 working days in case there are critical(2) medicinal products potentially affected by this statement.

Manufacturing Authorisation Holders directly affected by this statement have failed to comply with their obligations under Art. 46 of Directive 2001/83/EC or Art. 93(1)(j) to (l) of Regulation (EU) 2019/6 and as a consequence the Qualified Person referred to in Art. 48 of Directive 2001/83/EC and Art. 97(1) of Regulation (EU) 2019/6 is unable to perform the batch certification referred to in Art. 51 of Directive 2001/83/EC and Art. 97 (6) and (7) of Regulation (EU) 2019/6.

In exceptional circumstances there may be no objection to the Qualified Person certifying affected batches thereby allowing their release provided all of the following conditions are fulfilled:

1. Batch certification is performed in order to maintain supply of critical medicinal products only.
2. A documented risk assessment has been performed by, or on behalf of, the Qualified Person and additional actions have been implemented by the manufacturing and/or batch release site to mitigate the risks posed by the non-compliance. Note: Repeated testing alone is not normally sufficient risk mitigation but, together with other actions, can form part of a strategy commensurate with the nature and the level of risk.
3. A thorough risk-benefit evaluation has been performed for the acceptance of risk and a report prepared that takes full account of the nature of the non-compliance with the involvement of:
 - The Manufacturing Authorisation Holder and the Qualified Person of the site responsible for batch certification.
 - The manufacturing site subject to this Statement of Non-Compliance, if different from the above.

- The relevant Marketing Authorisation Holder(s).

The report has been shared with the National Competent Authorities of the countries in which distribution of the affected batches is anticipated and that any comments from those authorities have been taken into account.

4. Written confirmation has been obtained from the National Competent Authorities in whose territories the affected batches are intended to be distributed that the product is considered critical on its territory, and that there is no objection to distribution.
5. The Supervisory Authority has been informed, if different from the above, and it has not suspended or revoked the relevant Manufacturing Authorisation.
6. The affected Marketing Authorisations have not been revoked or suspended.
7. Any further conditions imposed by the Supervisory Authority and other involved National Competent Authorities are met.

¹The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and Art. 94(2) of Regulation (EU) 2019/6, as amended, is also applicable to importers.

²See Appendix 3 of the relevant procedure in the Compilation of Union Procedures.

Part 2

Human Medicinal Products	
1 NON-COMPLIANT MANUFACTURING OPERATIONS	
Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;	
1.4	Other products or manufacturing activity
	1.4.3 Other: active substance(en)

Manufacture of active substance. Names of substances subject to non-compliant:
OMEPRazole(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance: OMEPRazole	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallization
3.5	General Finishing Steps
	3.5.1 Physical processing steps: Micronising 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Part 3

1.Nature of non-compliance: During this inspection 18 deficiencies were identified in total, nine classified as major and nine classified as “other”. D1[Major]: A lack of QA oversight, insufficient knowledge of the current requirements of EU GMP and ineffective measures of quality risk management applied to activities with GMP impact, D2[Major]: The production buildings showed signs of outdated infrastructure and design, compromising the suitability for manufacturing activities. The facility lacks modernisation and fails to meet the standards as per current EU GMP guidelines, D3[Major]: Insufficient equipment cleaning and maintenance, D4[Major]: Inappropriate storage locations/conditions within the facility including insufficient storage capacity, traceability and accountability, D5[Major] Lack of systematic approach to properly identify and label some of the materials, with a risk of mix-up during storage and manufacture, potentially leading to product quality issues or contamination, D6[Major] Risk of breaches in data integrity and lack of control of computerised systems, D7[Major] The systems for managing deviations, investigations of deviations, complaints, out of specification/out of trend results and identification of corrective and preventative actions (CAPAs) presented some flaws, D8[Major] The system for evaluation and approval of suppliers of materials was found to be deficient, D9[Major] The system for handling changes, including the procedures for the introduction of new chemical entities, was found to be insufficient.
Action taken/proposed by the NCA Suspension or voiding of CEP (action to be taken by EDQM) CEP 2014-035/Omeprazole was suspended by EDQM 3 April 2024.
Additional comments The inspection was performed in the frame of the EDQM inspection programme.

2024-04-29

Name and signature of the authorised person of the
Competent Authority of Norway

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Tel:**Confidential**
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