National Centre For Public Health And Pharmacy

Report No: ***NNGYK/34812-5/2026***

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 manufacturer[1]

Part 1

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

The competent authority of Hungary confirms the following:
The manufacturer: ***Cadchem Laboratories Limited***
Site address: ***Village Jaula Khurd, Tehsil Derabassi, Lalru, Sahibzada Ajit Singh Nagar, Punjab, 140501, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100039011*** / ***LOC-100061396***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-03-18***, 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.

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[1] *The 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.*

[2] *See 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;

1.6	**Quality control testing**
	1.6.1 Microbiological: sterility
	1.6.2 Microbiological: non-sterility

Manufacture of active substance. Names of substances subject to non-compliant:
LEVETIRACETAM(en)
ROSUVASTATIN CALCIUM(en)
THIOCTIC ACID(en)
CLOPIDOGREL HYDROGEN SULFATE(en)

Part 3

1.Nature of non-compliance:

Critical and major GMP deficiencies were identified during the inspection of the manufacturing site. These included significant failures in quality management oversight, data integrity, materials management, equipment cleaning and maintenance, and facility conditions. The deficiencies demonstrated a lack of effective quality system and inadequate control over GMP-relevant operations. Critical data integrity issues were observed, undermining the reliability of manufacturing and quality control data. Due to the systemic nature of the deficiencies, it cannot be ensured that active substances manufactured at the site comply with EU GMP requirements. No specific evidence of defective batches placed on the market was identified during the inspection.

Action taken/proposed by the NCA

Suspension or voiding of CEP (action to be taken by EDQM)
It is recommended that the suspension of the following CEPs be considered: - CEP 2019-123 / Clopidogrel hydrogen sulfate - CEP 2020-318 / Levetiracetam - CEP 2023-153 / Rosuvastatin calcium - CEP 2024-419 / Thioctic acid - CEP 2014-176 / Clopidogrel hydrogen sulfate, Form I For CEP 2017-247 and CEP 2021-052, revision of the respective dossiers by removal of Cadchem Laboratories Limited as intermediate manufacturer is considered appropriate.

Additional comments
The case was reviewed by the EDQM AdHoc Committee, which endorsed regulatory action on the concerned CEPs. For certain CEPs, alternative manufacturers of the relevant intermediates are registered; therefore, removal of Cadchem Laboratories Limited from the respective dossiers is considered an adequate risk mitigation measure. The identified deficiencies are systemic and include critical failures in quality management and data integrity, affecting the reliability of GMP-relevant operations at the site.

2026-04-28

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

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