National Authority Of Medicines And Health Products

Report No: ***FT020/SA/002/2023/NCR***

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 Portugal confirms the following:
The manufacturer: ***Eugia Pharma Specialities Limited***
Site address: ***Unit 2 A 1128 B 1127, RIICO Industrial Area Phase III, District Khairthal Tijara, Bhiwadi, 301019, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100031553*** / ***LOC-100062231***

Other
(Human) Commission Delegated Regulation (EU) No 1252/2014 and Part II.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-02-27***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

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- 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;

1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms)
	1.1.1.6 Other: API Meropenen(en)
	Special Requirements
	1 B-lactam Antibiotics

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

Part 3

1.Nature of non-compliance:

A follow up inspection was conducted on 25–27 February 2026 to verify the implementation of corrective actions from the previous inspection and to assess the current state of GMP compliance at the manufacturing unit responsible for producing the Meropenem active substance. Several critical deficiencies previously identified remained uncorrected, and additional critical and major deficiencies were observed, collectively demonstrating that the quality of the active substance is compromised and leading to the issuance of this NCR. Critical deficiencies from the previous inspection persisted. Glove integrity checks on the mobile LAF (PB/LAF23) were not performed consistently during operations, despite video evidence showing occasional verification. The LAF and RABS doors in room PB032 showed degradation and breaches, failing to ensure segregation between cleanroom grades. Furthermore, no monitoring of pressure differentials between Grade A and Grade B was in place, as the manometer measured only blower to filter pressure, leaving no evidence of appropriate environmental control in this critical area. Additional critical deficiencies were identified. The risk assessment QRM/EU2/061/2025 did not evaluate the need for revalidation of the Meropenem API manufacturing process following the installation of new RABS and modification of the filling line layout. Material and component transfer into Grade A/B areas was not demonstrated to follow a unidirectional and continuous process, as the mobile LAF was removed mid operation to retrieve additional containers, contradicting the company's previous CAPA commitments. The cleaning of the filling line bin in PB032 was performed inside the room using a non closed, non automated process, with excess water drained into a bucket placed in front of the RABS, posing a significant contamination risk. Several major deficiencies were also identified. Change controls were not classified according to criticality, including those previously deemed critical. Procedures lacked clarity regarding definitions, responsibilities and operational steps, including the Change Control SOP and the SOP governing fingerprint access authorisation. The risk assessment did not clearly determine whether updates to the Batch Manufacturing Record were required. In Quality Control, no complete and updated analyst qualification matrix was available. Analyses assigned in LIMS to one analyst were performed by another, indicating non compliance with work allocation. QC logbooks lacked traceability and sequential documentation, with missing audit trails for key activities. Equipment status identification was inconsistent with LIMS records, and calibration responsibilities were not aligned with defined procedures. In the microbiology laboratory, an environmental monitoring sample was not provided in a timely manner, and critical temperature monitoring points in incubators were not identified. Maintenance of technical areas and utilities was inadequate. Replacement filters were stored in damaged and dirty boxes; ducts and insulation associated with AHU28 were degraded; the pre filter cleaning station and RO water pipe showed dirt and corrosion; and the pre filter inside AHU028 supplying PB32 appeared dirty despite recorded cleaning. Overall, the persistence of unresolved critical deficiencies, combined with newly identified critical and major findings, demonstrates a failure to ensure the required level of control for sterile API manufacturing. These deficiencies compromise the quality of the Meropenem active substance produced at this unit and justify the issuance of this NCR.

Action taken/proposed by the NCA

Prohibition of supply

Due to the number and severity of the deficiencies identified, the supply of finished products manufactured with the Meropenem active substance produced at Eugia Unit II should be prohibited. Portugal will conduct a full identification of all medicinal product batches containing Meropenem API manufactured at this unit, in order to proceed with their recall.

Additional comments

The inspection report was prepared and forwarded to the company concerned. A draft supervisory risk assessment was circulated through the rapid alert network for any comments by NCAs with a deadline for responses set to the 20th of March 2026. No replies were received and therefore the supervisory risk assessment and non-compliance statement along with their recommendation will be implemented.

2026-03-27

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

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