National Authority Of Medicines And Health Products

Report No: ***FT094/MH/001/2024/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: ***Ananta Medicare Limited***
Site address: ***Chak 17 M L Agro Food Park Road Riico Industrial Area, Udyog Vihar, Sri Ganganagar, Rajasthan, 335002, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100045961*** / ***LOC-100075811***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-07-09***, 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 Directive (EU) 2017/1572

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: Dry powder Injection(en) Special Requirements 7 Other: Cephalosporins(en)
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Part 3

1.Nature of non-compliance:

During the inspection, multiple critical and major deficiencies were identified across the facility, particularly in areas directly associated with the aseptic manufacture of medicinal products. The nature and extent of these deficiencies demonstrate systemic weaknesses in contamination control, aseptic behaviour, equipment integrity, data governance, and quality control practices, which collectively pose a significant risk to the sterility, safety and overall quality of the products manufactured in Block A. Critical failures were observed in facility design and pressure cascade maintenance, including inadequate differential pressures between classified and non classified areas, reversed pressure gradients, and layout constraints that resulted in sterile API being exposed in Grade B. These issues undermine the fundamental environmental controls required for aseptic processing. Serious concerns were also identified regarding personnel behaviour and aseptic practices, with operators failing to comply with gowning requirements, aseptic discipline, RABS handling procedures, and environmental protection measures. Such behaviours directly compromise sterility assurance and indicate insufficient training and oversight. The inspection further revealed equipment in poor condition, including rusted pass box, unclean balance and step ladder, and the use of open containers for rejected materials and IPC samples within Grade B. These deficiencies represent unacceptable contamination risks within critical manufacturing areas. Significant weaknesses were found in the organisation and control of materials and GMP documentation, including the presence of operational documents, microbiology records, Petri dishes, and other materials stored in uncontrolled areas such as the expansion zone. The discovery of a deteriorated and unidentified gas cylinder connected to a pipeline used for aseptic filling further heightened concerns regarding uncontrolled substances potentially coming into contact with the product. Critical data integrity failures were identified, including missing records, inconsistent entries, unclear terminology, and analytical activities reported but not performed. These issues undermine the reliability of GMP documentation and raise concerns regarding the accuracy of batch release decisions. In the Quality Control laboratories, essential tests for APIs were not performed by the manufacturer, retention samples were improperly stored, finished product samples lacked proper identification, and sterility testing was conducted using unsuitable equipment. These deficiencies critically affect the validity of analytical results and the assurance of product quality. Major gaps were also identified in the Contamination Control Strategy (CCS), which was implemented late and failed to address several contamination risks, including API exposure in Grade B, environmental monitoring vulnerabilities, personnel limits, HEPA filter replacement rationale, and disinfectant approval. Finally, batch documentation lacked evidence of required sampling and incomplete line clearance verification, compromising batch traceability and readiness for aseptic operations.

Action taken/proposed by the NCA

Others

The Portuguese market is not impacted, as no medicinal products have been placed on the market by the manufacturer concerned, and alternative manufacturers with medicinal products containing the same active substance and strength are authorised in Portugal. It was decided that, for the manufacturer concerned, a Non-Compliance Report (NCR) was issued until all critical and major deficiencies have been adequately addressed and their implementation confirmed through a follow-up inspection.

2026-08-06

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

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