Malta Medicines Authority

Report No: ***MT/003NCR/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 Malta confirms the following:
The manufacturer: ***Navesta Pharmaceuticals (Pvt) Ltd.***
Site address: ***107/a Nakandala Road Kindelpitiya, Millewa, Horana, 12422, Sri Lanka***
OMS Organisation Id. / OMS Location Id.: ***ORG-100053512*** / ***LOC-100094681***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-04-21***, 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) 1.1.1.5 Solids and implants Special Requirements 1 B-lactam Antibiotics
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* *1.6.4 Biological*

Clarifying remarks (for public users)

Inspection was product specific for Flucloxacillin Sodium for Injection BP 1000 mg. A separate OSD plant was also available but it was not within the scope of the inspection and it was not inspected.

Part 3

1.Nature of non-compliance:

An onsite GMP follow-up inspection was conducted after a very first inspection conducted in January 2025 following an application received by the company (Navesta Pharmaceuticals Private Limited), to assess compliance with EU GMP guidelines. The company did not bear an EU GMP certificate as it was their first application. During the onsite follow-up inspection performed between 16th – 21st April 2026, the inspectors observed 1 Critical, 5 Major and a total of 19 Other issues. The critical finding related to gowning procedures and changing room design, room finishes and installations in Grade B areas, environmental monitoring programme and poor aseptic practices. It was observed that the overall design, implementation, control and maintenance of the classified areas and the execution of critical aseptic processes were not adequate to ensure an appropriate level of sterility assurance, as the gowning systems, changing room design and personnel flows did not provide effective segregation between unclassified, lower-grade and higher-grade areas and allowed the potential transfer of contamination into Grade C, B and A environments. Grade B areas were equipped with unsuitable and degraded finishes and installations, including particle□ and fibre□shedding materials, damaged surfaces and exposed components, which were not compatible with the intended cleanroom classification and represented a direct risk to the controlled environment. The environmental monitoring programme was not sufficiently robust to identify, assess or control the risks associated with critical aseptic operations, owing to the absence of monitoring during key aseptic activities, deficiencies in the installation and positioning of monitoring equipment, an inadequately justified sampling strategy and the lack of regular scientific review of alert and action limits. Furthermore, it was observed that aseptic practices during routine operations were inadequate, as sterile components were handled and transferred in a manner that compromised contamination control, and unidirectional airflow protection was not consistently maintained. Five “Major” findings were identified related to qualification and control of gowning and garment cleaning processes, Contamination Control Strategy, management of Aseptic Process Simulations, Suppliers Approval system and management of the Quality Control laboratories. 19 findings which were classified as “Others” were also identified. As a result of this outcome, the Inspection Review Group (IRG) at the Malta Medicines Authority has met and decided that a Statement of Non-Compliance with the principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 is to be issued for the site.

Action taken/proposed by the NCA

Prohibition of supply

Member states should consider whether review of any current active marketing authorisations is necessary and should consider not initiating or authorising new marketing authorisations with this site listed as a finished product manufacturer until the recommended non-compliance statement to be issued remains in place.

2026-05-11

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

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Confidential
Malta Medicines Authority
Tel:***Confidential***
Fax:***Confidential***