Malta Medicines Authority

Report No: ***MT/002NCR/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: ***Zenzi Pharmaceutical Industries Private Limited***
Site address: ***Plot No. H 53, M.I.D.C Additional Murbad, Thane, Kudavali, 421401, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100039103*** / ***LOC-100061535***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-03-31***, 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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The GOSD block for the manufacturing of oral solid dosage forms including tablets and capsules for the EU market was within the scope of the inspection and was inspected. The separate hormone injectable block was not within the scope of the inspection and was not inspected.

Part 3

1.Nature of non-compliance:

An onsite GMP inspection was conducted following an application received by the company (Zenzi Pharmaceutical Industries Private Limited), to assess compliance with EU GMP guidelines. The company was previously granted EU GMP certificate DK/H/10000/726 dated 01/05/2023 following an EU GMP inspection conducted on 10/02/2023 (last day of the inspection). Since this inspection the business in the EU shifted from Dune Medicare ApS, Denmark to Forza Advance Limited, Malta with respect to responsibility for EU Batch Release. Three years since the last GMP inspection elapsed on 10/02/2026. During the onsite inspection performed between 26th – 31st March 2026, the inspectors observed 2 Critical, 7 Major and a total of 17 Other issues. The first critical finding related to the Pharmaceutical Quality System (PQS). The management and documentation of the PQS was found to be severely lacking in various aspects. The Quality Assurance department was also not adequately resourced. Senior management leadership and active participation was not ensuring an effective PQS. The headcount at QA was a total of 6 personnel shared between the inspected Oral Solid Dosage Block and a Sterile Injectable block (out of this inspection's scope). From the inspection findings and observations made it was clear that the QA department was not able to maintain an adequate PQS and could not respond to the inspection requests effectively. Control of documentation was not in place to ensure that documents are current, effectively updated and securely distributed. High-level documents were not current at the time of their effectiveness, nor identified for revision at the time of the inspection. The management of change control, deviations, risk assessments and good documentation practices within the organisation were also found to be severely lacking. The second critical finding related to Data Integrity violations which were observed during the inspection. Various Logbooks/Registers were present in various forms other than hard bound, ranging from clipped with different paper and ink, stapled and loose papers in plastic folders. Evidence of reissued parts of logbooks replacing original parts were observed during the inspection. This raised serious concerns related to integrity and reliance on logbooks' content. Other data integrity concerns included backdating practices which were observed three times on two occasions during the course of the inspection. Audit trail was disabled from chromatographic sequences in QC analysis. The password complexity policy for software was not enforced with high protection requirements. Deliberate false information was given to the inspector for the password length setting set by IT administrator in the Agilent Open Labs software. Sequence files for HPLC and GC were in folders with read/write access allowing renaming and deleting of data by analysts. Sequence files whose analysis was reviewed complete in one month showed modified dates in another month. Seven "Major" findings were identified related to supplier qualification, training and medical examination of employees, temperature mapping, primary and secondary packaging operations, Quality Control operations, sampling, and storage of API not in accordance with the product labelling. 17 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

Others

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.

2026-05-05

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

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Confidential
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