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: ***Aculife Healthcare Private Limited***
Site address: ***Unit 9, Village Sachana, Taluka Viramgam, Ahmedabad, Gujarat, 382150, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100047606*** / ***LOC-100093954***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-07-14***, 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).

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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.*

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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) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging

Part 3

1.Nature of non-compliance:

The inspection resulted in a critical deficiency on inadequate cleaning validation as well as eight (8) major findings. These dealt with inadequate control of identification labels inside the manufacturing area, inadequate management of visual inspection activities, sterilized product passing through an area where un-sterilized bags were waiting to be autoclaved, inadequate container closure integrity testing and delayed action to correct this very long standing issue, process validation inadequacies, deficient complaint management, deficient management of aseptic process simulations as well as insufficient qualification of manufacturers and suppliers of critical starting materials and no reassurance that primary packaging materials for ophthalmic products were free from contamination. There were also 24 other deficiencies, in addition to the critical and major findings. All these observed deficiencies raise concerns that the approach to the manufacturing of sterile products is not adequately managing inherent risks pertaining to sterile processes and is not in line with applicable EU GMP requirements. 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 EU Good Manufacturing Practice is to be issued for the site.

Action taken/proposed by the NCA

Prohibition of supply

No products batches manufactured at the site should be released to EEA markets until this noncompliance remains in place or is superseded by an EU GMP certificate.

Others

Member states 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 or is not superseded with a GMP certificate. The following applications are known to be ongoing: Sodium Chloride Intravenous Infusion – 0.9% w/v, nPVC bag 0.9% w/v Czechia (RMS), Germany (CMS), Spain (CMS) & Portugal (CMS) Ref. CZ/H/1558/001/DC Timolol 5 mg/mL Eye Drops Solution 5 mg/mL, 5 ml LDPE bottle Spain , Malta, Portugal, Hungary DCP slot requested in September 2025.

Additional comments

Since the site does not have any current valid EU-GMP certificates, there should not be any medicinal products manufactured at the site present in EEA markets. A teleconference has therefore not been proposed in view of this.

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2026-08-24

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

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