National Authority Of Medicines And Health Products

Report No: ***FT127/MH/001/2026/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: ***Halewood Laboratories Private Limited***
Site address: ***Unit II Sub Plot No. 10, Unit 27 Insta Industrial Park, Village Rupa, Taluka Bavla, Ahmedabad, Gujrat, 382220, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100055416*** / ***LOC-100098535***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-02-13***, 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.

---

[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) 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 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*

Part 3

1.Nature of non-compliance:

The inspection identified extensive critical and major deficiencies demonstrating a systemic failure to comply with EU GMP. Inadequate control of tablet manufacturing was identified. Manual loading of the compression equipment generated excessive dust and process interruptions, potentially compromising product quality. In addition, the primary packaging line could not be operated during the inspection. Inadequate control of liquid manufacturing was observed. There was inadequate control of the equipment used for bottle filling and sealing, with repeated stoppages and syrup spillages. Cleaning of affected areas and gloves was inadequate. No procedure was available describing the management of spillages or stoppages. Quality Control deficiencies were identified. Analyses were missing and Ph. Eur. reference standards were absent. An inappropriate reference to the Ph. Eur. was made for potable water testing. Inconsistencies were noted between system records and equipment status, including inconsistencies between computerised system records and the operational status of equipment. There was also a lack of clarity regarding the application of analytical methods for EU products (in-house versus Ph. Eur. methods). Validation deficiencies were observed. Validation testing was performed in other Indian laboratories for APIs and finished products. Process validation for EU products was incomplete, and no process validation was in place covering all stages of manufacture. Data integrity failures were identified. Inconsistencies were noted between records and the information declared by the entity. Cleaning activities and material traceability were inadequately documented. Logbooks were incomplete or inconsistent. Technical Agreement deficiencies were identified. Contracts did not clearly define responsibilities, scope of testing, or subcontracting conditions. The contract with the MAH was also incomplete regarding EU importation and PQR requirements. Inadequate contamination and cross-contamination controls were observed. Gowning practices were inadequate, including barefoot transitions between dirty and clean areas. Operators were observed handling product inappropriately. Segregation between clean and dirty areas was inadequate in some places and by some operators. Premature batch approval by Halewood was identified, as a batch was approval prior to approval of analytical results at Halewood. Deficiencies were also noted in finished goods storage, as no humidity records were available for EU finished products. Overall, the deficiencies represent a profound and systemic failure of GMP principles, compromising product quality, contamination control, data integrity and the reliability of operations. These failures collectively demonstrate that the site’s pharmaceutical quality system lacks the control, oversight and governance required to ensure compliant and reliable manufacturing operations. The extent and severity of the deficiencies show persistent weaknesses in risk management and an overall absence of effective quality oversight, resulting in a system that is not operating in a state of control.

Action taken/proposed by the NCA

Prohibition of supply

Given the deficiencies identified, an inspection report will be issued. The adequacy and effective implementation of the CAPA plan will be assessed during a follow-up inspection to determine whether compliance with Good Manufacturing Practice has been satisfactorily restored.

Additional comments

Given the deficiencies identified, an inspection report will be issued. The adequacy and effective implementation of the CAPA plan will be assessed during a follow-up inspection to determine whether compliance with Good Manufacturing Practice has been satisfactorily restored.

2026-03-10

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

---

Confidential
National Authority Of Medicines And Health Products
Tel:***Confidential***
Fax:***Confidential***