

Agency For Medicinal Products And Medical Devices Of Croatia

Report No: 530-10/26-06/04; 381-13-08/310-26-06

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 manufacturer¹

Part 1

Issued following an inspection in accordance with
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Croatia confirms the following:

The manufacturer: **Swiss Parenterals Limited**

Site address: **Unit II Plot No. 402 412-414 Kerala Industrial Estate, GIDC Near Bavla, Ahmedabad, Gujarat, 382220, India**

OMS Organisation Id. / OMS Location Id.: **ORG-100033193 / LOC-100051801**

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2026-03-13**, 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.

¹The 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.

²See 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
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.6 Other: Powder for solution for injection or infusion(en) Special Requirements 1 B-lactam Antibiotics
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

Clarifying remarks (for public users)

1.6.4. Refers to bacterial endotoxin testing

Part 3

1. Nature of non-compliance:

Onsite inspection identified 3 (three) Critical, 12 (twelve) Major and 2 (two) other deficiencies. The Critical deficiencies were related to: 1. The manufacturer failed to minimize risks from contamination associated with the direct human interventions in the critical zone (grade A) during aseptic operations related to the preparation of a sterile blend, and sampling and dispensing of sterile starting materials. Direct human interventions are performed under RLAF without any barrier system. The aseptic techniques/behaviour of the operators were also found not aligned with the requirements; 2. The manufacturer failed to implement adequate aseptic techniques and personnel behaviour, and failed to ensure sterility of disinfectants and garments used in grade A/B manufacturing areas; 3. The Pharmaceutical Quality System was not correctly implemented. A lack of adequate Quality Management oversight, recording, and investigation of all deviations individually or collectively, influences the quality of a product. The inspection team identified failures to ensure that all production deviations are reported, evaluated, and investigated, and the conclusions recorded, as multiple production deviations observed during inspection tours were unaddressed until inspectors informed personnel of the issues. Major deficiencies were found in the following areas: Material transfer in/out of clean areas across all production lines, Production area design and risks related to cross-contamination in Beta-Lactam production, The Contamination Control Strategy (CCS), Procedures for Aseptic Interventions and Aseptic Process Simulation, Cleanliness and maintenance of production facilities, Inadequate gowning and poor personnel hygiene practices, Premises and Equipment in clean production areas and maintenance, Visual Inspection and Container Closure Integrity Testing, Quality Control, Qualifications and Validations, Documentation control, and Computerised Systems.

Action taken/proposed by the NCA**Withdrawal, of current valid GMP certificate No. 530-10/24-06/08; 381-13-08/310-25-18**

Current certificate 530-10/24-06/08; 381-13-08/310-25-18 will be withdrawn.

Suspension of the marketing authorisation(s)

Member States should consider not authorising marketing authorisation applications/ variations to marketing authorisations with this site listed as a finished product manufacturing site until the non-compliance statement remains in place.

Recall of batches already released

Recall of medicinal products should be considered where potential quality defect has greater impact to public health than supply restriction in affected Member States.

Prohibition of supply

Following issuance of the final Statement of Non-Compliance with the principles and guidelines of GMP and as long as it remains in place, the prohibition of importation and/or supply from the site should be considered.

2026-04-17

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

Confidential

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Croatia**

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