Finnish Medicines Agency

Report No: ***FIMEA/2026/003795***

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 Finland confirms the following:
The manufacturer: ***Xi'an Guokang Ruijin Pharmaceutical Co. Ltd.***
Site address: ***No. 10 No. 7 Jingwei Road, Jinghe Industrial Park, Gaolingxian, Xi'an, 710299, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100039231*** / ***LOC-100096104***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-06-12***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC.

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;

1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of
	1.4.1.3 Other: active substance(en)

Manufacture of active substance. Names of substances subject to non-compliant:
DEXAMETHASONE SODIUM PHOSPHATE(en)
BETAMETHASONE(en)
DEXAMETHASONE(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:DEXAMETHASONE SODIUM PHOSPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance:BETAMETHASONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps:

	milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance:DEXAMETHASONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: milling 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Clarifying remarks (for public users)

Dexamethasone covers crystalline forms A and B

Part 3

1.Nature of non-compliance:
The inspection team identified 18 deficiencies (grouped) against EU GMP, of which 11 were classified as Major. The major deficiencies were related to: - Inadequacy of Quality Assurance oversight and Quality management system - Inadequate design, poor maintenance/cleaning, lack of contamination control in intermediates manufacturing facilities - Solvent recovery, lack of traceability and risk of cross-contamination - Risk of supplying non-GMP APIs for production of medicinal products for human or animal use - Change control - Data integrity of documentation and records - Traceability and control of material throughout the manufacturing process - Cleaning and process validation - Material management - Insufficient control of analytical methods - Incomplete understanding and incorrect application of fundamental GMP principles
Action taken/proposed by the NCA

Suspension or voiding of CEP (action to be taken by EDQM)
CEP 2023-042 / Dexamethasone sodium phosphate CEP 2023-086 / Betamethasone CEP 2023-244 / Dexamethasone Crystalline Form-B CEP 2023-305 / Dexamethasone Crystalline Form-A were suspended on July 29, 2026 by EDQM

Additional comments
The inspection was conducted as part of the EDQM Inspection Programme

2026-09-21

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

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