

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
Art. 15 of Directive 2001/20/EC

The competent authority of Spain confirms the following:

The manufacturer: ***NOVOCAT FARMA, S.A.***

Site address: ***C/Albert Einstein, 21B, Terrassa, Barcelona, 08223, Spain***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-06-04*** , 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 2003/94/EC

¹ *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

Human Medicinal Products
Human Investigational 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>1.1.3 Batch certification</i>

2 NON-COMPLIANT IMPORTATION OPERATIONS

2.1	Quality control testing of imported medicinal products
	<i>2.1.3 Chemical/Physical</i>
2.2	Batch certification of imported medicinal products
	<i>2.2.1 Sterile products</i> 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised

Part 3

1. Nature of non-compliance: a) Not having technical director or substitute technical director. b) During the period when the technical director was on sick leave, there are documents presumably signed by her in which the signature is falsified. c) The quality assurance system has stopped working on a regular basis since January 2019, as they have stopped recording the deviations and out of specifications results obtained in the quality controls of the drugs they carry out. d) The procedures that are followed in the quality control laboratory are not adequate to ensure compliance with GMP in the analysis of medicinal products.
Action taken/proposed by the NCA Suspension of the manufacturing authorisation No. 1099 in Full MIA temporarily suspended. Order to cease all medicinal product quality control activities. Withdrawal, of current valid GMP certificate No. NCF/1835/001/CAT GMP certificate is revoked
Additional comments The Non Compliance report has been issued by the Government of Catalonia (Spain) on June 2019, 27th

2019-07-01

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

Confidential
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Sanitarios
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