EudraGMDP

The Spanish Agency Of Medicines And Medical Devices

Report No:***NCF/NC2023/002/CAT***

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
Art. 94(2) of Regulation (EU) 2019/6 as amended

The competent authority of Spain confirms the following:

The manufacturer: **Serra Pamies S.A.**

Site address: **Avinguda Castellvell 24, Reus, 43206, Spain**

OMS Organisation Id. / OMS Location Id.: **ORG-100017839** / **LOC-100026600**

Other

(Human) Royal Legislative Decree 1/2015, of July 24, and Royal Decree 824/2010 of 25 June.

(Veterinary) Royal Legislative Decree 1/2015, of July 24, and Royal Decree 824/2010 of 25 June.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-05-23***, 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 and Commission Delegated Regulation (EU) 2017/1569 and Directive 91/412/EEC
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC Article 93(2) of Regulation (EU) 2019/6

(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

Veterinary Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.2 Terminally Sterilised (processing operations for the following dosage forms)
1.1.2.3 Small volume liquids
1.1.3 Batch certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.1 Capsules, hard shell
1.2.1.6 Liquids for internal use
1.2.1.8 Other solid dosage forms
1.2.1.13 Tablets
1.2.2 Batch certification

1.5 Packaging

1.5.1 Primary Packaging
1.5.1.1 Capsules, hard shell
1.5.1.6 Liquids for internal use
1.5.1.8 Other solid dosage forms
1.5.1.13 Tablets

1.6 Quality control testing

1.6.1 Microbiological: sterility

Clarifying remarks (for public users):
1.2.1.5 Oral liquids for external use are also included in this Statement of Non GMP compliance

Part 3

Nature of non-compliance: During the inspection carried out in May and June 2023, a lack of compliance with Part I of the EU-NCF was detected. Sixty-three (63) deficiencies were identified in total, nineteen (19) of them were classified as major. Important deficiencies were identified in the quality management system and the management's assurance of the provision of this system, in process validations, in software validations, in data integrity, in cleaning validations, in the management of personnel and their training, in the calibration of measuring and control instruments, in the management of expired raw materials, in the management of the autoclave, in the management of reprocesses, in the qualification of manufacturing and control clean areas, in the management of OOS, in the validation of analytical methods, in the analysis and release of Morphine, in the analysis of endotoxins, in the analysis of Muciplazma, in the management of donations and in self-inspections.

Action taken/proposed by the NCA:

Suspension of the manufacturing authorisation No. *0417* in Part
The activity of manufacturing of sterile and oral (hard capsules, liquids, other solid pharmaceutical forms and tablets) human and veterinary medicinal products, including primary packaging and certification of these dosage forms and microbiological quality control: sterile. has already been suspended as a precautionary measure. This measure has adopted due to the possible risk to animal/public health that may occur as a result of the criticality of the deficiencies identified during the inspection. This measure will be maintained until all the deficiencies observed in the inspection have been corrected and it has been verified, through a new inspection. This measure includes, in addition, the prohibition of placing on the market of any injectable, oral solid and liquid for internal use medicine that has been manufactured in the facilities of this pharmaceutical laboratory.

Recall of batches already released
No specific quality defects on concrete batches present in the market were detected, and thus no action/recall is deemed necessary against concrete batches released and placed on the market.

Additional comments: This statement of non-compliance is signed by Clara Pareja Rossell, Departament de Salut Direcció General d'Ordenació i Regulació Sanitària, Generalitat de Catalunya, and sent to Eudra GMDP by AEMPS.

Teleconference Date:	Teleconference Time (CET):	Dial in no.:

2023-08-21

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

Confidential

The Spanish Agency Of Medicines And Medical Devices

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