*Spanish Agency of Medicines and Medical Devices*

Report No: ***PE010-2625***

# 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 Spain confirms the following:
The manufacturer: ***Farma Química Sur S.L.***
Site address: ***Calle Carlo Goldoni 32, Poligono Industrial Guadalhorce, Malaga, Málaga, 29004, Spain***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-06-27*** , 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 .

[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

| 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*<br>1.4.1.4 Other: Active substance(en) |

4. Non-Compliant Other Activities - Active Substances :
***The Statement of Non-compliance with GMP is issued for all the active ingredients received, repacked and distributed by Farma Química Sur, S.L.***

## Part 3

**1. Nature of non-compliance:**

A lack of EU-GMP compliance was detected during the inspection carried out in June 2019. Thirty-one (31) deficiencies were identified in total. Three (3) of them were classified as critical deficiencies and twenty (20) of them were classified as major deficiencies. The three critical deficiencies are: 1. Farma Química Sur received two batches of Ivermectin in 2019 manufactured by ZHEJIAN HISUN PHARMACEUTICA, this site has a GMP non-compliance certificate since June/04/2016. This non compliance certificate includes all the active substances manufactured by the mentioned site. However, since this active substance was considered critical by the competent authority, its importation was permitted if a complete set of tests based on European Pharmacopeia requirements was performed on each batch. At this respect, this requirement has not been fulfilled by FQS. 2. Regarding the manufacturing (repackaging) activities of high pharmacological activity or toxicity active substances, they have incomplete documentation related with this activity (the cleaning validation has not been completed, the criteria of the worst case active substance selection is not deemed acceptable, the criteria used for calculation of residue limits is not deemed acceptable…), 3. the quality system is not considered appropriate nor effective. The implanted system does not allow to properly identifying the risks to permit the adoption of adequate measures for their prevention. Additionally, there is no active participation of management in the quality system. In addition, the inspectors find mayor deficiencies related with the quality system and with quality control activities. The severity of the critical and major deficiencies detected and the level of EU-GMP Non-compliance are such that the inspectors´ team recommends that interim supervisory measures are taken to remove a potential risk to public health. Furthermore, the company cannot ensure that mix-up/mislabelling between different APIs do not occur.

**Action taken/proposed by the NCA**

**Recall of batches already released**
Distributed only to certain compounding pharmacies in Spain the API: Omeprazol Ph.Eur. Farma-Química Sur S.L. Batch number: 11072/10/42 Expiry date: 03/2021 Class I Rapid Alert. The recalled batch does not meet specifications in identity assay.

**Prohibition of supply**
In addition of the prohibition of supply, the activities of the site have been suspended for all the APIs received, repacked and distributed.

**Additional comments**
Withdrawal, of current valid GMP : ES/020/17

***2019-08-07***

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

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