Spanish Agency of Medicines and Medical Devices

Report No: ***NCF-II/NCf2019/01/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

The competent authority of Spain confirms the following:
The manufacturer: ***UNION QUIMICO FARMACEUTICA, S.A***
Site address: ***Poligono industrial, el Pla. Avda, Puigcerdá, 9 C-17 Km 17,4, LliÇa de Vall, Barcelona, 08185, Spain***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-05*** , 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
	1.4.3 Other: Manufacture of Active Substances(en)

Manufacture of active substance. Names of substances subject to non-compliant :
CARNIDAZOLE(en)
CYCLOPENTOLATE HYDROCHLORIDE(en)
CLINDAMYCIN HYDROCHLORIDE(en)
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE(en)
ESOMEPRAZOLE SODIUM(en)
ETOFENAMATE(en)
FLUOXETINE(en)
KETOROLAC TROMETAMOL(en)
LAMOTRIGINE(en)
MEMANTINE HYDROCHLORIDE(en)
OMEPRAZOLE(en)
OMEPRAZOLE MAGNESIUM(en)
OMEPRAZOLE SODIUM(en)
PANTOPRAZOLE SODIUM SESQUIHYDRATE(en)
PETHIDINE HYDROCHLORIDE(en)
STRONTIUM RANELATE(en)
RANITIDINE(en)
RANITIDINE HYDROCHLORIDE(en)
RISEDRONATE SODIUM(en)
MIRABEGRON(en)
VALACICLOVIR HYDROCHLORIDE(en)
MINOCYCLINE HYDROCHLORIDE(en)
TAPENTADOL(en)
TAPENTADOL HYDROCHLORIDE(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : CARNIDAZOLE

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 : Precipitation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : CYCLOPENTOLATE HYDROCHLORIDE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : CLINDAMYCIN HYDROCHLORIDE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : drying, milling, seiving 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 : ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : ESOMEPRAZOLE SODIUM

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 3.6.4 Biological Testing

Active Substance : ETOFENAMATE

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 : Purification by distillation

3.5	**General Finishing Steps**
	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 : FLUOXETINE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, micronisation 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 : KETOROLAC TROMETAMOL

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : LAMOTRIGINE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : MEMANTINE HYDROCHLORIDE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, micronisation 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 : OMEPRAZOLE

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 : Pecipitation

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, micronisation 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 : OMEPRAZOLE MAGNESIUM

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : OMEPRAZOLE SODIUM

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : drying, milling, seiving 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 : PANTOPRAZOLE SODIUM SESQUIHYDRATE

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : drying, milling, seiving 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 : PETHIDINE HYDROCHLORIDE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, 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)

Active Substance : STRONTIUM RANELATE

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 and salt formation
3.5	**General Finishing Steps**

	3.5.1 Physical processing steps : Drying, milling, seiving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active Substance : RANITIDINE

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 : Precipitation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving 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 : RANITIDINE HYDROCHLORIDE

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, 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 : RISEDRONATE SODIUM

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

Active Substance : MIRABEGRON

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 : Drying, milling, seiving, micronisation 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 : VALACICLOVIR HYDROCHLORIDE

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 and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling, seiving, micronisation 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 : MINOCYCLINE HYDROCHLORIDE

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling and seiving 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 : TAPENTADOL

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 : Precipitación
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling and seiving 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 : TAPENTADOL HYDROCHLORIDE

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 : Precipitation and salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : Drying, milling and seiving 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

4. Non-Compliant Other Activities - Active Substances :
The site also imports ZOLPIDEM TARTRATE.

Part 3

1. Nature of non-compliance:

A lack of EU-GMP part II compliance was detected during the inspection carried out in September 2019. Eleven (11) deficiencies were indentified in total, four (4) of them were classified as critical deficiencies and six (6) as major. The critical deficiencies were observed in the Pharmaceutical quality system, manufacturing deviations and out of specification results (physical-chemical, including in process controls) that were not adequately handled and identified. Manufacturing processes were not properly controlled and recorded. a) The operations of adding variable amounts of a batch of active ingredient (fractions known as "Market B" that can be composed by one or more batches) are routinely performed, despite they are not justified nor documented in the batch record of the final batch. The traceability, regarding the exact batch-wise composition of the batch placed on the market is lost. No records are maintained of these operations, therefore it is unknown to what batches these portions have been added and which are the batches of origin of the added fraction and what amount has been added in each batch. b) In a systematic way, the production managers of the company have been obstructing and blocking the inspector's actions by not giving complete and clear information in response to the questions of the inspectors have made. Evidences were found of falsified and rewritten documents, hidden products, and destroyed documentation and electronic files. c) Failure on ensuring data integrity. In the production area there is a systematic practice of manipulation and falsification of data related to filling of the manufacturing batch records. It also affects the control in process unit, compromising the integrity of the data. d) Reprocessing of batches is not properly controlled and recorded, traceability of reprocessed batches is questioned. Label/batch number exchange operations between batches were detected in at least one reprocessed batch. In some occasions, fractions of batches that met specifications were mixed with batches that had quality defects in order to improve their analytical results. Major deficiencies were identified in the areas of production, sampling procedure (affecting release, stability, in process control and cleaning verification samples), cleaning procedures, operation supervision by key personnel, maintenance, site master file (some fractions reserved to be blended were found stored in an uncontrolled storage room excluded from the site master file) and information availability.

Action taken/proposed by the NCA

Prohibition of supply
Suspension of the distribution and sale of any active pharmaceutical ingredient or intermediate that has been manufactured, in whole or in part, in the facilities of UQUIFA SA at Lliçà de Vall, including those for which some phase of its processing is made in facilities of UQUIFA SA at Sant Celoni, unless there are not alternative suppliers and there is a risk of shortage. This action does not apply to clindamycin phosphate manufactured at Sant Celoni, but

the first steps are made at the facilities of UQUIFA SA at Lliçà de Vall.

Suspension or voiding of CEP (action to be taken by EDQM)
Suspension of CEP for the active substances manufactured in UQUIFA SA at Lliçà de Vall should be considered.

Others
ACTION ON THE MANUFACTURING ACTIVITY: Immediate action has been taken by temporarily suspending all manufacturing activities of active pharmaceutical ingredients and / or intermediates that are carried out at the UQUIFA SA plant in Lliçà de Vall. This measure will be maintained until all the deficiencies observed in the inspection have been corrected and it is verified through an inspection, that the company has an effective quality assurance system duly implemented and compliant with the EU-GMP part II. This site also holds a MIA: the activities related to the MIA, restricted to the quality control of the intermediate duloxetine pellets and also the active substance memantine , both totally produced in UQUIFA SA at Sant Celoni, are not affected by this measure. On 9th September, an inspection to the other manufacturing site of UQUIFA SA at Sant Celoni was performed. No evidences of GMP non-compliance were observed. Taking into account this temporarily suspension of activities, the register M00686 of manufacturer, importer or distributor of active substances to be used as starting materials in medicinal products for human use for UQUIFA SA plant in Lliçà de Vall has been withdrawn. WITHDRAWAL OF CURRENT VALID GMP CERTIFICATE: Current EU-GMP Part II certificate NCF-II/1923/001/CAT has been withdrawn from EudraGMDP. OTHER RECOMMENDATIONS/PROPOSED ACTIONS: a) Manufacturers of finished medicinal products are recommended to carry out a full testing on every container of active substance or intermediate received from the manufacturing plant of UQUIFA SA at Lliçà de Vall , ensuring a representative sampling is used (including sampling at different depths in the drum). In case out of specification results are detected, NCA should be informed by the MAH. This action has also to be carried out for the following active substance and intermediates received form manufacturing plant of UQUIFA SA at Sant Celoni which use active substances manufactured at Llicà de Vall: esomeprazole sodium liophylizate, esomeprazole magnesium (dihydrate), ranitidine compacted and omeprazole pellets. b) A new inspection is scheduled on November 13th.

Additional comments
This Statement of non-compliance is signed by Maria Sardà Raventós, Director General of Sanitary Management and Sanitary Regulation, competent authority in Catalonia, and sent to EudraGMDP by AEMPS.

2019-10-29

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

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Confidential
Spanish Agency of Medicines and Medical Devices
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