National Agency for Medicines and Medical Devices

Report No: ***NCF/012/RO***

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 Romania confirms the following:
The manufacturer: ***S.C. IRCON SRL***
Site address: ***Str. Calea Chişinăului nr. 6, Iaşi, Jud. Iaşi, 700181, Romania***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-12-04*** , 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

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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.8 Other solid dosage forms: ovules(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1. Nature of non-compliance:
During inspection a number of 34 deficiencies were found, out of which 4 critical and 10 major. Critical deficiencies are related to the quality management system, qualification/validation activities, manufacturing and material management documents documente and quality control laboratories activity.
Action taken/proposed by the NCA **Suspension of the manufacturing authorisation No. 50F in Full** there is no valid GMP Certificate, therefore the manufacturing authorisation is no longer renewed **Recall of batches already released** Recall of batches 455, 456 and 457 of Cervugid ovules. Batches are only distributed in Romania.
Additional comments The company holds only one marketing authorization in Romania (Cervugid ovules).There is no marketing authorization in other EU member state and no distribution of the product in EU

2016-01-18

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

---

Confidential
National Agency for Medicines and Medical Devices
Tel: ***Confidential***
Fax: ***Confidential***