Federal Agency for Medicines and Health Products

Report No: ***BE/NC/2022/02***

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 Belgium confirms the following:
The manufacturer: ***Pharmactive Ilac Sanayi Ve Ticaret A.S.***
Site address: ***Karaagac Mahallesi, Fatih Bulvari No 32, Kapakli, 59510, Turkey***
OMS Location: ***LOC-100061938***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-05-19***, 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) 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1.Nature of non-compliance:
Critical deficiencies: failure to manage risks of cross contamination with hazardous products.
Action taken/proposed by the NCA **Withdrawal, of current valid GMP certificate No. MT/008HM/2020** Restriction of current valid GMP certificate No. MT/008HM/2020, DE_HH_01_GMP_2017_1021, DE_HH_01_GMP_2019_0034 in FULL **Recall of batches already released** Consideration of recall, following NCA assessment of potential quality defect vs. supply restriction. **Prohibition of supply** No further batches to be supplied to the EU-market.

2022-05-31

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

---

Confidential
Federal Agency for Medicines and Health Products
Tel:***Confidential***
Fax:***Confidential***