Medicines and Healthcare Products Regulatory Agency

Report No: ***UK GMP 19756 INSP GMP19756/12912665-0002 NCR***

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 United Kingdom confirms the following:
The manufacturer: ***INDOCO REMEDIES LIMITED - PLANT II***
Site address: ***L-32, 33, 34 VERNA INDUSTRIAL AREA, PLANT II, VERNA, IN-403 722, India***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-09-21*** , 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;	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.6 Other: Sterile ophthalmic solutions(en)

Clarifying remarks (for public users)

The scope of this statement of non-compliance is limited to sterile ophthalmic eye drop solutions manufactured on filling lines I and II only in Plant II which are considered non-critical to public health.

Part 3

1. Nature of non-compliance:

This statement of non-compliance is issued because the company do not currently autoclave the change parts required to process the sterile, irradiated, open eye drop bottles on filling lines I and II. The change parts are currently only sanitised with disinfectant which does not provide adequate sterility assurance for aseptic eye drop filling. The company has committed to purchasing change parts which can be autoclaved but until these are installed, this statement of non-compliance should remain in force.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. UK GMP 19756 Insp GMP 19756/12912665-0001
Withdrawal of previous GMP Certificate No: UK GMP 19756 Insp GMP 19756/12912665-0001. Issue a statement of non-compliance and a restricted GMP certificate to permit continued manufacture of ampoules on Line III; vials, ophthalmic solutions on filling line IV and vials only on line I. Those ophthalmic products considered to be medically critical or to ensure continuity of supply on lines I and II, as determined by the national competent authority.

Prohibition of supply
No batches of non-critical ophthalmic products should be supplied to EU markets from lines I and II, plant II whilst this statement of non compliance remains in force.

Additional comments
There is no evidence of that the small numbers of eye drop batches filled to date on filling lines I and II have been adversely impacted and therefore the inspectorate does not recommend that any products are recalled. National Competent Authorities should evaluate the criticality of ophthalmic products supplied from filling lines I and II, Plant II by this manufacturing site and enact measures to ensure continued supplies where appropriate. Marketing Authorisation holders are requested to contact the relevant National Competent Authority to verify whether their products are considered medically critical to public health in their territory and therefore outside the scope of this non-compliance statement. It is understood that ophthalmic products are supplied to the UK/EU and other rest of the world countries.

Products manufactured at site, if known	Products	Dosage Form	Reference Member State, National or EMA
Human Medicinal Products	BRIMONIDINE TARTRATE/TIMOLOL 2 MG/ML + 5 MG/ML	EYEDROPS SOLUTION	NATIONAL
	STURIBAN 0.1MG/ML	EYEDROPS SOLUTION	NATIONAL
	STURIBAN 0.3MG/ML	EYEDROPS SOLUTION	NATIONAL
	DORZOLAMIDE / TIMOLOL 20 MG/ML + 5 MG/ML	EYEDROPS SOLUTION	NATIONAL
	LATANOPROST / TIMOLOL 50 MICROGRAMS / ML + 5 MG/ML	EYEDROPS SOLUTION	NATIONAL
	DORZOLAMIDE 20 MG/ML	EYEDROPS SOLUTION	NATIONAL
	BRIMONIDINE TARTRATE 2 MG/ML	EYEDROPS SOLUTION	NATIONAL

2019-01-21

Name and signature of the authorised person of the Competent Authority of United Kingdom

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