Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK MIA 42671 Insp GMP 42671/13896012-0003[H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

Issued following an inspection in accordance with : Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : COX PHARMACEUTICAL LIMITED

Site address : COX PHARMACEUTICAL LIMITED, UNIT 130-131, JOHN PLAYER BUILDING, STIRLING ENTERPRISE PARK, PLAYERS ROAD, STIRLING, FK7 7RP, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. UK MIA 42671 in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 01/06/2017, it is considered that it complies with

• The principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended)

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- (1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.
- (2) These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[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

[1.2.1.17] Other non-sterile medicinal products

Manufacturing operations limited to the dispensing of powders into containers (e.g. sodium bicarbona

					1	
[[1.2.2]B	atch certifica	tion				
[1.5] Pacl	kaging					
[1.5.1] P	rimary packa	ging		0		
[1.5.1.1]	7] Other nor	-sterile medicinal product	s			
Powders						
[1.5.2] S	econdary pa	ckaging				
Restrictions of	r Remarks					
The site only	dispenses ar	nd packages powders (So	dium bicarbonate and g	Jlucose).		
Only packagir	ng activities a	are carried out at site.				
No manufactu	iring operatio	ons are carried out.				
Any restrictior	ns related to	the scope of this certificat	e:		. C	
Building	Room	Line/equipment	QC Testing	Products		
				Sodium bicarbonate and glucose		
14/11/2017 Name and signature of the authorised person of the Competent Authority of United Kingdom						
	Confidential					
	Medicines and Healthcare products Regulatory Agency					
	Tel : Cont	Tel : Confidential				