Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/25-1/H/2015

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer IVERS LEE ITALIA S.P.A.
Site address CORSO DELLA VITTORIA, 1533 - 21042 CARONNO PERTUSELLA (VA)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 153/2014 dated 09/22/2014 in accordance with Art. 40 of Directive 2001/83/EC/ transposed in the following national legislation: D.Lvo 219/2006 art. 50.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 02/19/2014 it is considered that it complies with the Good Manufacturing Practice requirements referred to in The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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, after which time the issuing authority should be consulted.
The authenticity of this certificate may be verified with the issuing authority.

AIFA Italian Medicines Agency
Manufacturing Authorization Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 1149

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Part 2

Name and address of the site: IVERS LEE ITALIA S.P.A. - CORSO DELLA VITTORIA, 1533 , 21042 CARONNO PERTUSELLA(VA)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.4	Impregnated matrices
		1.2.1.5	Liquids for external use
		1.2.1.6	Liquids for internal use
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids Special Requirements: Hormones or substances with hormonal activity
1.5	**Packaging only**		
	1.5.2	*Secondary packing*	

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:

1.2.1.4 Impregnated matrices: Primary packing;
1.2.1.5 Liquids for external use: Primary packing;
1.2.1.6 Liquids for internal use: Primary packing;
1.2.1.8 Other solid dosage forms: Powders:primary packing and batch certification; Granules: primary packing;
1.2.1.11 Semi-solids: Primary packing: Hormones or substances with hormonal activity: no corticosteroid hormones;

Rome, 01/28/2015

Name and signature of the authorised person of the Competent Authority of Republic of Italy

Dott.ssa Isabella Marta
AIFA – Manufacturing Authorization Unit

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