Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/31-5/H/2017

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 ZAMBON S.P.A.
Site address VIA DELLA CHIMICA, 9 - 36100 VICENZA (VI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 224/2016 dated 12/28/2016 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 03/11/2016, 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
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 3010

LPC
GMP

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Part 2

Name and address of the site: ZAMBON S.P.A. - VIA DELLA CHIMICA, 9 , 36100 VICENZA(VI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)
Importation of medicinal products (Part 2)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.1	*Aseptically prepared*	
		1.1.1.2	Lyophilisates
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids
	1.1.3	*Batch certification*	
1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.1	Capsules, hard shell
		1.2.1.6	Liquids for internal use Special Requirements: Hormones or substances with hormonal activity
		1.2.1.8	Other solid dosage forms
		1.2.1.13	Tablets
	1.2.2	*Batch certification*	
1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.1	Capsules, hard shell
		1.5.1.6	Liquids for internal use Special Requirements: Hormones or substances with hormonal activity
		1.5.1.13	Tablets
	1.5.2	*Secondary packing*	

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1.6	**Quality control testing**	
	1.6.1	*Microbiological: sterility*
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*
	1.6.4	*Biological*

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

1.2.1.6 Liquids for internal use: hormones er substances with hormonal activity: corticosteroid hormones;

1.2.1.8 Other solid dosage forms: granules;

1.5.1.6 Liquids for internal use: hormones er substances with hormonal activity: corticosteroid hormones;

1.6.4 Biological: LAL test;

PART 2 - IMPORTATION OF MEDICAL PRODUCTS		
2.2	**Batch certification only (list of product types)**	
	2.2.1	*Sterile products*
	2.2.1.1	Aseptically prepared products Special Requirements: B-lactam antibiotics
	2.2.2	*Non-sterile products*
2.3	**Other importation activities**	
	2.3.1	*Site of physical importation*

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

2.2.1.1 Aseptically prepared products : powders;

2.2.2 Non-sterile products: tablets, other solid dosage forms: granules. ;

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AIFA

Rome, 03/06/2017

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

Dott. Giuseppe Pimpinella
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

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Apostille

(Convention de La Haye du 5 octobre 1961)

1. Stato: Italia

Il presente atto pubblico

2 . è stato firmato da: ***CUPELLI PIETRO***

3.operante in qualità di: ***FUNZIONARIO***

4. è munito del sigillo/bollo di : ***COMUNE DI GROTTAFERRATA***

Attestato

5.in : Roma 6: **16 MARZO 2017**

7. da: Prefettura di Roma – Ufficio Territoriale del Governo di Roma

8. col numero : **2090**

9. Sigillo/bollo :

Prefettura di Roma – Ufficio Territoriale del Governo di Roma

10. Firma

Funzionario Delegato

Giuseppe Patanè

Questa Apostille certifica solo la qualità del firmatario e il sigillo/timbro che è stato apposto. Non certifica il contenuto del documento per il quale è stata rilasciata.