Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/188-2/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 ZETA FARMACEUTICI S.P.A.
Site address VIA GALVANI, 10 - 36066 SANDRIGO (VI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 161/2017 dated 08/30/2017 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 05/18/2017, 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.+390659784410 Fax +390659784312
website: www.agenziafarmaco.it
SIS : 6685

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Part 2

Name and address of the site: ZETA FARMACEUTICI S.P.A. - VIA GALVANI, 10 , 36066 SANDRIGO(VI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.2	**Non-sterile products**		
	1.2.1	*Non-sterile products*	
		1.2.1.5	Liquids for external use Special Requirements: Hormones or substances with hormonal activity
		1.2.1.6	Liquids for internal use Special Requirements: Hormones or substances with hormonal activity
		1.2.1.8	Other solid dosage forms
		1.2.1.11	Semi-solids Special Requirements: Hormones or substances with hormonal activity
		1.2.1.12	Suppositories Special Requirements: Hormones or substances with hormonal activity
		1.2.1.13	Tablets
	1.2.2	*Batch certification*	
1.3	**Biological medicinal products**		
	1.3.1	*Biological medicinal products*	
		1.3.1.7	Other biological medicinal products: Live Biotherapeutic Products
	1.3.2	*Batch certification*	
		1.3.2.7	Other biological medicinal products: live biotherapeutic products

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1.5	**Packaging**		
	1.5.1	*Primary packing*	
		1.5.1.2	Capsules, soft shell
		1.5.1.5	Liquids for external use Special Requirements: Hormones or substances with hormonal activity
		1.5.1.6	Liquids for internal use Special Requirements: Hormones or substances with hormonal activity
		1.5.1.8	Other solid dosage forms
		1.5.1.11	Semi-solids Special Requirements: Hormones or substances with hormonal activity
		1.5.1.12	Suppositories Special Requirements: Hormones or substances with hormonal activity
	1.5.2	*Secondary packing*	
1.6	**Quality control testing**		
	1.6.2	*Microbiological: non-sterility*	
	1.6.3	*Chemical/Physical*	

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

1.2.1.5 Liquids for external use: Hormones or substances with hormonal activity : only corticosteroid hormones;

1.2.1.6 Liquids for internal use: Hormones or substances with hormonal activity : only corticosteroid hormones;

1.2.1.8 Other solid dosage forms: Powders;

1.2.1.11 Semi-solids: Hormones or substances with hormonal activity : only corticosteroid hormones;

1.2.1.12 Suppositories: hormones or substances with hormonal activity: only corticosteroid hormones;

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1.2.1.13 Tablets: no primary packing;
1.3.1.7 Other biological medicinal products (Live Biotherapeutic Products): only powders primary packaging;
1.3.2.7 Other biological medicinal products (live biotherapeutic products): powders;
1.5.1.5 Liquids for external use: Hormones or substances with hormonal activity : only corticosteroid hormones;
1.5.1.6 Liquids for internal use: Hormones or substances with hormonal activity: only corticosteroid hormones;
1.5.1.8 Other solid dosage forms: powder; also live biotherapeutic products;
1.5.1.11 Semi-solids: Hormones or substances with hormonal activity: only corticosteroid hormones;
1.5.1.12 Suppositories: Hormones or substances with hormonal activity: only corticosteroid hormones;

Name and address of the site:	ZETA FARMACEUTICI S.P.A. - VIA GALVANI, 10 , 36066 SANDRIGO(VI)

Human Medicinal Products

Authorised Operations
Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS OF INVESTIGATIONAL MEDICINAL PRODUCTS

1.2	**Non-sterile investigational medical products**	
	1.2.1	*Non-sterile products*
		1.2.1.5 Liquids for external use
		1.2.1.6 Liquids for internal use
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.5 Liquids for external use
		1.5.1.6 Liquids for internal use
	1.5.2	*Secondary packing*

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

Rome, 09/28/2017

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

Dott. Renato Massimi
GMP Inspections and Manufacturing Authorizations of Medicinal Products Office

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