

Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/279-1/H/2016

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 FRESENIUS KABI ANTI-INFECTIVES S.R.L.
Site address LOC.MASSERIE ARMIERI - 86077 POZZILLI (IS)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 168/2016 dated 10/13/2016 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 03/17/2016, 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 : 1752

PC
GMP

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Part 2

Name and address of the site: FRESENIUS KABI ANTI-INFECTIVES S.R.L. - LOC.MASSERIE ARMIERI , 86077 POZZILLI(IS)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.1	*Aseptically prepared*
		1.1.1.6 Other aseptically prepared products Special Requirements: B-lactam antibiotics
	1.1.3	*Batch certification*
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
		1.2.1.8 Other solid dosage forms
	1.2.2	*Batch certification*
1.5	**Packaging**	
	1.5.1	*Primary packing*
		1.5.1.8 Other solid dosage forms
	1.5.2	*Secondary packing*

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

1.1.1.6 Other aseptically prepared products: bulk freeze-dried: penicillins;
1.1.3 Batch certification: products aseptically prepared;
1.2.1.8 Other solid dosage forms: lyophilisate powders;
1.5.1.8 Other solid dosage forms: freeze-dried powders, bulk;

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Rome, 11/16/2016

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

CITTA' DI CERNUSCO SUL NAVIGLIO
AUTENTICAZIONE DI COPIA DI ATTI E DOCUMENTI
Si attesta che la presente copia, formata da n° 3 pagine, E' CONFORME all'originale, a norma dell'art. 18, comma 2, del T.U. 28/12/2000 n° 445.
Cernusco sul Naviglio, 14 FEB. 2017
IL FUNZIONARIO INCARICATO

Collaboratore Professionale Terminalista
(Pierangelo del Carro)

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Ministero dell'Economia e delle Finanze
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SEDICI/00
Agenzia Entrate
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4578-00010 6C15CA4B64CB3DAA
IDENTIFICATIVO : 01150993297045
Cernusco s/N.
Euro 0,52
Dir. Prov.

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Paese: ITALIA

Il presente atto pubblico

2. è stato sottoscritto da: DEL CARRO PIERANGELO

3. agente in qualità di: FUNZ. INC.

4. porta il sigillo/timbro di: CERNUSCO SUL NAVIGLIO COMUNE

ATTESTATO

5. a MILANO 6. data 16 FEB. 2017

7. dalla Prefettura (Ufficio Territoriale del Governo)

8. sotto il numero 2320

9. sigillo/timbro PREFETTURA DI MILANO

10. firma Il Funzionario Amministrativo
(Dott.ssa Claudia Barbieri)

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

This Apostille only certifies the signature, the capacity of the signer and the seal or stamp it bears. It does not certify the content of the document for which it was issued

Ministero dell'Economia e delle Finanze
Agenzia Entrate
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