Agenzia Italiana del Farmaco

Certificate No: IT/41-2/H/2012

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 GIOVANNI OGNA E FIGLI S.P.A.
Site address VIA FIGINI, 41 - 20053 MUGGIO' (MB)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aAMM - 57/2011 dated 06/17/2011 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 01/27/2011 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 : 97

GA
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Part 2 *Agenzia Italiana del Farmaco*

Name and address of the site: GIOVANNI OGNA E FIGLI S.P.A. - VIA FIGINI, 41 , 20053 MUGGIO'(MB)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**	
	1.1.3	*Batch certification only*
1.2	**Non-sterile products**	
	1.2.1	*Non-sterile products*
		1.2.1.6 Liquids for internal use
		1.2.1.11 Semi-solids
	1.2.2	*Batch certification only*
1.5	**Packaging only**	
	1.5.2	*Secondary packing*
1.6	**Quality control testing**	
	1.6.2	*Microbiological: non-sterility*
	1.6.3	*Chemical/Physical*

Rome, 02/20/2012

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

Dott. Renato Massimi
AIFA – Manufacturing Authorization Unit

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