Agenzia Italiana del Farmaco

AIFA

Certificate No: IT/240-4/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 LABORATORI BALDACCI S.P.A.
Site address VIA SAN MICHELE DEGLI SCALZI 73 - 56100 PISA (PI)

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. aM - 84/2012 dated 07/05/2012 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 10/12/2011 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 : 522

PC
GMP

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Part 2

Name and address of the site:	LABORATORI BALDACCI S.P.A. - VIA SAN MICHELE DEGLI SCALZI 73 , 56100 PISA(PI)

Human Medicinal Products

Authorised Operations

Manufacturing Operations (Part 1)

PART 1 - MANUFACTURING OPERATIONS

1.1	**Sterile Products**		
	1.1.2	*Terminally sterilised*	
		1.1.2.3	Small volume liquids
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
		1.2.1.8	Other solid dosage forms
		1.2.1.13	Tablets

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

1.1.2.3 Small volume liquids: chemical / physical controls;
1.2.1.8 Other solid dosage forms: powders;

Rome, 09/25/2012

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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