Agenzia Italiana del Farmaco

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate N° IT /aMP/89/2012

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of **Republic of Italy** confirms the following:
The manufacturer: **LABORATORI BALDACCI S.P.A.**
Site address: **PISA (PI) - VIA SAN MICHELE DEGLI SCALZI 73**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24th April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, that was conducted on 23 th February 2012, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substance referred to in Article 47 of Directive 2001/83/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.

Manufacture of active substance. Name of substances subject to inspection:
Chemical synthesis:
METADOXINA
D.L-1-(P-OSSIFENIL)-PROPILAMINA IODIDRATO
ARGININA-L-2-PIRROLIDON-5-CARBOSSILATO

Drying
LACTOBACILLUS RHAMNOSUS

28 th June 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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Manufacturing Authorization Unit
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