Agenzia Italiana del Farmaco

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate N° IT /aMP/10/2013

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: **ERREGIERRE S.P.A.**
Site address: **SOVERE (BG) - VIA VALLE DELLE FONTANE, 2 E LOC. PERTEGALLI,60**

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 10th May 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:

BUPROPIONE CLORIDRATO
CLOTRIMAZOLO
GABAPENTIN
MEBIDROLINA NAFTALIN 1.5 DISULFONATO
MESALAZINA
MESALAZINA H.D.
MOCLOBEMIDE
TICLOPIDINA CLORIDRATO
OMISSIS
AMBROXOL CLORIDRATO

Chemical synthesis, purification, quality control and batch certification:

ACIDO TIAPROFENICO
BUFLOMEDIL CLORIDRATO

Agenzia Italiana del Farmaco

14 th February 2013

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

Dott. Renato Massimi
AIFA – Manufacturing Authorization Unit

AIFA Italian Medicines Agency
Manufacturing Authorization Unit
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+390659784489 Fax +390659784312
website: www.agenziafarmaco.it