AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/199/H/2018

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 ERREGIERRE S.P.A.
Site address VIA VALLE DELLE FONTANE, 2 (loc. PERTEGALLI, 60) - 24060 SOVERE (BG)

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, the latest of which was conducted on 2018/06/14, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances 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. However, this period of validity may be reduced orextended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.
The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 1727

VI
GMP

Part 2

Name and address of the site:

ERREGIERRE S.P.A. - VIA VALLE DELLE FONTANE, 2 (loc.PERTEGALLI, 60), 24060 SOVERE (BG)

Name of the active Substances manufactured or imported:
TIAPROFENIC ACID CRUDE
AMBROXOL HYDROCHLORIDE
BUPROPION HYDROCHLORIDE
CLOTRIMAZOLE
GABAPENTIN
MEBHYDROLIN NAPADISYLATE
MESALAZINE
MESALAZINE HIGH DENSITY
MOCLOBEMIDE
TICLOPIDINE HYDROCHLORIDE
UMIFENOVIR

OMISSIS

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 1727

VI
GMP

Certificate No: IT-API/199/H/2018

OMISSIS

Pages from 3 to 8

AIFA
AGENZIA ITALIANA DEL FARMACO

Restrictions or clarifying remarks:

Micronisation operations, when performed, are outsourced. The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 48 months from the last general GMP inspection, which was conducted on 06/14/2018. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2018/11/14

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

Dott.ssa Marisa Delbò
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 1727