AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/75/H/2024

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

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 MINERARIA SACILESE SPA
Site address strada per fratte 39/A - 33077 SACILE (PN)

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 2023/12/01, 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 or extended 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
website: www.agenziafarmaco.it
SIS : 6064

VI
GMP

Rome, 2024/04/09

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

Dott. Michele Marangi
AIFA - GMP Inspections and Manufacturing Authorizations of APIs Office

Electronically signed according to the Italian legislation

Stamp duty paid according to the current Italian legislation.

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel.+39065978401
website: www.agenziafarmaco.it
SIS : 6064

VI
GMP