AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/79/H/2024

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 EIGENMANN & VERONELLI S.P.A.
Site address Via Vigevano, 63/A - 28069 TRECATE (NO)

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 2023/01/27, 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 : 1726

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Part 2

Name and address of the site:
EIGENMANN & VERONELLI S.P.A. - Via Vigevano, 63/A, 28069 TRECATE (NO)

Name of the active Substances manufactured or imported:
SIMETICONE

3 - Manufacturing Operations - Active Substances

SIMETICONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2. Manufacture of crude active substance **3.1.3.** Salt formation / Purification steps: filtration
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

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Restrictions or clarifying remarks:

On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 48 months from the latest general GMP inspection conducted on 2023/01/27, except for AIFA's re-evaluation of the risk profile.

Rome, 2024/04/10

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.

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Ai sensi dell'art. 23 del D.Lgs 82/2005 e dell'art. 18 del D.P.R. 445/2000 e successive modifiche si attesta che la presente copia analogica è conforme al documento informatico originale formato da questo Ufficio e detenuto presso i propri archivi informatici.

Qui di seguito i dati del documento informatico originale e di colui che ne attesta la conformità

Dati del documento informatico originale (GMP IT-API/79/H/2024 del 10/04/2024):	
Nome e cognome del firmatario:	MICHELE MARANGI
Formato firma elettronica e Ente Certificatore	PADES - ArubaPEC S.p.A. NG CA 3, ArubaPEC S.p.A., IT
Data in cui è stata apposta la firma:	12/04/2024
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Stato del documento:	Documento emesso dall'Ufficio GMPAPI

Dati relativi a colui che attesta la conformità della copia analogica al documento informatico originale:	
Nome e cognome:	Dr. Michele Marangi
Firma:	
Qualifica:	Dirigente Ufficio Ispezioni e Autorizzazioni GMP Materie Prime
Data:	16/04/2024