Certificate No: IT-API/91/H/2021

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 DEIMOS S.R.L.
Site address Viale Emilia, 92/94 - 20093 COLOGNO MONZESE (MI)

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 2020/02/13, 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 : 2109

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GMP

Part 2

Name and address of the site:
DEIMOS S.R.L. - Viale Emilia, 92/94, 20093 COLOGNO MONZESE (MI)

Name of the active Substances manufactured or imported:
ACICLOVIR
FOLIC ACID HYDRATE
VALRPOIC ACID
ALENDRONATE SODIUM TRIHYDRATE
CARVEDILOL
CIPROFLOXACIN HYDROCHLORIDE
CITALOPRAM HYDROBROMIDE
CITALOPRAM HYDROCHLORIDE
DOMPERIDONE
FLUCONAZOLE
HYDROCHLOROTHIAZIDE
IRBESARTAN
LAMOTRIGINE
LATANOPROST
METOPROLOL TARTRATE
PREGABALIN
RIFAMYCIN O

4. Other Activities - Active Substance:

Importation of:
ACICLOVIR; FOLIC ACID HYDRATE; VALRPOIC ACID; ALENDRONATE SODIUM TRIHYDRATE; CARVEDILOL; CIPROFLOXACIN HYDROCHLORIDE; CITALOPRAM HYDROBROMIDE; CITALOPRAM HYDROCHLORIDE; DOMPERIDONE; FLUCONAZOLE; HYDROCHLOROTHIAZIDE; IRBESARTAN; LAMOTRIGINE; LATANOPROST; METOPROLOL TARTRATE; PREGABALIN; RIFAMYCIN O

Restrictions or clarifying remarks:

Imported active substances can be given only to medicinal products/active substances manufacturers for human use. 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 2020/02/13. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2021/07/12

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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