Certificate No: IT-API/154/H/2023

**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 2023/03/30, 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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**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 |
| BROMFENAC SODIUM SESQUIHYDRATE |
| CARVEDILOL |
| CIPROFLOXACIN HYDROCHLORIDE |
| CITALOPRAM HYDROBROMIDE |
| CITALOPRAM HYDROCHLORIDE |
| FLUCONAZOLE |
| HYDROCHLOROTHIAZIDE |
| IRBESARTAN |
| LAMOTRIGINE |
| LATANOPROST |
| METOPROLOL TARTRATE |
| PREGABALIN |
| RIFAMYCIN O |
| ROSUVASTATIN CALCIUM |
| RUFLOXACIN HYDROCHLORIDE |

# 4. Other Activities - Active Substance:

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

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## Restrictions or clarifying remarks:

Imported active substances (AS) can be given only to medicinal products/AS manufacturers for human use. 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 2023/03/30, except for AIFA's re-evaluation of the risk profile.

Rome, 2023/06/23

**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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