Certificate No: IT-API/180/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 OLD PHARMA INTERNATIONAL SRL
Site address VIA QUINTILIANO, 30 - 20138 MILANO (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 2022/05/12, 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 : 3789

CV
GMP

Part 2

Name and address of the site:
OLD PHARMA INTERNATIONAL SRL - VIA QUINTILIANO, 30, 20138 MILANO (MI)

Name of the active Substances manufactured or imported:
AMITRIPTYLINE HYDROCHLORIDE
AMLODIPINE BESILATE
AMOXICILLIN TRIHYDRATE
ATENOLOL
BENZOCAINE
BETAMETHASONE SODIUM PHOSPHATE
CIPROFLOXACIN HYDROCHLORIDE
CITALOPRAM HYDROBROMIDE
CLINDAMYCIN PHOSPHATE
CHLORAMPHENICOL
CHOLINE ALFOSCERATE
DEXAMETHASONE SODIUM PHOSPHATE
DICLOFENAC
DICLOFENAC SODIUM
DILTIAZEM HYDROCHLORIDE
DORZOLAMIDE HYDROCHLORIDE
PHENYLEPHRINE HYDROCHLORIDE
FLUCONAZOLE
GABAPENTIN
LERCANIDIPINE HYDROCHLORIDE
LETROZOLE
MELATONIN
MESALAZINE
NIFEDIPINE
PAROXETINE HYDROCHLORIDE
PENTOXIFYLLINE
RIZATRIPTAN BENZOATE
SERTRALINE HYDROCHLORIDE
SUCRALFATE
TOPIRAMATE

4. Other Activities - Active Substance:

Importation of:
AMITRIPTYLINE HYDROCHLORIDE; AMLODIPINE BESILATE; AMOXICILLIN TRIHYDRATE; ATENOLOL; BENZOCAINE; BETAMETHASONE SODIUM PHOSPHATE; CIPROFLOXACIN HYDROCHLORIDE; CITALOPRAM HYDROBROMIDE; CLINDAMYCIN PHOSPHATE; CHLORAMPHENICOL; CHOLINE ALFOSCERATE; DEXAMETHASONE SODIUM PHOSPHATE; DICLOFENAC; DICLOFENAC SODIUM; DILTIAZEM HYDROCHLORIDE; DORZOLAMIDE HYDROCHLORIDE; PHENYLEPHRINE HYDROCHLORIDE; FLUCONAZOLE; GABAPENTIN; LERCANIDIPINE HYDROCHLORIDE; LETROZOLE; MELATONIN; MESALAZINE; NIFEDIPINE;PAROXETINE HYDROCHLORIDE; PENTOXIFYLLINE; RIZATRIPTAN BENZOATE; SERTRALINE HYDROCHLORIDE; SUCRALFATE; TOPIRAMATE

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 42 months from the latest general GMP inspection conducted on 2022/05/12, except for AIFA's re-evaluation of the risk profile.

Rome, 2023/07/21

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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