



Certificate No: IT-API/16/H/2019

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 F.I.S. FABBRICA ITALIANA SINTETICI S.P.A.

Site address Viale Milano, 26 - 36075 MONTECCHIO MAGGIORE (VI)

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**

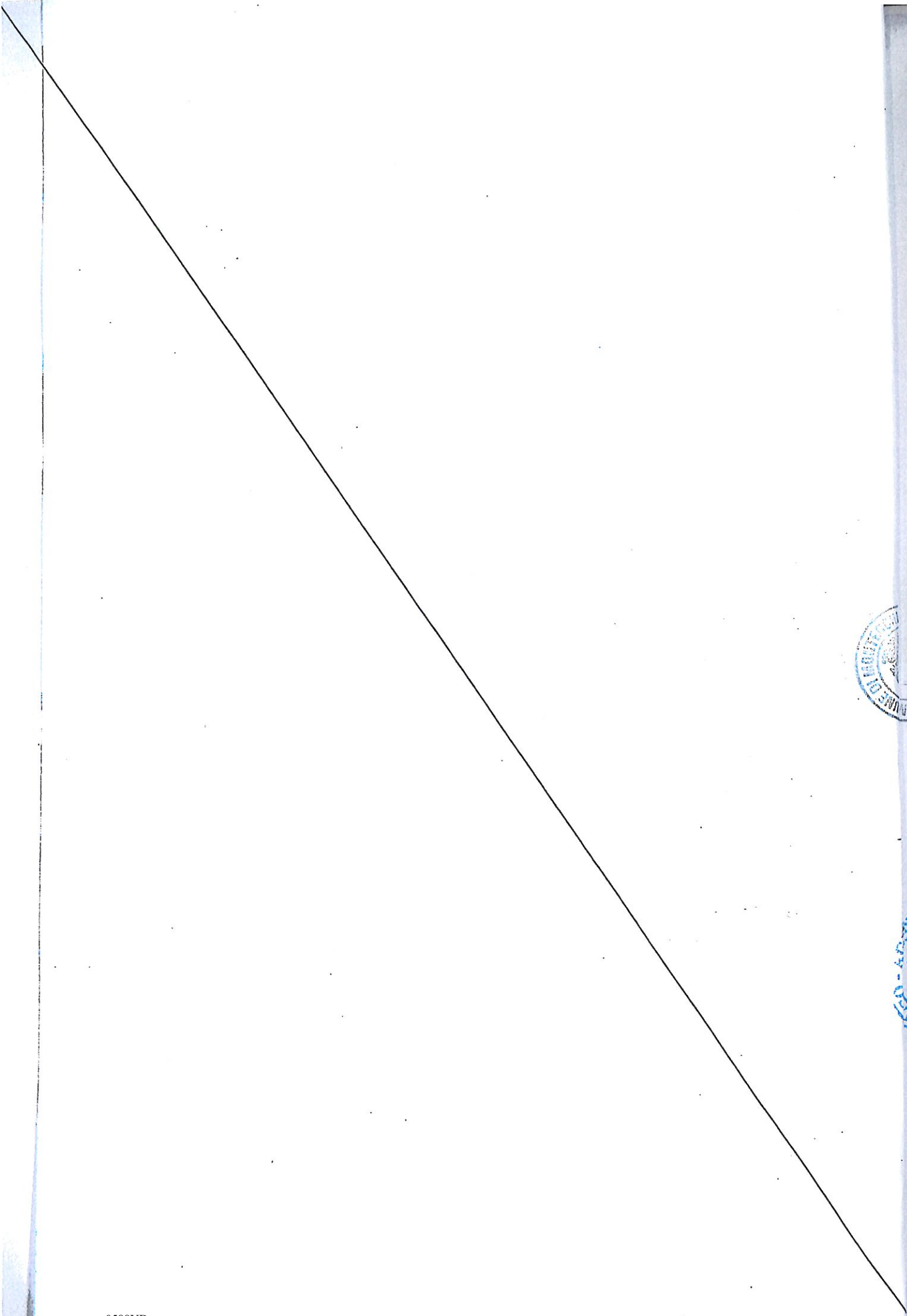
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2018/07/06, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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.



A handwritten signature in blue ink, likely of an official, is located in the bottom right corner of the page.



160-4700



AGENZIA ITALIANA DEL FARMACO

Part 2

Name and address of the site:

F.I.S. FABBRICA ITALIANA SINTETICI S.P.A. - Viale Milano, 26, 36075
MONTECCHIO MAGGIORE (VI)

Name of the active Substances manufactured or imported:

[REDACTED]

OMISSIS

FEB 19 2019

ANACETRAPIB

[REDACTED]

OMISSIS

FEB 19 2019

BROMAZEPAM

CARBAMAZEPINE

CLOBAZAM

CLOMIPHENE CITRATE

CLONAZEPAM

CHLORDIAZEPOXIDE

CHLORDIAZEPOXIDE HYDROCHLORIDE

CLOTRIMAZOLE

[REDACTED]

OMISSIS

FEB 19 2019

DELORAZEPAM

[REDACTED]

OMISSIS

FEB 19 2019

DIAZEPAM

DUTASTERIDE

EFAVIRENZ

ELETRIPTAN HYDROBROMIDE

[REDACTED]

OMISSIS

FEB 19 2019

ENCLOMIFENE CITRATE

ENTACAPONE

ERLOTINIB HYDROCHLORIDE

ESOMEPRAZOLE MAGNESIUM DIHYDRATE

AIFA - Italian Medicines Agency
GMP Inspections and Manufacturing Authorizations of APIs Office
Via del Tritone, n° 181 - 00187 ROMA (ITALY)
Tel. +39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 1730

VI
GMP

0588YD

[Handwritten signature]



AGENZIA ITALIANA DEL FARMACO

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

ESTAZOLAM

ETORICOXIB TOSYLATE SALT

[REDACTED]

OMISSIS

FEB 19 2019

FINASTERIDE

PHLOROGLUCINOL ANHYDROUS

PHLOROGLUCINOL HYDRATE

FLUNITRAZEPAM

FLURAZEPAM

FLURAZEPAM DIHYDROCHLORIDE

FLURAZEPAM MONOHYDROCHLORIDE

PLUVASTATIN SODIUM

CREATINE PHOSPHATE DISODIUM

[REDACTED]

OMISSIS

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FUROSEMIDE

[REDACTED]

OMISSIS

FEB 19 2019

IMATINIB MESILATE

INDOMETACIN

INDOMETACIN SODIUM

[REDACTED]

OMISSIS

FEB 19 2019

KETAZOLAM

[REDACTED]

OMISSIS

FEB 19 2019

LORAZEPAM

[REDACTED]

OMISSIS

FEB 19 2019

MIDAZOLAM

MIDAZOLAM HYDROCHLORIDE

MIDAZOLAM MALEATE

MOXIFLOXACIN HYDROCHLORIDE

[REDACTED]

OMISSIS

FEB 19 2019

NILOTINIB DIHYDROCHLORIDE DIHYDRATE

NITRAZEPAM

NITROFURANTOIN

NITROFURANTOIN MACROCRYSTALS

NITROFURANTOIN MONOHYDRATE

OLOPATADINE HYDROCHLORIDE

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AIFA

AGENZIA ITALIANA DEL FARMACO



0 1 16 189593 550 9



[REDACTED]	OMISSIS	FEB 19 2019
OXAZEPAM		
OXCARBAZEPINE		
PENTAZOCINE		
PENTAZOCINE HYDROCHLORIDE		
[REDACTED]	OMISSIS	FEB 19 2019
PRAZEPAM		
[REDACTED]	OMISSIS	FEB 19 2019
PROGESTERONE		
QUETIAPINE FUMARATE		
[REDACTED]	OMISSIS	FEB 19 2019
ROSUVASTATIN CALCIUM		
[REDACTED]	OMISSIS	FEB 19 2019
SITAGLIPTIN PHOSPHATE MONOHYDRATE		
[REDACTED]	OMISSIS	FEB 19 2019
SOLIFENACIN SUCCINATE		
[REDACTED]	OMISSIS	FEB 19 2019
SUMATRIPTAN SUCCINATE		
TEMAZEPAM		
TESTOSTERONE		
TESTOSTERONE CYPIONATE		
TESTOSTERONE PROPIONATE		
TETRAZEPAM		
[REDACTED]	OMISSIS	FEB 19 2019
TRIMETYLPHLOROGLUCINOL		
[REDACTED]	OMISSIS	FEB 19 2019
UPRIFOSBUVIR (MK-3682)		
URIDINE		
[REDACTED]	OMISSIS	FEB 19 2019

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and confidentiality agreement.

FEB 19 2019 FIS' Authorized signature

Antonio Baral



AGENZIA ITALIANA DEL FARMACO

	packaging material which is in direct contact with the substance)
	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing
	3.6.2. Microbiological testing (excluding sterility testing)

4. Other Activities - Active Substance:

Importation of:

URIDINE (Confidential);

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Restrictions or clarifying remarks:

Imported active substances, marked as confidential, plus [REDACTED], are used for manufacturing active substances and/or medicinal products within the importing site and/or a contractor. Importation of active substances used for manufacturing medicinal products falls under the responsibility of the QP/QPs listed in the MIA held by this production plant. Manufactured APIs marked as confidential are for clinical use only. The validity of the GMP certificate for this manufacturing site is 24 months from the last general GMP inspection, which was conducted on 2018/07/06. According to Italian legislation, all the sterile and/or of biological origin active substances listed in this document have undergone an authorization procedure. During inspection it was verified that the aseptic processing of sterile active substances is performed in accordance with the principles and guidelines of GMP as laid down in Directive 2003/94/EC and interpreted in the GMP Guide, including its Annex 1.

OMISSIS FEB 19 2019

Rome, 2019/01/21

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

Dott.ssa Marisa Delbò

AIFA - GMP Inspections and Manufacturing
Authorizations of APIs Office

Marisa Delbò

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GMP Inspections and Manufacturing Authorizations of APIs Office
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FIS Authorized signature
Azule Berle





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Prefettura -Ufficio Territoriale del Governo di Roma

Legalizzazione Area IV Quinquies

Apostille (Convention de La Haye du 5 octobre 1961)	
1. Stato (Country/Pays/Pais):	ITALIA
il presente atto pubblico (This public document / Le présent acte public / El presente documento público)	
2. E' stato firmato da: (Has been signed by/A été signé par/ Ha sido firmado por)	DELBO' MARISA
3. Operante in Qualità di : (Acting in the capacity of/Agissant en qualité de/Quein actue en calidad de)	DIRIGENTE
4. E' munito del sigillo/bollo di : (Bears the seal/stamp of/Est revêtu du sceau/ timbre de / Y está revestido del sello/ timbre de)	AIFA - AGENZIA ITALIANA DEL FARMACO
Attestato (Certified/Attesté/Certificado)	
5. in: Roma (At/A/En)	6. il: 31/01/2019 09:33 (On/Le/El día)
7. da: Prefettura di Roma - Ufficio Territoriale del Governo di Roma (Prefecture of Rome - Local Government in Rome / Préfecture de Rome - Le gouvernement local à Rome / Prefectura de Roma - Gobierno Local en Roma)	
8. col numero (No / Sous no / Bajo el número)	1524 / 2019
9. Sigillo / Bollo (Seal / Stämp / Sceau / Timbre / Sello / Timbre)	
10. Firma (Signature) FUNZIONARIO DELEGATO ANTONELLA SERGIO	

Questa Apostille certifica solo la qualità del firmatario e il sigillo che è stato apposto. Non certifica il contenuto del documento per il quale è stata rilasciata

This Apostille only certifies the signature, the capacity of the signer and the seal or stamp it bears. It does not certify the content of the document which it was issued.

Cette Apostille only certifies quela qualité du signataire e le sceau / timbre qui est fixé. Il ne certifie pas le contenu du document pour lequel il a été délivré.

Esta Apostilla solo certifica la calidad del firmante y el sello / timbro se fija. No certifica el contenido del documento para el que se expidió.



COMUNE DI MONTECCHIO MAGGIORE
AUTENTICAZIONE DI COPIE DI ATTI E DOCUMENTI
(art. 18 D.P.R. 445/2000)

La presente copia, composta di n. 67 fogli, è conforme
all'originale esibito dal Sig. Romio Remo
nato a Montecchio Maggiore il 23-05-1968
identificato mediante ca 956870488 del
09-09-2011 Brendola ed è
stata rilasciata previa responsabilità sulla respon-
sabilità penale che p[er] il [caso] in caso di esibizione
di atto falso o contenente dati non più rispondenti a verità.
Data 13-02-2019



IL FUNZIONARIO INCARICATO DAL SINDACO
IL FUNZIONARIO INCARICATO
DAL SINDACO
Perin Lett. Paola

Dimensione € 0,52