AGENZIA ITALIANA DEL FARMACO

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.

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

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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

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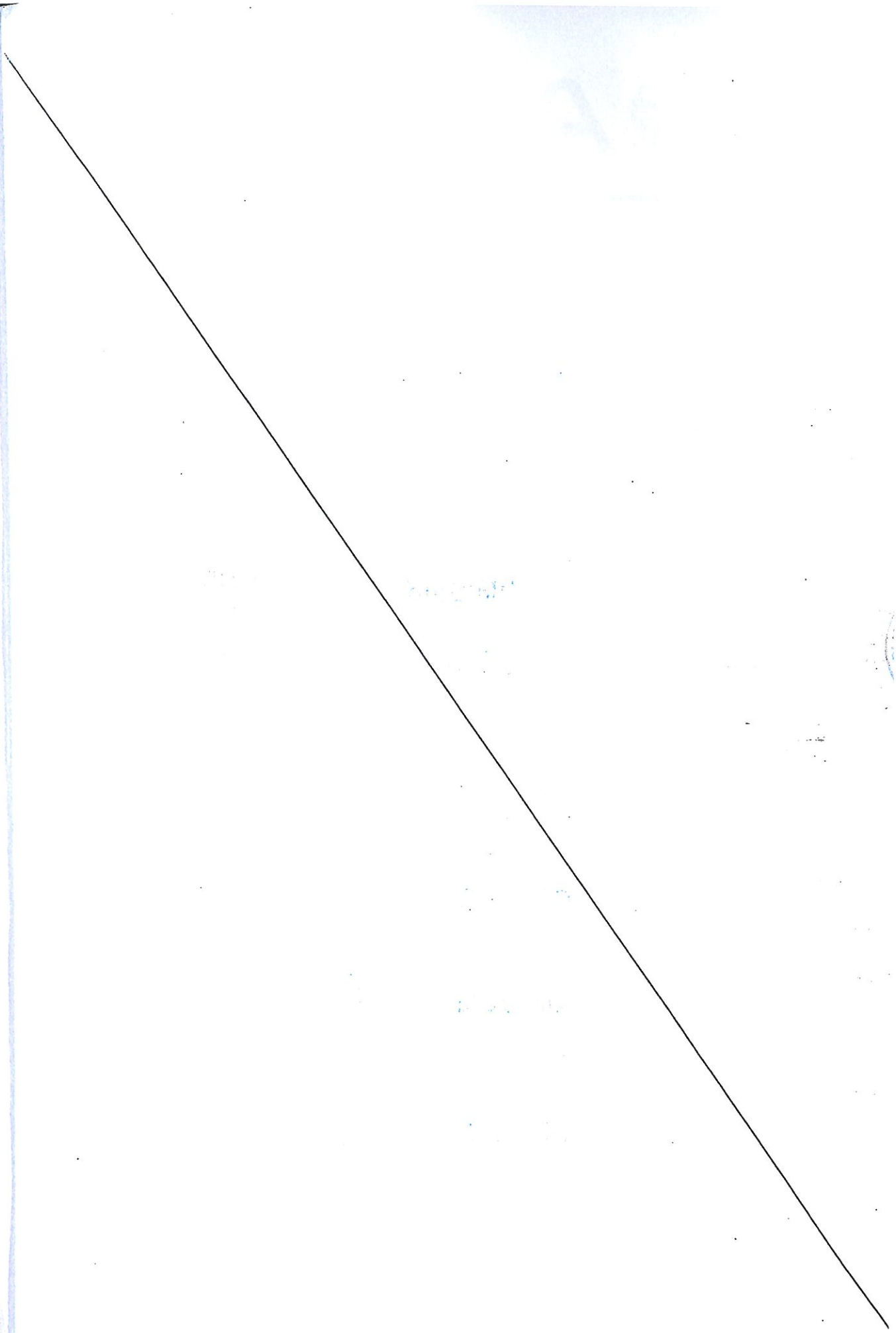

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AGENZIA ITALIANA DEL FARMACO

ESOMEPRAZOLE MAGNESIUM TRIHYDRATE
ESTAZOLAM
ETORICOXIB TOSYLATE SALT
[redacted] OMISSIS FEB 19 2019
FINASTERIDE
PHLOROGLUCINOL ANHYDROUS
PHLOROGLUCINOL HYDRATE
FLUNITRAZEPAM
FLURAZEPAM
FLURAZEPAM DIHYDROCHLORIDE
FLURAZEPAM MONOHYDROCHLORIDE
FLUVASTATIN SODIUM
CREATINE PHOSPHATE DISODIUM
[redacted] OMISSIS FEB 19 2019
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 MONOHYDRATE
NITRAZEPAM
NITROFURANTOIN
NITROFURANTOIN MACROCRYSTALS
NITROFURANTOIN MONOHYDRATE
OLOPATADINE HYDROCHLORIDE

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AGENZIA ITALIANA DEL FARMACO

MARCA DA BOLLO €16,00

[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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OMISSIS: Product manufactured under exclusivity and confidentiality agreement.

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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)

FEB 19 2019

4. Other Activities - Active Substance:

OMISSIS

Importation of:

[redacted] URIDINE (Confidential); [redacted]

Restrictions or clarifying remarks:

OMISSIS FEB 19 2019

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.

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

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FIS' Authorized signature

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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 preséntancte 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 sceac/ timbre de / Y está' revestito 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 dia)

7. da: Prefettura di Roma - Ufficio Territoriale del Governo di Roma

(Precture of Rome - Local Governement in Rome / Préfecture de Rome - Le gouvernement local à Rome / Prefectura de Roma - Gabierno Local en Roma

8. col numero (No / Sous no / Bajo el nùmero)	**1524 / 2019**
9. Sigillo / Bollo (Seal / Stamp / Sceau / Timbre / Sello / Timbre)	PREFETTURA DI ROMA - U.T.G.
10. Firma (Signature) **FUNZIONARIO DELEGATO** **ANTONELLA SERGIO**	

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

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

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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 Renato nato a Montecchio Maggiore il 23-05-1968 identificato mediante CI AS 6970488 del 09-09-2011 Brembo ed è stata rilasciata previo richiamo detto sulla responsabilità penale che [illegible] 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
Per. Istr. Paola

Diritti € 0,52

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