AGENZIA ITALIANA DEL FARMACO

Certificate No: IT-API/201/H/2018

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 FARMABIOS S.P.A.
Site address Via Pavia, 1 - 27027 GROPELLO CAIROLI (PV)

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 2018/06/01, 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 regulatoryrisk 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 : 1732

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Part 2

Name and address of the site:
FARMABIOS S.P.A. - Via Pavia, 1, 27027 GROPELLO CAIROLI (PV)

Name of the active Substances manufactured or imported:
CHOLIC ACID
URSODEOXYCHOLIC ACID
HALCINONIDE
HALOMETASONE MONOHYDRATE
AMCINONIDE
AZACITIDINE
BECLOMETASONE DIPROPIONATE
BECLOMETASONE DIPROPIONATE MONOHYDRATE
BECLOMETASONE DIPROPIONATE STERILE
BENDAMUSTINE HYDROCHLORIDE
BETAMETHASONE
BETAMETHASONE DIPROPIONATE
BETAMETHASONE VALERATE
BUDESONIDE
BUDESONIDE STERILE
BUSULFAN
CYPROTERONE ACETATE
CLOBETASOL PROPIONATE
CLOBETASONE BUTYRATE
CLOCORTOLONE PIVALATE
CHLORMADINONE ACETATE
CORTEXOLONE 17 ALPHA PROPIONATE
DELMADINONE ACETATE
DEXAMETHASONE
DESONIDE
DESONIDE DISODIUM PHOSPHATE
DESOXIMETASONE
DIFLORASONE
DIFLUCORTOLONE VALERATE
DIFLUPREDNATE
EXEMESTANE

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2

FLUDROCORTISONE
FLUDROCORTISONE ACETATE
FLUDROXYCORTIDE
FLUMETASONE
FLUMETASONE PIVALATE
FLUNISOLIDE
FLUNISOLIDE HEMIHYDRATE
FLUOCINOLONE ACETONIDE
FLUOCINONIDE
FLUPREDNINENE ACETATO
FLUTICASONE PROPIONATE
FORMOTEROL FUMARATE DIHYDRATE
FULVESTRANT
HYDROCORTISONE
HYDROCORTISONE ACETATE
HYDROCORTISONE ACETATE STERILE
HYDROCORTISONE HYDROGEN SUCCINATE
ISOPROTERENOL HYDROCHLORIDE
LOTEPREDNOL ETABONATE
LOTEPREDNOL ETABONATE STERILE
MEDROXYPROGESTERONE ACETATE
MEDROXYPROGESTERONE ACETATE STERILE
MEGESTROL ACETATE
MELPHALAN HYDROCHLORIDE
METHYLPREDNISOLONE
METHYLPREDNISOLONE ACETATE STERILE
METHYLTESTOSTERONE
MIVACURIUM CHLORIDE
MOMETASONE FUROATE
OSATERONE ACETATE
PARAMETHASONE ACETATE
PEMETREXED DISODIUM HEMIPENTAHYDRATE
PREDNICARBATE
PREDNISOLONE
PREDNISOLONE 17-VALERATE 21-ACETATE
PREDNISOLONE ACETATE STERILE
SALMETEROL XINAFOATE
TESTOSTERONE
TESTOSTERONE CYPIONATE

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TIROFIBAN HYDROCHLORIDE MONOHYDRATE TRIAMCINOLONE TRIAMCINOLONE ACETONIDE TRIAMCINOLONE ACETONIDE STERILE TRIAMCINOLONE BENETONIDE TRIAMCINOLONE DIACETATE TRIAMCINOLONE HEXACETONIDE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances
URSODEOXYCHOLIC ACID

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1. Manufacture of active substance intermediates **3.1.3.** Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1. Physical processing steps drying **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a 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)

3 - Manufacturing Operations - Active Substances
HALCINONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.5.1. Physical processing steps drying **3.5.2.** Primary Packaging (enclosing / sealing the active substance within a 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

4. Other Activities - Active Substance:

Importation of:
CHOLIC ACID (Confidential); BETAMETHASONE (Confidential); HYDROCORTISONE (Confidential); METHYLPREDNISOLONE (Confidential); PREDNISOLONE (Confidential); TESTOSTERONE (Confidential)

Restrictions or clarifying remarks:

Manufactured APIs marked as confidential are for clinical use only. Imported APIs marked as confidential undergo further processing within the importing site. Terminal sterilisation by gamma irradiation is outsourced to another site for MEDROXYPROGESTERONE ACETATE STERILE and as an alternative to sterile filtration even for BECLOMETASONE DIPROPIONATE STERILE. 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 30 months from the last general GMP inspection, which was conducted on 2018/06/01. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2018/11/16

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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Ministero dell'Economia e delle Finanze
Agenzia Entrate
MARCA DA BOLLO
€16,00
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4578-00088 542EB035F5738FC6
IDENTIFICATIVO : 01171243014284
0 1 17 124301 428 4

Comune di GROPELLO CAIROLI
Provincia di Pavia

La presente copia composta di n. 5
fogli è conforme all'originale esibitomi dall'interessato.
Gropello Cairoli, li 26 GIU. 2019

D'Ordine del Sindaco
L'Applicato Amministrativo
(Cimino Laura)

Prefettura di Pavia

REPUBBLICA ITALIANA
APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. Stato: **ITALIA**

Il presente atto pubblico

2. è stato firmato dalla Sig.ra Cimino Laura
3. operante in qualità di Applicato Amministrativo
4. è munito del sigillo/bollo del Comune di Gropello Cairoli

ATTESTATO

5. in **PAVIA**
6. il 01-07-2019
7. dalla **PREFETTURA DI PAVIA**
8. col numero 80300
9. Sigillo/bollo
10. Firma

p. IL PREFETTO

PREFETTURA DI PAVIA

IL FUNZIONARIO AMMINISTRATIVO
(A. Robino)

Ministero dell'Economia e delle Finanze
MARCA DA BOLLO
€16,00
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Agenzia Entrate
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00024082 01/07/2019 11:55:12
4578-00088 9AAF806D0ED2463
IDENTIFICATIVO : 01171243013831
0 1 17 124301 383 1

PREFETTURA DI PAVIA * GOVERNO *

Prot. n. 2019-0039441