

Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: *IT-API/112./H/2020*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER^{1, 2}

Part 1

Issued following an inspection in accordance with :

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:

The manufacturer: ***FARMABIOS S.P.A.***

Site address: ***Via Pavia, 1, GROPELLO CAIROLI, 27027, Italy***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-06-12*** , it is considered that it complies with :

- The principles of GMP for active substances³ 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. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

² Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection :

FLUPREDNIDENE ACETATE(en)
OSATERONE ACETATE(en)
FLUTICASONE PROPIONATE(en)
MOMETASONE FUROATE(en)
METHYLTESTOSTERONE(en)
SALMETEROL XINAFOATE(en)
CLOBETASOL PROPIONATE(en)
CLOCORTOLONE PIVALATE(en)
PREDNISOLONE ACETATE STERILE(en)
CANNABIDIOL(en)
DIFLUCORTOLONE VALERATE(en)
BETAMETHASONE DIPROPIONATE(en)
FLUDROCORTISONE(en)
FLUNISOLIDE(en)
FLUNISOLIDE HEMIHYDRATE(en)
FULVESTRANT(en)
TESTOSTERONE CYPIONATE(en)
TIROFIBAN HYDROCHLORIDE MONOHYDRATE(en)
TRIAMCINOLONE(en)
TRIAMCINOLONE ACETONIDE STERILE(en)
BUSULFAN(en)
FLUMETASONE PIVALATE(en)
FORMOTEROL FUMARATE DIHYDRATE(en)
MEDROXYPROGESTERONE ACETATE(en)
HALCINONIDE(en)
BECLOMETASONE DIPROPIONATE MONOHYDRATE(en)
BUDESONIDE STERILE(en)
PARAMETHASONE ACETATE(en)
DEXAMETHASONE(en)
HALOMETASONE MONOHYDRATE(en)
AMCINONIDE(en)
BUDESONIDE(en)
TRIAMCINOLONE BENETONIDE(en)
TRIAMCINOLONE HEXACETONIDE(en)
PREDNICARBATE(en)
TRIAMCINOLONE DIACETATE(en)
MELPHALAN HYDROCHLORIDE(en)
FLUDROXYCORTIDE(en)
BETAMETHASONE VALERATE(en)
CHLORMADINONE ACETATE(en)
DELMADINONE ACETATE(en)
DIFLUPREDNATE(en)
FLUDROCORTISONE ACETATE(en)

LOTEPREDNOL ETABONATE(en)
URSODEOXYCHOLIC ACID(en)
DIFLORASONE(en)
EXEMESTANE(en)
FLUOCINOLONE ACETONIDE(en)
FLUOCINONIDE(en)
FLUTICASONE FUROATE(en)
HYDROCORTISONE ACETATE(en)
HYDROCORTISONE HYDROGEN SUCCINATE(en)
MIVACURIUM CHLORIDE(en)
MEGESTROL ACETATE(en)
TRIAMCINOLONE ACETONIDE(en)
CLOBETASONE BUTYRATE(en)
MEDROXYPROGESTERONE ACETATE STERILE(en)
NORURSODEOXYCHOLIC ACID(en)
DESONIDE(en)
DESONIDE DISODIUM PHOSPHATE(en)
BECLOMETASONE DIPROPIONATE(en)
METHYLPREDNISOLONE ACETATE STERILE(en)
LOTEPREDNOL ETABONATE STERILE(en)
DESOXIMETASONE(en)
PREDNISOLONE ACETATE(en)
PREDNISOLONE 17-VALERATE 21-ACETATE(en)
CYPROTERONE ACETATE(en)
BECLOMETASONE DIPROPIONATE STERILE(en)
HYDROCORTISONE ACETATE STERILE(en)
FLUMETASONE(en)
ISOPROTERENOL HYDROCHLORIDE(en)

4. Other Activities - Active Substances :

Importation of: CHOLIC ACID (confidential), BETAMETHASONE (confidential), HYDROCORTISONE (confidential), METHYLPREDNISOLONE (confidential), PREDNISOLONE (confidential), TESTOSTERONE (confidential)

Clarifying remarks (for public users)

Manufactured active substances(AS) marked as confidential are for clinical use. Imported AS marked as confidential undergo further processing within the site. Terminal steril. By gamma irradiation is outsourced for MEDROXYPROGESTERONE ACETATE STERILE and as an alternative even for BECLOMETASONE DIPROPIONATE STERILE. According to Italian legisl., all the sterile and/or biological AS and/or AS deriving from human and animal tissues, organs, fluids listed in this document have undergone an authoriz. proced. Due to the restriction caused by COVID-19, it was verified by distant assessment that the aseptic process is performed according to GMP as laid down in Dir. 2003/94/EC and interpreted in the GMP Guide, includ. Annex 1. The Inspectorate adopted a risk-based approach for planning of inspections; therefore, the validity of the GMP certif. for this site is not more than 30 months from the last general GMP inspection conducted on 2019/09/20, except for AIFA re-evaluation of the risk profile.

2020-07-07

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

Confidential
Agenzia Italiana del Farmaco
Tel: *Confidential*
Fax: *Confidential*