

Italian Medicines Agency

CERTIFICATE NUMBER: **IT-API/121/H/2015**

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: **FARMALABOR S.R.L.**

Site address: **Via Pozzillo, zona ind. - II traversa a sinistra, CANOSA DI PUGLIA, 76012, 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 **2014-08-27** , 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 EudraGMP. 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 :

DESAMETASONE(it) / DEXAMETHASONE(en)
ATENOLOLO(it) / ATENOLOL(en)
BUSPIRONE CLORIDRATO(it) / BUSPIRONE HYDROCHLORIDE(en)
ISOPROPAMIDE IODURO(it) / ISOPROPAMIDE IODIDE(en)
PENTOSSIFILLINA(it) / PENTOXIFYLLINE(en)
FLUTAMIDE(it) / FLUTAMIDE(en)
FUROSEMIDE(it) / FUROSEMIDE(en)
METOCLOPRAMIDE CLORIDRATO(it) / METOCLOPRAMIDE HYDROCHLORIDE(en)
KETOPROFENE(it) / KETOPROFEN(en)
PROPAFENONE CLORIDRATO(it) / PROPAFENONE HYDROCHLORIDE(en)
PROPRANOLOLO CLORIDRATO(it) / PROPRANOLOL HYDROCHLORIDE(en)
CARVEDILOLO(it) / CARVEDILOL(en)
PARACETAMOLO(it) / PARACETAMOL(en)
PIRANTEL PAMOATO(it) / PYRANTEL PAMOATE(en)
CALCIO FOLINATO(it) / CALCIUM FOLINATE(en)
ACIDO URSODESOSSICOLICO(it) / URSODEOXYCHOLIC ACID(en)
CICLOSPORINA(it) / CICLOSPORIN(en)
TRIAMCINOLONE ACETONIDE(it) / TRIAMCINOLONE ACETONIDE(en)
CLOBETASOLO PROPIONATO(it) / CLOBETASOL PROPIONATE(en)
SULFADIAZINA(it) / SULFADIAZINE(en)
FENILE SALICILATO(it) / PHENYL SALICYLATE(en)
AMITRIPTILINA CLORIDRATO(it) / AMITRIPTYLINE HYDROCHLORIDE(en)
DIFENIDRAMINA CLORIDRATO(it) / DIPHENHYDRAMINE HYDROCHLORIDE(en)
OSSIBUTININA CLORIDRATO(it) / OXYBUTYNIN HYDROCHLORIDE(en)
ALOOPERIDOLO(it) / HALOPERIDOL(en)
BETAMETASONE VALERATO(it) / BETAMETHASONE VALERATE(en)
ESTRADIOLO VALERATO(it) / ESTRADIOL VALERATE(en)
FLUOCINOLONE ACETONIDE(it) / FLUOCINOLONE ACETONIDE(en)
SODIO CROMOGLICATO(it) / SODIUM CROMOGLICATE(en)
NIMESULIDE(it) / NIMESULIDE(en)
NISTATINA(it) / NYSTATIN(en)
LATTULOSIO(it) / LACTULOSE(en)
LIDOCAINA(it) / LIDOCAINE(en)
METILPREDNISOLONE(it) / METHYLPREDNISOLONE(en)
PROGESTERONE(it) / PROGESTERONE(en)
SALBUTAMOLO SOLFATO(it) / SALBUTAMOL SULFATE(en)
SELEGILINA CLORIDRATO(it) / SELEGILINE HYDROCHLORIDE(en)
PILOCARPINA CLORIDRATO(it) / PILOCARPINE HYDROCHLORIDE(en)
DEANOLO BITARTRATO(it) / DEANOL BITARTRATE(en)
YOHIMBINA CLORIDRATO(it) / YOHIMBINE HYDROCHLORIDE(en)
ERITROMICINA(it) / ERYTHROMYCIN(en)
ESTRADIOLO(it) / ESTRADIOL(en)
ETINILESTRADIOLO(it) / ETHINYLESTRADIOL(en)

ACIDO DEIDROCOLICO(it) / DEHYDROCHOLIC ACID(en)
IDROCLOROTIAZIDE(it) / HYDROCHLOROTHIAZIDE(en)
IDROCORTISONE(it) / HYDROCORTISONE(en)
IDROCORTISONE ACETATO(it) / HYDROCORTISONE ACETATE(en)
NADOLOLO(it) / NADOLOL(en)
IDROSSIPROGESTERONE CAPROATO(it) / HYDROXYPROGESTERONE CAPROATE(en)
PSEUDOEFEDRINA CLORIDRATO(it) / PSEUDOEPHEDRINE HYDROCHLORIDE(en)
CHININA CLORIDRATO(it) / QUININE HYDROCHLORIDE(en)
PIRACETAM(it) / PIRACETAM(en)
PIRENZEPINA CLORIDRATO(it) / PIRENZEPINE HYDROCHLORIDE(en)
TEOFILLINA(it) / THEOPHYLLINE(en)
CLOTRIMAZOLO(it) / CLOTRIMAZOLE(en)
VINPOCETINA(it) / VINPOCETINE(en)
ICTAMMOLO(it) / ICHTHAMMOL(en)
AMBROXOLO CLORIDRATO(it) / AMBROXOL HYDROCHLORIDE(en)
FLECAINIDE ACETATO(it) / FLECAINIDE ACETATE(en)
FLUOXETINA CLORIDRATO(it) / FLUOXETINE HYDROCHLORIDE(en)
ISOXSUPRINA CLORIDRATO(it) / ISOXSUPRINE HYDROCHLORIDE(en)
LANSOPRAZOLO(it) / LANSOPRAZOLE(en)
LITIO CARBONATO(it) / LITHIUM CARBONATE(en)
PROGLUMIDE(it) / PROGLUMIDE(en)
PROMETAZINA CLORIDRATO(it) / PROMETHAZINE HYDROCHLORIDE(en)
CHININA SOLFATO(it) / QUININE SULFATE(en)
CLORAZEPATO DIPOTASSICO(it) / DIPOTASSIUM CLORAZEPATE(en)
CORTISONE ACETATO(it) / CORTISONE ACETATE(en)
ALENDRONATO SODICO TRIIDRATO(it) / ALENDRONATE SODIUM TRIHYDRATE(en)
SODIO DEIDROCOLATO(it) / SODIUM DEHYDROCHOLATE(en)
CLORALIO IDRATO(it) / CHLORAL HYDRATE(en)
BEZAFIBRATO(it) / BEZAFIBRATE(en)
BISACODILE(it) / BISACODYL(en)
FLUDROCORTISONE ACETATO(it) / FLUDROCORTISONE ACETATE(en)
SULFATIAZOLO(it) / SULFATHIAZOLE(en)
NIMODIPINA(it) / NIMODIPINE(en)
OMEPRAZOLO(it) / OMEPRAZOLE(en)
INDOMETACINA(it) / INDOMETACIN(en)
LIDOCAINA CLORIDRATO(it) / LIDOCAINE HYDROCHLORIDE(en)
PREDNISONE(it) / PREDNISONE(en)
PROCAINA CLORIDRATO(it) / PROCAINE HYDROCHLORIDE(en)
RANITIDINA CLORIDRATO(it) / RANITIDINE HYDROCHLORIDE(en)
ESTRONE(it) / ESTRONE(en)
DICLOFENAC SODICO(it) / DICLOFENAC SODIUM(en)
TRINITROGLICERINA(it) / GLYCERYL TRINITRATE(en)
EPARINA SODICA(it) / HEPARIN SODIUM(en)
FINASTERIDE(it) / FINASTERIDE(en)
GEMFIBROZIL(it) / GEMFIBROZIL(en)
IBUPROFENE(it) / IBUPROFEN(en)
METOPROLOLO TARTRATO(it) / METOPROLOL TARTRATE(en)
MICONAZOLO(it) / MICONAZOLE(en)

NALTREXONE CLORIDRATO(it) / NALTREXONE HYDROCHLORIDE(en)
KETOCONAZOLO(it) / KETOCONAZOLE(en)
METFORMINA CLORIDRATO(it) / METFORMIN HYDROCHLORIDE(en)
METILE SALICILATO(it) / METHYL SALICYLATE(en)
POTASSIO CANRENOATO(it) / POTASSIUM CANRENOATE(en)
SILDENAFIL CITRATO(it) / SILDENAFIL CITRATE(en)
TESTOSTERONE PROPIONATO(it) / TESTOSTERONE PROPIONATE(en)
TETRACAINA CLORIDRATO(it) / TETRACAINE HYDROCHLORIDE(en)
TICLOPIDINA CLORIDRATO(it) / TICLOPIDINE HYDROCHLORIDE(en)
CLIOCHINOLO(it) / CLIOQUINOL(en)
IDROSSIZINA DICLORIDRATO(it) / HYDROXYZINE DIHYDROCHLORIDE(en)
AMILOCAINA CLORIDRATO(it) / AMYLOCAINE HYDROCHLORIDE(en)
AMINOFILLINA(it) / AMINOPHYLLINE(en)
SULFADIAZINA ARGENTICA(it) / SULFADIAZINE SILVER(en)
OSSITETRACICLINA CLORIDRATO(it) / OXYTETRACYCLINE HYDROCHLORIDE(en)
ALLOPURINOLO(it) / ALLOPURINOL(en)
BENZOCAINA(it) / BENZOCAINE(en)
ECONAZOLO NITRATO(it) / ECONAZOLE NITRATE(en)
ERGOTAMINA TARTRATO(it) / ERGOTAMINE TARTRATE(en)
FLUCONAZOLO(it) / FLUCONAZOLE(en)
MINOXIDIL(it) / MINOXIDIL(en)
NIFEDIPINA(it) / NIFEDIPINE(en)
MEDROSSIPROGESTERONE ACETATO(it) / MEDROXYPROGESTERONE ACETATE(en)
PREDNISOLONE(it) / PREDNISOLONE(en)
SPIRONOLATTONE(it) / SPIRONOLACTONE(en)
PAPAVERINA CLORIDRATO(it) / PAPAVERINE HYDROCHLORIDE(en)
AMIODARONE CLORIDRATO(it) / AMIODARONE HYDROCHLORIDE(en)
BETAMETASONE DIPROPIONATO(it) / BETAMETHASONE DIPROPIONATE(en)
EFEDRINA CLORIDRATO(it) / EPHEDRINE HYDROCHLORIDE(en)
BUPROPIONE CLORIDRATO(it) / BUPROPION HYDROCHLORIDE(en)
GABAPENTINA(it) / GABAPENTIN(en)
ATROPINA SOLFATO(it) / ATROPINE SULFATE(en)
IDROCORTISONE BUTIRRATO(it) / HYDROCORTISONE BUTYRATE(en)
PRILOCAINA CLORIDRATO(it) / PRILOCAINE HYDROCHLORIDE(en)
METRONIDAZOLO(it) / METRONIDAZOLE(en)
CARBOCISTEINA(it) / CARBOCISTEINE(en)
PIROXICAM(it) / PIROXICAM(en)
ACICLOVIR(it) / ACICLOVIR(en)
ACIDO ACETILSALICILICO(it) / ACETYLSALICYLIC ACID(en)
CIMETIDINA(it) / CIMETIDINE(en)
TOPIRAMATO(it) / TOPIRAMATE(en)
CIPROTERONE ACETATO(it) / CYPROTERONE ACETATE(en)
CLINDAMICINA FOSFATO(it) / CLINDAMYCIN PHOSPHATE(en)
LEVOTIROXINA SODICA(it) / LEVOTHYROXINE SODIUM(en)

4. Other Activities - Active Substances :

Importation of: ERYTHROMYCIN, IBUPROFEN, PARACETAMOL, PRILOCAINE HYDROCHLORIDE, TETRACAINE HYDROCHLORIDE, VINPOCETINE

Clarifying remarks (for public users)

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 48 months from the last general GMP inspection, which was conducted on 2014/08/27. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

2015-10-26

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

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