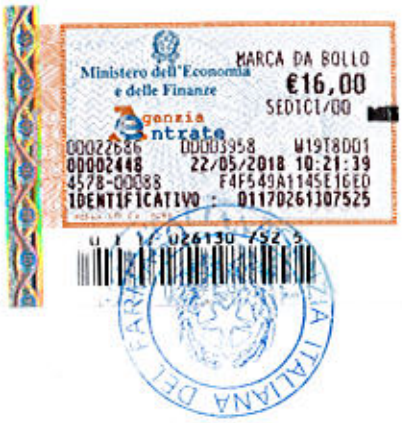

Certificate No: IT-API/104/H/2018

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 FARMALABOR S.R.L.
Site address Via Pozzillo, zona ind. - II traversa a sinistra - 76012 CANOSA DI PUGLIA (BT)

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 2017/11/29, 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.

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GMP Inspections and Manufacturing Authorizations of APIs Office
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Tel.+39065978401 Fax +390659784617
website: www.agenziafarmaco.it
SIS : 3558

CG
GMP

Part 2

Name and address of the site:

FARMALABOR S.R.L. - Via Pozzillo, zona ind. - II traversa a sinistra, 76012 CANOSA DI PUGLIA (BT)

Name of the active Substances manufactured or imported:
17-ALPHA ESTRADIOL
ACICLOVIR
ACETYLSALICYLIC ACID
DEHYDROCHOLIC ACID
URSODEOXYCHOLIC ACID
ALENDRONATE SODIUM TRIHYDRATE
ALLOPURINOL
HALOPERIDOL
AMBROXOL HYDROCHLORIDE
AMYLOCAINE HYDROCHLORIDE
AMINOPHYLLINE
AMIODARONE HYDROCHLORIDE
AMITRIPTYLINE HYDROCHLORIDE
ATENOLOL
ATROPINE SULFATE
BACLOFEN
BENZOCAINE
BETAMETHASONE DIPROPIONATE
BETAMETHASONE VALERATE
BEZAFIBRATE
BIFONAZOLE
BISACODYL
BUPROPION HYDROCHLORIDE
BUSPIRONE HYDROCHLORIDE
CALCIUM FOLINATE
CARBOCISTEINE
CARVEDILOL
CETIRIZINE DIHYDROCHLORIDE
QUININE HYDROCHLORIDE

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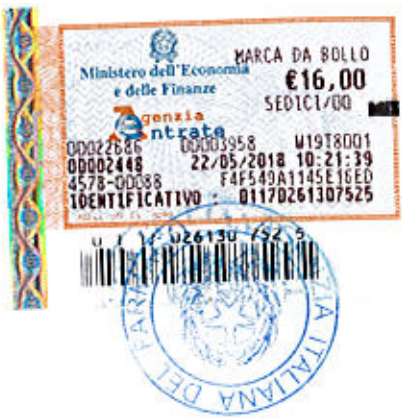

Certificate No: IT-API/104/H/2018

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 FARMALABOR S.R.L.
Site address Via Pozzillo, zona ind. - II traversa a sinistra - 76012 CANOSA DI PUGLIA (BT)

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 2017/11/29, 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.
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site: www.agenziafarmaco.it

Part 2

Name and address of the site:

FARMALABOR S.R.L. - Via Pozzillo, zona ind. - II traversa a sinistra, 76012 CANOSA DI PUGLIA (BT)

Name of the active Substances manufactured or imported:

17-ALPHA ESTRADIOL
ACICLOVIR
ACETYLSALICYLIC ACID
DEHYDROCHOLIC ACID
URSODEOXYCHOLIC ACID
ALENDRONATE SODIUM TRIHYDRATE
ALLOPURINOL
HALOPERIDOL
AMBROXOL HYDROCHLORIDE
AMYLOCAINE HYDROCHLORIDE
AMINOPHYLLINE
AMIODARONE HYDROCHLORIDE
AMITRIPTYLINE HYDROCHLORIDE
ATENOLOL
ATROPINE SULFATE
BACLOFEN
BENZOCAINE
BETAMETHASONE DIPROPIONATE
BETAMETHASONE VALERATE
BEZAFIBRATE
BIFONAZOLE
BISACODYL
BUPROPION HYDROCHLORIDE
BUSPIRONE HYDROCHLORIDE
CALCIUM FOLINATE
CARBOCISTEINE
CARVEDILOL
CETIRIZINE DIHYDROCHLORIDE
QUININE HYDROCHLORIDE

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AGENZIA ITALIANA DEL FARMACO

QUININE SULFATE
CICLOSPORIN
CIMETIDINE
CYPROTERONE ACETATE
CLINDAMYCIN HYDROCHLORIDE
CLINDAMYCIN PHOSPHATE
CLIOQUINOL
CLOBETASOL PROPIONATE
CHLORAL HYDRATE
DIPOTASSIUM CLORAZEPATE
CLOTRIMAZOLE
CODEINE
CODEINE PHOSPHATE HEMIHYDRATE
CORTISONE ACETATE
DEANOL BITARTRATE
DEXAMETHASONE
DEXTROMETHORPHAN HYDROBROMIDE
DIAZEPAM
DICLOFENAC SODIUM
DIPHENHYDRAMINE HYDROCHLORIDE
DITHRANOL
DOXYCYCLINE HYCLATE
ECONAZOLE NITRATE
EPHEDRINE HYDROCHLORIDE
HEPARIN SODIUM
ERGOTAMINE TARTRATE
ERYTHROMYCIN
ERYTHROMYCIN LACTOBIONATE
ESTRADIOL
ESTRADIOL VALERATE
ESTRONE
ETHINYLESTRADIOL
PHENYL SALICYLATE
FINASTERIDE
FLECAINIDE ACETATE
FLUCONAZOLE
FLUDROCORTISONE ACETATE
FLUOCINOLONE ACETONIDE
FLUOXETINE HYDROCHLORIDE

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AGENZIA ITALIANA DEL FARMACO

FLUTAMIDE
FUROSEMIDE
GABAPENTIN
GEMFIBROZIL
IBUPROFEN
ICHTHAMMOL
HYDROCHLOROTHIAZIDE
HYDROCORTISONE
HYDROCORTISONE ACETATE
HYDROCORTISONE BUTYRATE
HYDROXYPROGESTERONE CAPROATE
HYDROXYZINE DIHYDROCHLORIDE
INDOMETACIN
ISOPROPAMIDE IODIDE
ISOXSUPRINE HYDROCHLORIDE
KETOCONAZOLE
KETOPROFEN
LANSOPRAZOLE
LACTULOSE
LEVOTHYROXINE SODIUM
LIDOCAINE
LIDOCAINE HYDROCHLORIDE
LITHIUM CARBONATE
MEDROXYPROGESTERONE ACETATE
METHADONE HYDROCHLORIDE
METFORMIN HYDROCHLORIDE
METHYL SALICYLATE
METHYLPREDNISOLONE
METOCLOPRAMIDE HYDROCHLORIDE
METOPROLOL TARTRATE
METHOXSALEN
METRONIDAZOLE
MICONAZOLE
MICONAZOLE NITRATE
MINOCYCLINE HYDROCHLORIDE
MINOXIDIL
NADOLOL
NALTREXONE HYDROCHLORIDE
NIFEDIPINE

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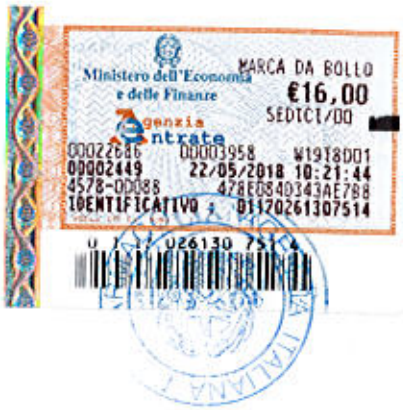

AGENZIA ITALIANA DEL FARMACO

NIFUROXAZIDE
NIMESULIDE
NIMODIPINE
NYSTATIN
OMEPRAZOLE
OXYBUTYNIN HYDROCHLORIDE
OXYTETRACYCLINE HYDROCHLORIDE
PAPAVERINE HYDROCHLORIDE
PARACETAMOL
PENTOXIFYLLINE
PILOCARPINE HYDROCHLORIDE
PIRACETAM
PYRANTEL PAMOATE
PIRENZEPINE HYDROCHLORIDE
PIROXICAM
POTASSIUM CANRENOATE
PRASTERONE
PREDNISOLONE
PREDNISONE
PRILOCAINE HYDROCHLORIDE
PROCAINE HYDROCHLORIDE
PROGESTERONE
PROGLUMIDE
PROMETHAZINE HYDROCHLORIDE
PROPAFENONE HYDROCHLORIDE
PROPRANOLOL HYDROCHLORIDE
PSEUDOEPHEDRINE HYDROCHLORIDE
RANITIDINE HYDROCHLORIDE
SALBUTAMOL SULFATE
SELEGILINE HYDROCHLORIDE
SILDENAFIL CITRATE CROMOGLICATE
SODIUM DEHYDROCHOLATE
SPIRONOLACTONE
SULFADIAZINE
SULFADIAZINE SILVER
SULFATHIAZOLE
SULPIRIDE
THEOPHYLLINE
TESTOSTERONE PROPIONATE

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TETRACAINE HYDROCHLORIDE TICLOPIDINE HYDROCHLORIDE TOPIRAMATE TRIAMCINOLONE ACETONIDE TRIMETHOPRIM GLYCERYL TRINITRATE VINPOCETINE XYLOMETAZOLINE HYDROCHLORIDE YOHIMBINE HYDROCHLORIDE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

17-ALPHA ESTRADIOL

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

ACICLOVIR

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3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ACETYLSALICYLIC ACID

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

DEHYDROCHOLIC ACID

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3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

URSODEOXYCHOLIC ACID

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ALENDRONATE SODIUM TRIHYDRATE

3.5	**General Finishing Steps**

	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 - Manufacturing Operations - Active Substances

ALLOPURINOL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

HALOPERIDOL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

AMBROXOL HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

AMYLOCAINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

AMINOPHYLLINE

3.5	**General Finishing Steps**
	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 thesealed 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 - Manufacturing Operations - Active Substances

AMIODARONE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

AMITRIPTYLINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ATENOLOL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ATROPINE SULFATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BACLOFEN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BENZOCAINE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BETAMETHASONE DIPROPIONATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

BETAMETHASONE VALERATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

BEZAFIBRATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

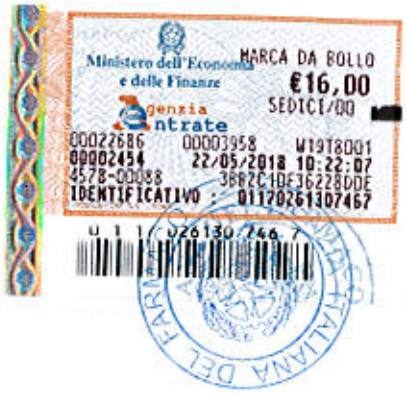
BIFONAZOLE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BISACODYL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BUPROPION HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

BUSPIRONE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

CALCIUM FOLINATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

CARBOCISTEINE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

CARVEDILOL

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

CETIRIZINE DIHYDROCHLORIDE

3.5	General Finishing Steps
	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

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	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

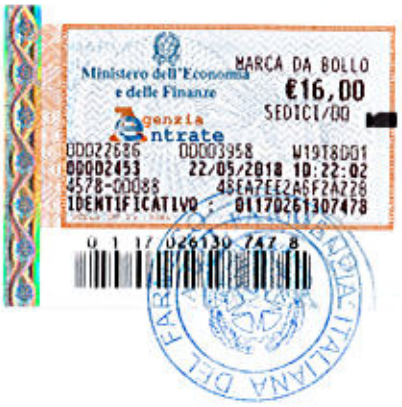
QUININE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

QUININE SULFATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances CICLOSPORIN	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances CIMETIDINE	
3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances

CYPROTERONE ACETATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging(enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

CLINDAMYCIN HYDROCHLORIDE

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances

CLINDAMYCIN PHOSPHATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

CLIOQUINOL

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances

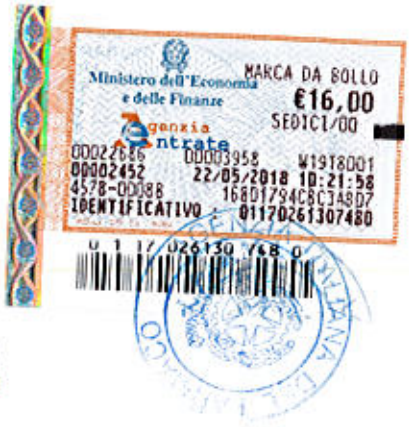
CLOBETASOL PROPIONATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

CHLORAL HYDRATE

3.5	**General Finishing Steps**
	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



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3 - Manufacturing Operations - Active Substances DIPOTASSIUM CLORAZEPATE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances CLOTRIMAZOLE	
3.5	**General Finishing Steps**
	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

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AGENZIA ITALIANA DEL FARMACO

3 - Manufacturing Operations - Active Substances

CODEINE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

CODEINE PHOSPHATE HEMIHYDRATE

3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances CORTISONE ACETATE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances DEANOL BITARTRATE	
3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances DEXAMETHASONE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances DEXTROMETHORPHAN HYDROBROMIDE	
3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances DIAZEPAM	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances DICLOFENAC SODIUM	
3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances

DIPHENHYDRAMINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

DITHRANOL

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing theactive 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

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3 - Manufacturing Operations - Active Substances

DOXYCYCLINE HYCLATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ECONAZOLE NITRATE

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances EPHEDRINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) **.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 - Manufacturing Operations - Active Substances HEPARIN SODIUM	
3.5	**General Finishing Steps**
	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

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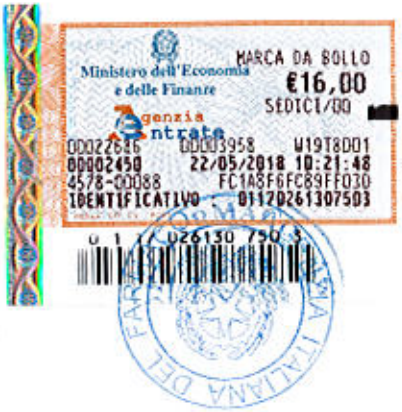

3 - Manufacturing Operations - Active Substances ERGOTAMINE TARTRATE	
3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package 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 - Manufacturing Operations - Active Substances ERYTHROMYCIN	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

ERYTHROMYCIN LACTOBIONATE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances ESTRADIOL	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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

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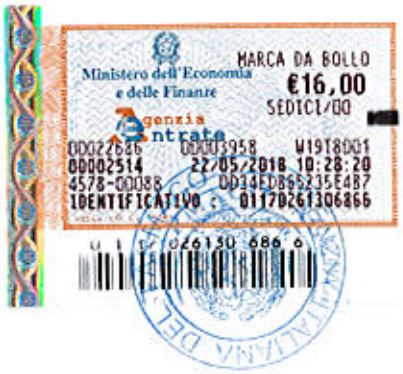
3 - Manufacturing Operations - Active Substances ESTRADIOL VALERATE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances ESTRONE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances ETHINYLESTRADIOL	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances PHENYL SALICYLATE	
3.5	**General Finishing Steps**
	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



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3 - Manufacturing Operations - Active Substances FINASTERIDE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances FLECAINIDE ACETATE	
3.5	**General Finishing Steps**
	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**

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	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances FLUCONAZOLE	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances FLUDROCORTISONE ACETATE	
3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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)

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3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

FLUOCINOLONE ACETONIDE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

FLUOXETINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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

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	numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

FLUTAMIDE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

FUROSEMIDE

3.5	**General Finishing Steps**
	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

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	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 - Manufacturing Operations - Active Substances

GABAPENTIN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

GEMFIBROZIL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

IBUPROFEN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ICHTHAMMOL

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

HYDROCHLOROTHIAZIDE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

HYDROCORTISONE

3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

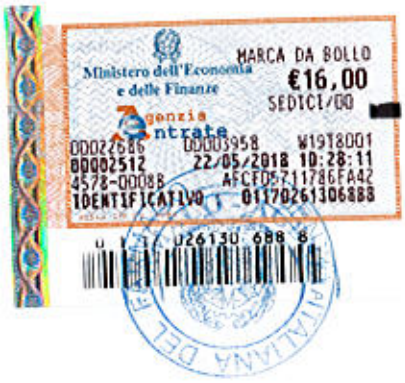
HYDROCORTISONE ACETATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

HYDROCORTISONE BUTYRATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity



AGENZIA ITALIANA DEL FARMACO

	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 - Manufacturing Operations - Active Substances

HYDROXYPROGESTERONE CAPROATE

3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

HYDROXYZINE DIHYDROCHLORIDE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

INDOMETACIN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ISOPROPAMIDE IODIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

ISOXSUPRINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

KETOCONAZOLE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

KETOPROFEN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

LANSOPRAZOLE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

LACTULOSE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

LEVOTHYROXINE SODIUM

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

LIDOCAINE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

LIDOCAINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

LITHIUM CARBONATE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

MEDROXYPROGESTERONE ACETATE

3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

METHADONE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

METFORMIN HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

METHYL SALICYLATE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

METHYLPREDNISOLONE

3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

METOCLOPRAMIDE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

METOPROLOL TARTRATE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

METHOXSALEN

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

METRONIDAZOLE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

MICONAZOLE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

MICONAZOLE NITRATE

3.5	**General Finishing Steps**
	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)

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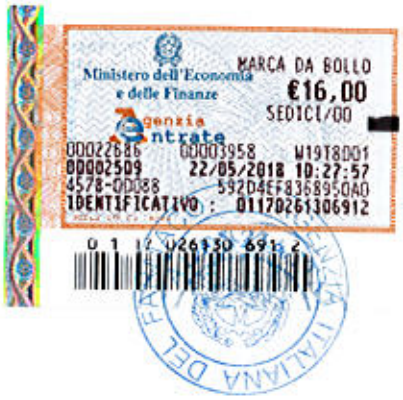

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3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

MINOCYCLINE HYDROCHLORIDE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

MINOXIDIL

3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contactwith 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 - Manufacturing Operations - Active Substances

NADOLOL

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

NALTREXONE HYDROCHLORIDE

3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances

NIFEDIPINE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

NIFUROXAZIDE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

NIMESULIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

NIMODIPINE

3.5	**General Finishing Steps**
	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

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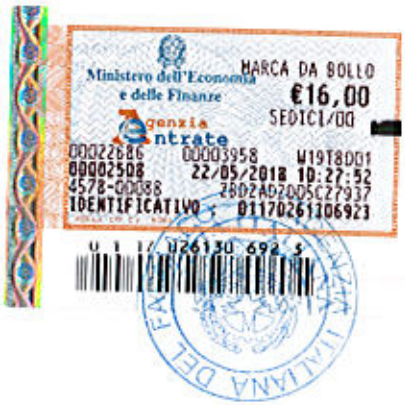

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3 - Manufacturing Operations - Active Substances

NYSTATIN

3.5	**General Finishing Steps**
	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

OMEPRAZOLE

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances

OXYBUTYNIN HYDROCHLORIDE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

OXYTETRACYCLINE HYDROCHLORIDE

3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances PAPAVERINE HYDROCHLORIDE	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances PARACETAMOL	
3.5	General Finishing Steps
	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

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3 - Manufacturing Operations - Active Substances PENTOXIFYLLINE	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances PILOCARPINE HYDROCHLORIDE	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

PIRACETAM	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances PYRANTEL PAMOATE	
3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

PIRENZEPINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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 packagewithin 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 - Manufacturing Operations - Active Substances

PIROXICAM

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

POTASSIUM CANRENOATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

PRASTERONE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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

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3 - Manufacturing Operations - Active Substances PREDNISOLONE	
3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances PREDNISONE	
3.5	General Finishing Steps
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity 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 - Manufacturing Operations - Active Substances

PRILOCAINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

PROCAINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances PROGESTERONE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances PROGLUMIDE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

PROMETHAZINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

PROPAFENONE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances PROPRANOLOL HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances PSEUDOEPHEDRINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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

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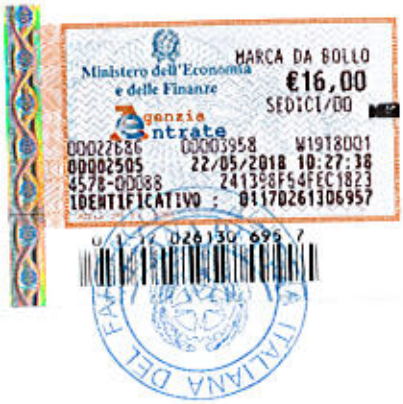

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AGENZIA ITALIANA DEL FARMACO

3 - Manufacturing Operations - Active Substances RANITIDINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances SALBUTAMOL SULFATE	
3.5	**General Finishing Steps**
	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

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3 - Manufacturing Operations - Active Substances SELEGILINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances SILDENAFIL CITRATE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

SODIUM CROMOGLICATE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

SODIUM DEHYDROCHOLATE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

SPIRONOLACTONE	
3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

SULFADIAZINE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

SULFADIAZINE SILVER	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances SULFATHIAZOLE	
3.5	**General Finishing Steps**
	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

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SULPIRIDE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

THEOPHYLLINE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

TESTOSTERONE PROPIONATE

3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

TETRACAINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

TICLOPIDINE HYDROCHLORIDE	
3.5	**General Finishing Steps**
	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

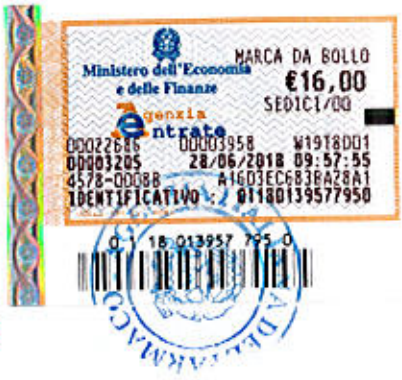
3 - Manufacturing Operations - Active Substances

TOPIRAMATE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

TRIAMCINOLONE ACETONIDE



3.5	**General Finishing Steps**
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Special Requirements Other: Hormones or substances with hormonal activity **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 - Manufacturing Operations - Active Substances

TRIMETHOPRIM

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

GLYCERYL TRINITRATE	
3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

VINPOCETINE

3.5	General Finishing Steps
	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 - Manufacturing Operations - Active Substances

XYLOMETAZOLINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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 - Manufacturing Operations - Active Substances

YOHIMBINE HYDROCHLORIDE

3.5	**General Finishing Steps**
	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:
ERYTHROMYCIN; IBUPROFEN; PARACETAMOL; PRILOCAINE HYDROCHLORIDE; TETRACAINE HYDROCHLORIDE; VINPOCETINE

AGENZIA ITALIANA DEL FARMACO

Restrictions or clarifying remarks:

The Inspectorate adopteda risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 36 months from the last general GMP inspection, which was conducted on 2017/11/29. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2018/06/14

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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