



Certificate No. IT-API/44/H/2019

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of Italy confirms the following:
The manufacturer **CAMBREX PROFARMACO MILANO S.R.L.**
Site address **Via Curiel, 34 - 20067 PAULLO (MI)**

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 2019/01/31, 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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Part 2

Name and address of the site:

**CAMBREX PROFARMACO MILANO S.R.L. - Via Curiel, 34, 20067
PAULLO (MI)**

Name of the active Substances manufactured or imported:

4-AMINO-6-CHLORO-1,3-BENZENEDISULFONAMIDE (DSA)
ACEBUTOLOL HYDROCHLORIDE
EPINEPHRINE
EPINEPHRINE BITARTRATE
ALOGLIPTIN BENZOATE
ALPRAZOLAM
AMBROXOL HYDROCHLORIDE
AMILORIDE HYDROCHLORIDE DIHYDRATE
AMIODARONE HYDROCHLORIDE
ARIPIPRAZOLE
BISACODYL
BREXPIPAZOLE
BROMAZEPAM
BROTIZOLAM
CINACALCET HYDROCHLORIDE
CYSTEAMINE BITARTRATE
CYSTEAMINE HYDROCHLORIDE CRUDE
CLOBAZAM
CLONAZEPAM
DIPOTASSIUM CLORAZEPATE
CHLORDIAZEPOXIDE
CHLORDIAZEPOXIDE HYDROCHLORIDE
CHLORMADINONE ACETATE
CHLOROTHIAZIDE
CLOZAPINE
DIAZEPAM
DILTIAZEM HYDROCHLORIDE
DRONEDARONE
DRONEDARONE HYDROCHLORIDE

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AGENZIA ITALIANA DEL FARMACO

ELETRIPTAN HYDROBROMIDE
ELTROMBOPAG OLAMINE
EMTRICITABINE
ERYTHROMYCIN
ERYTHROMYCIN LACTOBIONATE STERILE
ESTAZOLAM
ETIZOLAM
FLUCYTOSINE CRUDE
FLUNITRAZEPAM
FLURAZEPAM DIHYDROCHLORIDE
FLURAZEPAM MONOHYDROCHLORIDE
GLIBENCLAMIDE
GLIPIZIDE
GS-9674-02
HYDROCHLOROTHIAZIDE
LABETALOL HYDROCHLORIDE
LACOSAMIDE
LORAZEPAM
LORMETAZEPAM
MARAVIROC
MEDAZEPAM
METHYCLOTHIAZIDE
MIDAZOLAM
MIDAZOLAM HYDROCHLORIDE
MIDAZOLAM MALEATE
NITAZOXANIDE
NITRAZEPAM
NOREPINEPHRINE TARTRATE
ORCIPRENALINE SULFATE
OXAZEPAM
PARACETAMOL
PRANOPROFEN
PRAZEPAM
PROPAFENONE HYDROCHLORIDE
RALOXIFENE HYDROCHLORIDE
RALTEGRAVIR POTASSIUM
RANOLAZINE
RIFAXIMIN
RIVAROXABAN

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AGENZIA ITALIANA DEL FARMACO

SALBUTAMOL CRUDE
SALBUTAMOL SULFATE
SODIUM CROMOGLICATE
SODIUM PICOSULFATE
SOLIFENACIN SUCCINATE
SOTALOL HYDROCHLORIDE
TEMAZEPAM
TERBUTALINE SULFATE
TERPIN HYDRATE
TOLTERODINE TARTRATE
TRIAZOLAM
TRIMETHOXYBENZENE
VILDAGLIPTIN
ZOLPIDEM TARTRATE

3. Manufacturing Operations - Active Substances

3 - Manufacturing Operations - Active Substances

ACEBUTOLOL HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation /Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 EPINEPHRINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,sieving 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 EPINEPHRINE BITARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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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 ALOGLIPTIN BENZOATE

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.2. Manufacture of crude active substance

3.1.3. Salt formation / Purification steps:
crystallisation

3.5 General Finishing Steps

3.5.1. Physical processing steps
drying, milling

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 ALPRAZOLAM

3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.1. Manufacture of active substance intermediates

3.1.2. Manufacture of crude active substance

3.1.3. Salt formation / Purification steps:

	crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

AMILORIDE HYDROCHLORIDE DIHYDRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

AMIODARONE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 ARIPRAZOLE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 BREXPIRAZOLE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling
	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 BROMAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 BROTIZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 CINACALCET HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation 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 CYSTEAMINE BITARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, sieving
	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 CLOBAZAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 CLONAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 DIPOTASSIUM CLORAZEPATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 CHLORDIAZEPOXIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 CHLORDIAZEPOXIDE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 CHLORMADINONE ACETATE

3.5	General Finishing Steps
	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) Special Requirements Other: Hormones or substances with hormonal activity
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances CHLOROTHIAZIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 CLOZAPINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 DILTIAZEM HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 DRONEDARONE (Confidential)

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling, micronisation, sieving 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 DRONEDARONE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 ELETRIPTAN HYDROBROMIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation
	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 ELTROMBOPAG OLAMINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances EMTRICITABINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

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	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 STERILE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
3.5	General Finishing Steps
	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 ESTAZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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

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	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 ETIZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 FLUNITRAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps:

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	crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 FLURAZEPAM DIHYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 FLURAZEPAM MONOHYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 GLIBENCLAMIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation/ Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 GLIPIZIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 GS-9674-02 (Confidential)

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying
	3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)

3 - Manufacturing Operations - Active Substances

HYDROCHLOROTHIAZIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 LABETALOL HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 LACOSAMIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling, micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 LORAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 LORMETAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 MARAVIROC

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, sieving, milling/micronisation
	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 MEDAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 METHYLCLOTHIAZIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 MIDAZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 MIDAZOLAM HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 MIDAZOLAM MALEATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

NITAZOXANIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 packaging 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

NITRAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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

NOREPINEPHRINE TARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, sieving 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

ORCIPRENALINE SULFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, sieving 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 OXAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: pulping
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 PRANOPROFEN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 PRAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 RALOXIFENE HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

RALTEGRAVIR POTASSIUM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling 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

RANOLAZINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

RIFAXIMIN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps sieving, milling/micronisation 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

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	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 RIVAROXABAN	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling 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 CRUDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance
3.5	General Finishing Steps

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	3.5.1. Physical processing steps drying 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1. Physical / Chemical testing

3 - Manufacturing Operations - Active Substances

SALBUTAMOL SULFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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



AGENZIA ITALIANA DEL FARMACO

3 - Manufacturing Operations - Active Substances SODIUM CROMOGLICATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 PICOSULFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling, sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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 SOLIFENACIN SUCCINATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 SOTALOL HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance

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	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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 TEMAZEPAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates
	3.1.2. Manufacture of crude active substance
	3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving
	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

TERBUTALINE SULFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, sieving 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

TERPIN HYDRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 TOLTERODINE TARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 TRIAZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation

3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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

TRIMETHOXYBENZENE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation, sieving 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 VILDAGLIPTIN

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying,milling 3.5.2. PrimaryPackaging (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 ZOLPIDEM TARTRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1. Manufacture of active substance intermediates 3.1.2. Manufacture of crude active substance 3.1.3. Salt formation / Purification steps: salt formation, crystallisation
3.5	General Finishing Steps
	3.5.1. Physical processing steps drying, milling/micronisation,sieving 3.5.2. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

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	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:

4-AMINO-6-CHLORO-1,3-BENZENEDISULFONAMIDE (DSA) (Confidential); CYSTEAMINE HYDROCHLORIDE CRUDE (Confidential); ERYTHROMYCIN (Confidential); FLUCYTOSINE CRUDE (Confidential); PARACETAMOL (Confidential)

Restrictions or clarifying remarks:

For STERILE ERYTHROMYCIN LACTOBIONATE, sterile filtration and microbiological testing (including sterility testing) are outsourced. Manufactured APIs marked as confidential are for clinical use only. GS-9674-02: no batch certification. Imported APIs marked as confidential undergo further processing within the importing site. According to Italian regulation, all the sterile and/or of biological origin active substances listed in this document have undergone an authorization procedure. The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 42 months from the last general GMP inspection, which was conducted on 2017/05/19. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

Rome, 2019/03/05

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



Dott.ssa Marisa Delbò
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