Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: 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 as amended

The competent authority of Italy confirms the following:

The manufacturer: CAMBREX PROFARMACO MILANO S.R.L.

Site address: Via Curiel, 34, PAULLO, 20067, Italy

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-01-31**, it is considered that it complies with:

• The principles of GMP for active substances ³ referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Online EudraGMDP, Ref key: 56178 Issuance Date: 2019-03-11 Signatory: Confidential Page 1 of 33

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

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

³ These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

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

ARIPIPRAZOLE(en)

BROMAZEPAM(en)

ETIZOLAM(en)

CHLOROTHIAZIDE(en)

MIDAZOLAM HYDROCHLORIDE(en)

NITRAZEPAM(en)

LABETALOL HYDROCHLORIDE(en)

EPINEPHRINE BITARTRATE(en)

ELTROMBOPAG OLAMINE(en)

DILTIAZEM HYDROCHLORIDE(en)

LACOSAMIDE(en)

TRIAZOLAM(en)

BISACODYL(en)

NITAZOXANIDE(en)

GLIBENCLAMIDE(en)

MIDAZOLAM MALEATE(en)

ORCIPRENALINE SULFATE(en)

LORAZEPAM(en)

SOLIFENACIN SUCCINATE(en)

CHLORDIAZEPOXIDE(en)

DRONEDARONE HYDROCHLORIDE (en)

RIVAROXABAN(en)

ESTAZOLAM(en)

CHLORMADINONE ACETATE(en)

CINACALCET HYDROCHLORIDE(en)

SALBUTAMOL SULFATE(en)

ACEBUTOLOL HYDROCHLORIDE(en)

DIPOTASSIUM CLORAZEPATE(en)

RALTEGRAVIR POTASSIUM(en)

ALOGLIPTIN BENZOATE(en)

RANOLAZINE(en)

SODIUM CROMOGLICATE(en)

MIDAZOLAM(en)

RIFAXIMIN(en)

CLOBAZAM(en)

BREXPIPRAZOLE(en)

ZOLPIDEM TARTRATE(en)

BROTIZOLAM(en)

AMILORIDE HYDROCHLORIDE DIHYDRATE(en)

METHYCLOTHIAZIDE(en)

HYDROCHLOROTHIAZIDE(en)

VILDAGLIPTIN(en)

PROPAFENONE HYDROCHLORIDE(en)

EPINEPHRINE(en)

TERBUTALINE SULFATE(en)

MARAVIROC(en)

EMTRICITABINE(en)

CYSTEAMINE BITARTRATE(en)

FLURAZEPAM MONOHYDROCHLORIDE(en)

GLIPIZIDE(en)

LORMETAZEPAM(en)

SOTALOL HYDROCHLORIDE(en)

CLONAZEPAM(en)

CHLORDIAZEPOXIDE HYDROCHLORIDE(en)

SALBUTAMOL CRUDE(en)

DIAZEPAM(en)

ALPRAZOLAM(en)

AMBROXOL HYDROCHLORIDE(en)

FLUNITRAZEPAM(en)

NOREPINEPHRINE TARTRATE(en)

MEDAZEPAM(en)

RALOXIFENE HYDROCHLORIDE(en)

SODIUM PICOSULFATE(en)

TOLTERODINE TARTRATE(en)

CLOZAPINE(en)

AMIODARONE HYDROCHLORIDE(en)

ELETRIPTAN HYDROBROMIDE(en)

ERYTHROMYCIN LACTOBIONATE STERILE(en)

FLURAZEPAM DIHYDROCHLORIDE(en)

TRIMETHOXYBENZENE(en)

PRANOPROFEN(en)

OXAZEPAM(en)

TEMAZEPAM(en)

TERPIN HYDRATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: ARIPIPRAZOLE

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

	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.0.1 Filysical / Chemical testing
	e Substance : BROMAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation Concrete Finishing Steps
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : ETIZOLAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : CHLOROTHIAZIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:

	crystallisation
3.5	General Finishing Steps
3.3	
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : MIDAZOLAM HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
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Activ	e Substance : NITRAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing

	3.6.1 Physical / Chemical testing		
	3.6.1 Physical / Chemical testing		
Activ	Active Substance : LABETALOL HYDROCHLORIDE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	3.1.3 Salt formation / Purification steps :		
	salt formation, crystallisation		
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)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.1 Physical processing steps :		
	drying, milling/micronisation, sieving		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	e Substance : EPINEPHRINE BITARTRATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.3 Salt formation / Purification steps :		
	crystallisation		
	3.1.2 Manufacture of crude active substance		
	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)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.1 Physical processing steps :		
	drying, sieving		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	e Substance : ELTROMBOPAG OLAMINE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.3 Salt formation / Purification steps :		
	crystallisation		
	3.1.2 Manufacture of crude active substance		
3.5	General Finishing Steps		

	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : DILTIAZEM HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : LACOSAMIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1	· · · · · · · · · · · · · · · · · · ·
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying,milling,micronisation,sieving
3.6	Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Active	e Substance : TRIAZOLAM

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance) 3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.0.1 Physical / Chemical testing
Active	e Substance : BISACODYL
3.1	Manufacture of Active Substance by Chemical Synthesis
5.1	
	3.1.2 Manufacture of crude active substance3.1.1 Manufacture of active substance intermediates
	3.1.1 Manufacture of active substance intermediates 3.1.2 Salt formation / Purification steps:
	crystallisation
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)
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	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)3.5.1 Physical processing steps :
2.6	 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
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3.1 3.5	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:

	which is in direct contact with the substance)
	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : GLIBENCLAMIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation General Finishing Steps
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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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : MIDAZOLAM MALEATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : ORCIPRENALINE SULFATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :

	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying, sieving Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
	C. L. J. OD AZEDAM
Active	e Substance : LORAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps:
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
2.6	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing
3.6	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing
Active	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE
Active	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis
Active	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
Active	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
Active	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.2 Salt formation / Purification steps: salt formation, crystallisation General Finishing Steps
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation General Finishing Steps 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: SOLIFENACIN SUCCINATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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)

	drying milling/migranisation giaving
3.6	drying, milling/micronisation, sieving Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Activ	e Substance : CHLORDIAZEPOXIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.5	crystallisation Congrel Finishing Stone
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : DRONEDARONE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : RIVAROXABAN
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : crystallisation 3.1.2 Manufacture of crude active substance

	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
5. 5	- ·
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying,milling
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance : ESTAZOLAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : 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:
	7. Other:
	Other: Hormones or substances with hormonal activity
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	,
Active	e Substance : CINACALCET HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :

	. We are
	crystallisation
	3.1.2 Manufacture of crude active substance
2.5	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying,milling/micronisation
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : SALBUTAMOL SULFATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps:
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
3.6	3.5.1 Physical processing steps:
3.6	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing
Activ	3.5.1 Physical processing steps:
Activ	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis
Activ	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
Activ	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
Activ	3.5.1 Physical processing steps:
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation General Finishing Steps
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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)
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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
Active 3.1	3.5.1 Physical processing steps: drying, milling/micronisation, sieving Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: ACEBUTOLOL HYDROCHLORIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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)

	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance : DIPOTASSIUM CLORAZEPATE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : RALTEGRAVIR POTASSIUM
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation General Finishing Steps
3.3	
	 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : ALOGLIPTIN BENZOATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : crystallisation
I	3.1.2 Manufacture of crude active substance

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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps : drying,milling
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : RANOLAZINE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps : crystallisation
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
2.6	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : SODIUM CROMOGLICATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
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Activ	e Substance : MIDAZOLAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation 3.1.2 Manufacture of crude active substance
	3.1.2 Manufacture of crude active substance3.1.1 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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance) 3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : RIFAXIMIN
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
2.5	3.1.2 Manufacture of crude active substance
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
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	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)3.5.1 Physical processing steps :
3.6	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 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) 3.5.1 Physical processing steps: sieving,milling/micronisation Quality Control Testing
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: sieving,milling/micronisation Quality Control Testing 3.6.1 Physical / Chemical testing
Activ	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: sieving,milling/micronisation Quality Control Testing 3.6.1 Physical / Chemical testing e Substance: CLOBAZAM
Activ	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: sieving,milling/micronisation Quality Control Testing 3.6.1 Physical / Chemical testing Esubstance: CLOBAZAM Manufacture of Active Substance by Chemical Synthesis
Activ	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
Activ	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
Activ	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
Activo	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:

	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	re Substance : BREXPIPRAZOLE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying,milling
3.6	Quality Control Testing
	2 (1 Physical / Charge al Lating
	3.6.1 Physical / Chemical testing
Activ	re Substance : ZOLPIDEM TARTRATE
Activ	
	e Substance : ZOLPIDEM TARTRATE
	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis
	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : salt formation, crystallisation
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation 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
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.2 Salt formation / Purification steps: salt formation, crystallisation 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.5	e Substance : ZOLPIDEM TARTRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :

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	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	,
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
A -4.	a Cubatagras AMII ODIDE HVDDOCHI ODIDE DHIVDDATE
Active	e Substance : AMILORIDE HYDROCHLORIDE DIHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps:
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.1 Physical / Chemical testing
Active	3.6.1 Physical / Chemical testing e Substance : METHYCLOTHIAZIDE
Active 3.1	, and the second
	e Substance : METHYCLOTHIAZIDE
	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis
	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.1	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:
3.1	e Substance : METHYCLOTHIAZIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:

	3.5.1 Physical processing steps:
2.6	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : HYDROCHLOROTHIAZIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : VILDAGLIPTIN
Active 3.1	e Substance : VILDAGLIPTIN Manufacture of Active Substance by Chemical Synthesis
	Manufacture of Active Substance by Chemical Synthesis
	Manufacture of Active Substance by Chemical Synthesis
	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: crystallisation
	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.5	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.5	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1 3.5 Active	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:

	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	This superior continue
Active	e Substance : PROPAFENONE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
2.6	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
A ctiv	e Substance : EPINEPHRINE
3.1	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, sieving

3.6	Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Active	e Substance : TERBUTALINE SULFATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: salt formation, crystallisation
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active 3.1	e Substance : MARAVIROC Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation 3.1.2 Manufacture of crude active substance 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : EMTRICITABINE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : CYSTEAMINE BITARTRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps : salt formation, crystallisation
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps : drying, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : FLURAZEPAM MONOHYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : salt formation, crystallisation
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	drying, milling/micronisation, sieving Quality Control Testing
	3.6.1 Physical / Chemical testing
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Activ	e Substance : GLIPIZIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : LORMETAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.3 Salt formation / Purification steps :
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : SOTALOL HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.0.1 Thysical / Chemical testing
Activ	e Substance : CLONAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	drying, milling/micronisation, sieving
3.0	Quality Control Testing
	3.6.1 Physical / Chemical testing
	G. L. C. CIM ODDIA ZEDOVIDE HVDDOCIH ODIDE
	e Substance : CHLORDIAZEPOXIDE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : SALBUTAMOL CRUDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
A ctiv	e Substance : DIAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation Conord Finishing Stone
3.3	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
ļ	
Active	e Substance : ALPRAZOLAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
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	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : AMBROXOL HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
3.5	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	, and the second
Activ	e Substance : FLUNITRAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps : crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying, milling/micronisation, sieving Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Activ	e Substance : NOREPINEPHRINE TARTRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :

	crystallisation
3.5	General Finishing Steps
	<u> </u>
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps :
	drying,sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : MEDAZEPAM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps: drying, milling/micronisation, sieving
3.6	Quality Control Testing
2.0	3.6.1 Physical / Chemical testing
	5.0.1 Physical / Chemical testing
Active	e Substance : RALOXIFENE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	and the control of th
	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
2.6	
3.6	Quality Control Testing

	2 (1 Di 1 Cl 1 1 1 1		
	3.6.1 Physical / Chemical testing		
Active Substance : SODIUM PICOSULFATE			
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	3.1.3 Salt formation / Purification steps :		
	salt formation, crystallisation		
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)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.1 Physical processing steps :		
	drying,milling,sieving		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	e Substance : TOLTERODINE TARTRATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.3 Salt formation / Purification steps :		
	crystallisation		
	3.1.2 Manufacture of crude active substance		
	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)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.1 Physical processing steps :		
	drying, milling/micronisation, sieving		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	Active Substance : CLOZAPINE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	3.1.3 Salt formation / Purification steps :		
	crystallisation		
3.5	General Finishing Steps		

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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving 3.6 **Quality Control Testing** Physical / Chemical testing 3.6.1 Active Substance: AMIODARONE HYDROCHLORIDE 3.1 Manufacture of Active Substance by Chemical Synthesis 3 1 2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation 3.5 **General Finishing Steps** 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving 3.6 **Quality Control Testing** 3.6.1 Physical / Chemical testing Active Substance: 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** 3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation 3.6 **Quality Control Testing** Physical / Chemical testing 3.6.1

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Active Substance: 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
Activo	e Substance : FLURAZEPAM DIHYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :
	salt formation, crystallisation
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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : TRIMETHOXYBENZENE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :
	crystallisation
	3.1.2 Manufacture of crude active substance
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
26	drying, milling/micronisation, sieving Ouglity Control Testing
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance : PRANOPROFEN		
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.3 Salt formation / Purification steps:	
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Active	Active Substance : OXAZEPAM	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : pulping 	
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, milling/micronisation, sieving	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Active	e Substance : TEMAZEPAM	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps :	
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance: TERPIN HYDRATE

3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	3.1.3 Salt formation / Purification steps :	
	crystallisation	
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)	
	3.5.1 Physical processing steps :	
	drying, milling/micronisation, sieving	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	

4. Other Activities - Active Substances:

Importation of: 4-AMINO-6-CHLORO-1,3-BENZENEDISULFONAMIDE (DSA) (confidential), CYSTEAMINE HYDROCHLORIDE CRUDE (confidential), ERYTHROMYCIN (confidential), FLUCYTOSINE CRUDE (confidential), PARACETAMOL (confidential)

Clarifying remarks (for public users)

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.

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