Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: ***IT-API/44/H/2019***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

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

The competent authority of Italy confirms the following:
The manufacturer: ***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.

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[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)
PRAZEPAM(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

Active Substance : BROMAZEPAM

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 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 : 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 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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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 : 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

Active 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

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

Active 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

Active 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**
	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**
	3.6.1 Physical / Chemical testing

Active 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 Substance : LACOSAMIDE

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 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

Active Substance : BISACODYL

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 Substance : NITAZOXANIDE

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 Substance : GLIBENCLAMIDE

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

Active Substance : MIDAZOLAM MALEATE

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 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 : drying,sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : SOLIFENACIN SUCCINATE

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

Active 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 : 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 Substance : DRONEDARONE 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 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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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

Active 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 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 Substance : CINACALCET 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
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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) 3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : ACEBUTOLOL 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

Active Substance : DIPOTASSIUM CLORAZEPATE

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

Active Substance : RALTEGRAVIR POTASSIUM

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

Active Substance : ALOGLIPTIN BENZOATE

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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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

Active 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 3.1.1 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 Substance : RIFAXIMIN

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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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 : sieving,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : CLOBAZAM

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 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**
	3.6.1 Physical / Chemical testing

Active Substance : ZOLPIDEM 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 : 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

Active Substance : BROTIZOLAM

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 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

Active Substance : METHYCLOTHIAZIDE

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 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

Active Substance : VILDAGLIPTIN

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**
	3.6.1 Physical / Chemical testing

Active Substance : PRAZEPAM

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 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : EPINEPHRINE

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**
	3.6.1 Physical / Chemical testing

Active 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 : drying,sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance : MARAVIROC

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,milling/micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 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 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 : 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 Substance : LORMETAZEPAM

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 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

Active 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) 3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active 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**
	3.6.1 Physical / Chemical testing

Active 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 : 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 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) 3.5.1 Physical processing steps :

	drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 3.1.1 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 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 : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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 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**
	3.6.1 Physical / Chemical testing

Active 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) 3.5.1 Physical processing steps : drying, milling/micronisation, sieving
3.6	**Quality Control Testing**

	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

Active 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

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**

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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 : 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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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**
	3.6.1 Physical / Chemical testing

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

Active 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

Active 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 : drying, milling/micronisation, sieving
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 : 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 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 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 : 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 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.

2019-03-11

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

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