Competent Regional Authority. Dirección de Regulación, Planificación y Recursos Sanitarios. Departamento de Salud. Generalitat de Catalunya

CERTIFICATE NUMBER: NCF-II/1767/001/CAT

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 Spain confirms the following:

The manufacturer: MOEHS CATALANA, S.L.

Site address: POLÍGONO INDUSTRIAL RUBI SUR, C/CESAR MARTINELL I BRUNET, 12A, RUBI,

Barcelona, 08191, Spain

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 **2017-09-18**, 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:

ACETILCISTEINA(es)/ACETYLCYSTEINE(en)

AMANTADINA HIDROCLORURO(es) / AMANTADINE HYDROCHLORIDE(en)

AMLODIPINO BESILATO(es) / AMLODIPINE BESILATE(en)

BISOPROLOL FUMARATO(es) / BISOPROLOL FUMARATE(en)

BUPIVACAINA HIDROCLORURO(es) / BUPIVACAINE HYDROCHLORIDE(en)

CARBOCISTEINA(es) / CARBOCISTEINE(en)

CARBOCISTEINA LISINA(es) / CARBOCISTEINE LYSINE(en)

CARVEDILOL(es) / carvedilol(en)

CELIPROLOL HIDROCLORURO(es) / CELIPROLOL HYDROCHLORIDE(en)

EBERCONAZOL NITRATO(es) / EBERCONAZOLE NITRATE(en)

EZETIMIBA(es) / ezetimibe(en)

IRBESARTAN(es) / IRBESARTAN(en)

LANSOPRAZOL(es) / lansoprazole(en)

LIDOCAINA(es)/LIDOCAINE(en)

LIDOCAINA HIDROCLORURO(es) / LIDOCAINE HYDROCHLORIDE(en)

MEPIVACAINA HIDROCLORURO(es) / MEPIVACAINE HYDROCHLORIDE(en)

METOPROLOL SUCCINATO(es) / METOPROLOL SUCCINATE(en)

METOPROLOL TARTRATO(es) / METOPROLOL TARTRATE(en)

NICLOSAMIDA(es) / niclosamide(en)

NIFEDIPINO(es) / nifedipine(en)

OLANZAPINA(es)/OLANZAPINE(en)

OLMESARTAN MEDOXOMILO(es) / OLMESARTAN MEDOXOMIL(en)

PIRANTEL PAMOATO(es) / PYRANTEL PAMOATE(en)

PREGABALINA(es)/pregabalin(en)

RABEPRAZOL SODICO(es) / RABEPRAZOLE SODIUM(en)

RIVAROXABAN(es) / RIVAROXABAN(en)

SERTRALINA HIDROCLORURO(es) / SERTRALINE HYDROCHLORIDE(en)

SOTALOL HIDROCLORURO(es)/SOTALOL HYDROCHLORIDE(en)

SUMATRIPTAN(es)/SUMATRIPTAN(en)

SUMATRIPTAN SUCCINATO(es) / SUMATRIPTAN SUCCINATE(en)

TELMISARTAN(es) / TELMISARTAN(en)

TRIAMTERENO(es) / triamterene(en)

TRIMEBUTINA MALEATO(es) / TRIMEBUTINE MALEATE(en)

VALSARTAN(es) / VALSARTAN(en)

VILDAGLIPTINA(es) / vildagliptin(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ACETYLCYSTEINE

3	5.1	Manufacture of Active Substance by Chemical Synthesis	
		3.1.1 Manufacture of active substance intermediates	
		3.1.2 Manufacture of crude active substance	

	3.1.3 Salt formation / Purification steps :
3.5	CRYSTALLISATION Congret Finishing Stone
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : AMANTADINE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
• •	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
A ativ	e Substance : AMLODIPINE BESILATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
2.5	CRISTALLIZATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps: HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
5.0	Quality Control I County

	2.6.1 Physical / Chamical testing		
	3.6.1 Physical / Chemical testing		
Active	Active Substance : BISOPROLOL FUMARATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.1 Manufacture of active substance intermediates		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
	CRYSTALLISATION		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	HOMOGENIZATION, MILLING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	ya aa a a a a a a a a a a a a a a a a a		
	e Substance : BUPIVACAINE HYDROCHLORIDE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.1 Manufacture of active substance intermediates		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
2.5	Caracal Einiching Stone		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	HOMOGENIZATION AND SIEVING		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	ya an a a a a a a a a a a a a a a a a a		
Active	e Substance : CARBOCISTEINE		
2.1	Manufacture of Active Substance by Chemical Synthesis		
3.1	Manufacture of Active Substance by Chemical Synthesis		
3.1	3.1.2 Manufacture of crude active substance		
3.1			
3.1	3.1.2 Manufacture of crude active substance		
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps :		

HOMOGENIZATION, MILLING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.6 **Quality Control Testing** Physical / Chemical testing 3.6.1 Active Substance: CARBOCISTEINE LYSINE **Manufacture of Active Substance by Chemical Synthesis** Manufacture of active substance intermediates 3 1 2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: **CRYSTALLISATION** 3.5 **General Finishing Steps** 3.5.1 Physical processing steps: HOMOGENIZATION, MILLING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.6 **Quality Control Testing** Physical / Chemical testing 3.6.1 Active Substance: carvedilol Manufacture of Active Substance by Chemical Synthesis Manufacture of active substance intermediates 3.1.1 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: **CRYSTALLISATION** 3.5 **General Finishing Steps** Physical processing steps: 3.5.1 HOMOGENIZATION, MILLING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) **Quality Control Testing** 3.6 Physical / Chemical testing 3.6.1

Active Substance: CELIPROLOL HYDROCHLORIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps : CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing
5.0	- •
	3.6.1 Physical / Chemical testing
Activ	e Substance : EBERCONAZOLE NITRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps: HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : ezetimibe
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging

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

3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
2.0	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : LIDOCAINE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING. BUT THE MILLING STEP COULD
	BE EXTERNALISED
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance : MEPIVACAINE HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps: HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
0.0	Quanty Control Testing

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

	HOMOGENIZATION, MILLING AND SIEVING	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	Active Substance : nifedipine	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.1 Manufacture of active substance intermediates	
	3.1.2 Manufacture of crude active substance	
	3.1.3 Salt formation / Purification steps :	
	CRYSTALLISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	HOMOGENIZATION, MILLING AND SIEVING. BUT THE MILLING STEP COULD	
	BE EXTERNALISED	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
3.6	Quality Control Testing	
5.0		
	3.6.1 Physical / Chemical testing	
A aties	e Substance : OLANZAPINE	
Acuv	e Substance : OLANZAPINE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.2 Manufacture of crude active substance	
	3.1.3 Salt formation / Purification steps :	
	CRYSTALLISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	HOMOGENIZATION, MILLING AND SIEVING	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	e Substance : OLMESARTAN MEDOXOMIL	

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing
3.0	- · · · · · · · · · · · · · · · · · · ·
	3.6.1 Physical / Chemical testing
Active	e Substance : PYRANTEL PAMOATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
2.5	Canada Finishing Stone
3.5	General Finishing Steps
	3.5.1 Physical processing steps: HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : pregabalin
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
Online Eu	which is in direct contact with the substance) draGMDP, Ref key: 45721

3.5.3 Secondary Packaging (placing the sealed primary package with	
material or 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 : RABEPRAZOLE SODIUM	
3.1 Manufacture of Active Substance by Chemical Synthesis	
3.1.1 Manufacture of active substance intermediates	
3.1.2 Manufacture of crude active substance	
3.1.3 Salt formation / Purification steps :	
CRYSTALLISATION	
3.5 General Finishing Steps	
3.5.1 Physical processing steps :	
HOMOGENIZATION, MILLING AND SIEVING	
3.5.2 Primary Packaging (enclosing / sealing the active substance w	vithin a packaging material
which is in direct contact with the substance)	.1.
3.5.3 Secondary Packaging (placing the sealed primary package with	
material or container. This also includes any labelling of the material identification or traceability (lot numbering) of the active substance)	which could be used for
3.6 Quality Control Testing	
3.6.1 Physical / Chemical testing	
Active Substance : RIVAROXABAN	
3.1 Manufacture of Active Substance by Chemical Synthesis	
3.1.1 Manufacture of active substance intermediates	
3.1.2 Manufacture of crude active substance	
3.1.3 Salt formation / Purification steps:	
CRYSTALLISATION	
3.5 General Finishing Steps	
3.5.1 Physical processing steps:	
HOMOGENIZATION, MILLING AND SIEVING	iidhin o maalaaaissa sa da'i 1
3.5.2 Primary Packaging (enclosing / sealing the active substance w which is in direct contact with the substance)	runin a packaging material
3.5.3 Secondary Packaging (placing the sealed primary package with	thin an outer nackaging
material or container. This also includes any labelling of the material	1 0 0
identification or traceability (lot numbering) of the active substance)	milen could be used for
3.6 Quality Control Testing	
3.6 Quality Control Testing	
3.6 Quality Control Testing	
3.6 Quality Control Testing 3.6.1 Physical / Chemical testing	

	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
2.5	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps : HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	, ,
Active	e Substance : SOTALOL HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance : SUMATRIPTAN
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	draGMDP Ref key: 45721 Issuance Date: 2017-12-22 Signatory: Confidential Page 13 of 16

	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	Utota Tajotom Chomatom vootang
Activ	e Substance : SUMATRIPTAN SUCCINATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance3.1.3 Salt formation / Purification steps :
	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION, MILLING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : TELMISARTAN
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps : CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps :
	HOMOGENIZATION AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : triamterene
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps :

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

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

2017-12-22

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

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Competent Regional Authority. Dirección de Regulación, Planificación y Recursos Sanitarios. Departamento de Salud. Generalitat de Catalunya

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Issuance Date: 2017-12-22