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 [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 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.*

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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

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

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	3.1.3 Salt formation / Purification steps : CRYSTALLISATION
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps : 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

Active 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

Active 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 : 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**

	3.6.1 Physical / Chemical testing

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

Active 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 : 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

Active Substance : CARBOCISTEINE

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

Active Substance : CARBOCISTEINE LYSINE

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 Substance : carvedilol

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 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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active 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 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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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	**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 Substance : LIDOCAINE

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 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 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

Active 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**

	3.6.1 Physical / Chemical testing

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

Active 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

Active 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 : 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 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**
	3.6.1 Physical / Chemical testing

Active 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

Active 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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 : 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 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)

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

Active 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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

	identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 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 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

Active 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

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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**

	3.6.1 Physical / Chemical testing
Active Substance : vildagliptin	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 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

2017-12-22

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

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