Generalitat De Catalunya

CERTIFICATE NUMBER: NCF-II/2307/001/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: Inke S.A.

Site address: Carrer De L'Argent 1, Area Industrial Del Llobregat, Castellbisbal, 08755

OMS Organisation Id. / OMS Location Id.: ORG-100020253 / LOC-100029013

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

Other

artículo 108, Real Decreto Legislativo 1/2015, de 24 de julio, artículo 64, Real Decreto Legislativo 1/2015, de 24 de julio, Real Decreto 824/2010, de 25 de junio, artículo 47 de la Directiva 2001/83/CE

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2019-04-08, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.³
- 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Online EudraGMDP, Ref key: 162326

Issuance Date 2023-03-06

Signatory: Confidential

¹The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.

 $^{^2}$ Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

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

ACLIDINIUM BROMIDE(en)

APREPITANT(en)

ARFORMOTEROL TARTRATE(en)

ASENAPINE MALEATE(en)

carvedilol(en)

CLEVIDIPINE BUTYRATE(en)

desloratadine(en)

ELETRIPTAN HYDROBROMIDE(en)

ENALAPRIL MALEATE(en)

fluconazole(en)

FORMOTEROL FUMARATE DIHYDRATE(en)

GLYCOPYRROLATE(en)

GLYCOPYRRONIUM BROMIDE(en)

GRANISETRON(en)

GRANISETRON HYDROCHLORIDE(en)

IMIDAPRIL HYDROCHLORIDE(en)

INDACATEROL MALEATE(en)

loratadine(en)

MONTELUKAST SODIUM(en)

nitrendipine(en)

OLANZAPINE(en)

ONDANSETRON(en)

ONDANSETRON HYDROCHLORIDE DIHYDRATE(en)

OTILONIUM BROMIDE(en)

PRASUGREL(en)

PRASUGREL HYDROCHLORIDE(en)

QUETIAPINE HEMIFUMARATE(en)

REVEFENACIN TRIHYDRATE(en)

RISPERIDONE(en)

RIZATRIPTAN BENZOATE(en)

SALMETEROL XINAFOATE(en)

TETRABENAZINE(en)

TIOTROPIUM BROMIDE MONOHYDRATE(en)

VILANTEROL TRIFENATATE(en)

ZOLMITRIPTAN(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: ACLIDINIUM BROMIDE

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	CRYSTALLISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activ	e Substance:APREPITANT
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:
	CRISTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONIZATION
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	DRYING, SIEVING AND MICRONIZATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
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	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activo	e Substance: ASENAPINE 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:
	CRYSTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
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	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Active	e 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:
	CRISTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING AND SIEVING
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	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	Carrant Finishing States
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING 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
3.0	
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activ	e Substance:desloratadine
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:
	CRISTALISATION
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3.5	General Finishing Steps
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3.6 Active	General Finishing Steps 3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
3.6	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing Substance:ELETRIPTAN HYDROBROMIDE Manufacture of Active Substance by Chemical Synthesis
3.6 Active	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing Esubstance: ELETRIPTAN HYDROBROMIDE Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates
3.6 Active	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing Esubstance: ELETRIPTAN HYDROBROMIDE Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.6 Active	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing ESubstance:ELETRIPTAN HYDROBROMIDE 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:
3.6 Active	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing Esubstance: ELETRIPTAN HYDROBROMIDE Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.6 Active 3.1	3.5.1 Physical processing steps:
3.6 Active 3.1	3.5.1 Physical processing steps: DRYING. SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance:ELETRIPTAN HYDROBROMIDE 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: CRYSTALISATION

	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Active	e Substance:ENALAPRIL 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:
	CRISTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING AND SIEVING
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
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	identification or traceability (lot numbering) of the active substance)
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3.6	Quality Control Testing 3.6.1 Physical / Chemical testing
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	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
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	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance: fluconazole
Active	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance: fluconazole Manufacture of Active Substance by Chemical Synthesis
Active	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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:
Active 3.1	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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: CRISTALISATION
Active	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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: CRISTALISATION General Finishing Steps
Active 3.1	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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: CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps:
Active 3.1	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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: CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING AND SIEVING
Active 3.1	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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: CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
Active 3.1	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance:fluconazole 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:
Active 3.1	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance: fluconazole 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:
Active 3.1	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing E Substance:fluconazole 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: CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING 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
3.1 3.5	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance:fluconazole 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:
Active 3.1	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance:fluconazole 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:
3.1 3.5	Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance:fluconazole 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:

Active	Active Substance:FORMOTEROL FUMARATE DIHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: CRISTALISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing	
	2.0.2 Therefore resums energing stering	
Activ	e Substance:GLYCOPYRROLATE	
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: DRYING, SIEVING AND MICRONIZATION 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 testing3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance:GLYCOPYRRONIUM BROMIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	

	DRYING, SIEVING AND MICRONIZATION	
	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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	Active Substance:GRANISETRON	
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:	
	CRISTALISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	DRYING 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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance:GRANISETRON 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:	
	3.1.3 Salt formation / Purification steps: CRISTALISATION	
3.5	3.1.3 Salt formation / Purification steps: CRISTALISATION General Finishing Steps	
3.5	CRISTALISATION	
3.5	CRISTALISATION General Finishing Steps	
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps:	
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING AND SIEVING	
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING AND SIEVING 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING 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	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING 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	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING 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	

	3.6.2 Microbiological testing excluding sterility testing	
A 04:22	Active Substance:IMIDAPRIL HYDROCHLORIDE	
3.1		
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:	
	CRYSTALISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	DRYING 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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	Active Substance:INDACATEROL 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: CRISTALISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	DRYING, SIEVING AND MICRONISATION	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing	
3.0		
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing	
	3.0.2 Whereborogical costing excitating stermity testing	
Activ	e Substance:Ioratadine	
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:	
I	CRISTALISATION	

3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activ	e Substance:MONTELUKAST 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:
	CRIYSTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING 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
	3.6.2 Microbiological testing excluding sterility testing
A	
	e Substance:nitrendipine
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
	3.1.2 Manufacture of crude active substance3.1.3 Salt formation / Purification steps:
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: CRISTALISATION
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
3.5	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:

3.6	Quality Control Testing
3.0	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activo	e Substance:OLANZAPINE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: CRISTALISATION General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING 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
	3.6.2 Microbiological testing excluding sterility testing
A otiva	e Substance:ONDANSETRON
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
	2.1.2 Salt formation / Dwifigation starge
	3.1.3 Salt formation / Purification steps:
3.5	CRISTALISATION
3.5	CRISTALISATION General Finishing Steps
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps:
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
3.6	General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for
	General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
	General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing
3.6	General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing
3.6	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
3.6	CRISTALISATION General Finishing Steps 3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing Esubstance:ONDANSETRON HYDROCHLORIDE DIHYDRATE

	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps: CRISTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Activ	e Substance:OTILONIUM BROMIDE
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	CRISTALISATION General Finishing Steps
3.3	
	3.5.1 Physical processing steps: DRYING 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
	3.6.2 Microbiological testing excluding sterility testing
	e Substance:PRASUGREL
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: CRISTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING 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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	Active Substance:PRASUGREL HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.1 Manufacture of active substance intermediates	
	3.1.2 Manufacture of crude active substance	
	3.1.3 Salt formation / Purification steps:	
	CRYSTALLISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	DRYING 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	
	3.6.2 Microbiological testing excluding sterility testing	
	C. L. A. OLIETIA PINE HEMIELIMA DA TE	
	e Substance: QUETIAPINE HEMIFUMARATE	
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:	
	CRISTALISATION	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	DRYING 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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance:REVEFENACIN TRIHYDRATE	

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

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	Active Substance:SALMETEROL XINAFOATE		
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:		
	CRISTTALISATION		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	DRYING, SIEVING AND MICRONISATION		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		
3.0			
	3.6.1 Physical / Chemical testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	e Substance:TETRABENAZINE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.1 Manufacture of active substance intermediates		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps:		
	CRYSTALLISATION		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	DRYING 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		
	3.6.2 Microbiological testing excluding sterility testing		

Active	e Substance:TIOTROPIUM BROMIDE MONOHYDRATE
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	CRYSTALISATION General Finishing Steps
3.3	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Active	e Substance:VILANTEROL TRIFENATATE
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:
	CRYSTALISATION
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONIZATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing
Active	e Substance:ZOLMITRIPTAN
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:
	CRYSTALISATION
3.5	General Finishing Steps
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	3.5.1 Physical processing steps:
	DRYING, SIEVING AND MICRONISATION
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing excluding sterility testing

2023-03-06

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

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

Tel:*Confidential* Fax:*Confidential*