

Generalitat De Catalunya

CERTIFICATE NUMBER: *NCF-II/2307/001/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: ***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 substances³ 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.

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

²Guidance 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: 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
Active 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 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 Substance:ARFORMOTEROL 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: CRISTALISATION
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 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
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility 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: 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
Active Substance:CLEVIDIPINE BUTYRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis

	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRYSTALLISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:desloratadine	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:ELETRIPTAN HYDROBROMIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRYSTALLISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONIZATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material</p>

	<p>which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:ENALAPRIL MALEATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:fluconazole	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>

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
Active 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: CRISTALISATION
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 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:

	<p style="text-align: center;">DRYING, SIEVING AND MICRONIZATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:GRANISETRON	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:GRANISETRON HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p>

	3.6.2 Microbiological testing excluding sterility testing
Active Substance:IMIDAPRIL 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: 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
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 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 Substance:loratadine	
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
	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:MONTELUKAST SODIUM	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRIYSTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:nitrendipine	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONIZATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing
Active Substance:OLANZAPINE	
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
Active 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 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
Active Substance:ONDANSETRON HYDROCHLORIDE 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 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 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: 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
Active 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

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

Active 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

Active 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

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

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

	<p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:SALMETEROL XINAFOATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRISTTALISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>
Active Substance:TETRABENAZINE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	<p>3.1.1 Manufacture of active substance intermediates</p> <p>3.1.2 Manufacture of crude active substance</p> <p>3.1.3 Salt formation / Purification steps: CRYSTALLISATION</p>
3.5	General Finishing Steps
	<p>3.5.1 Physical processing steps: DRYING AND SIEVING</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>

Active 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: 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
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing

Active 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 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

	<p>3.5.1 Physical processing steps: DRYING, SIEVING AND MICRONISATION</p> <p>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</p> <p>3.5.3 Secondary Packaging (placing 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)</p>
3.6	Quality Control Testing
	<p>3.6.1 Physical / Chemical testing</p> <p>3.6.2 Microbiological testing excluding sterility testing</p>

2023-03-06

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

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