



CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

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

The Medicines Authority of Malta confirms the following:

The manufacturer: **Amino Chemicals Ltd.**

Site address: **MRA 050X Industrial Estate, Marsa MRS 3000, Malta**

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

Medicines Act 2003 Part III Title II Articles 42 and 102

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **6th – 8th May 2019**, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substances 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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12 SEP 2019

12th June 2019

Dr. Mark Cilia
Director Inspectorate and Enforcement Directorate
Medicines Authority
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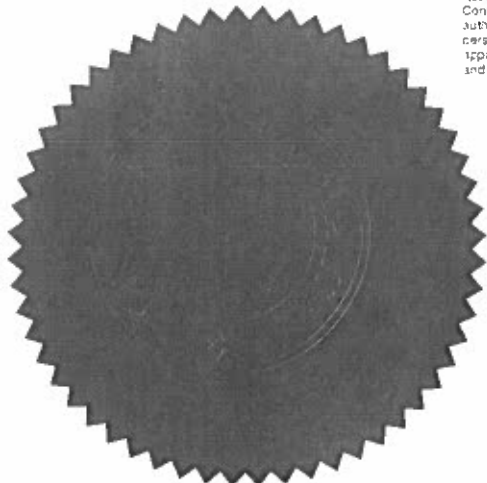
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Notary Public & Solicitor for Courts
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Convention de La Haye du 5 octobre 1961

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This public document
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3. acting in the capacity of: **Notary Public and Commissioner
for Oaths**
4. bears the seal / stamp of: **Same**
Certified
5. at **Ministry for Foreign Affairs and Trade Promotion,
Valletta**
6. the **18 SEP 2019**
7. by **Kenneth Burnell - Legalisation Officer**
8. No: **381607**
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Part 2

3. MANUFACTURING OPERATIONS – ACTIVE SUBSTANCES

Active Substance(s): **APIXABAN**

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: drying, 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*

Active Substance(s): **ARMODAFINIL (R-MODAFINIL)**

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: milling*
- 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*

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12 SEP 2019

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12th June 2019

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Active Substance(s): **BENAZEPRIL 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: 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*

Active Substance(s): **BOSENTAN 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 : crystallisation*

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3.5 General Finishing Steps

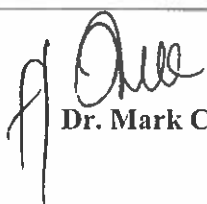
- 3.5.1 Physical processing steps: micronisation*
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)*
- 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. 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*

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Active Substance(s): **CINACALCET 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: 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*

Active Substance(s): **CIPROHEPTADINE OROTATE****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

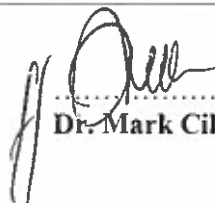
- 3.5.1 Physical processing steps: sieving*
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)*
- 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. 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*

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Active Substance(s): **DEFERASIROX****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, milling*
- 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(s): **DEXLANSOPRAZOLE AMORPHOUS****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*

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3.5 General Finishing Steps

- 3.5.1 *Physical processing steps: 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*

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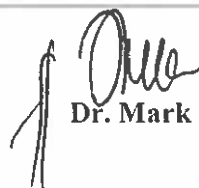
Active Substance(s): **DEXLANSOPRAZOLE ANHYDROUS**

3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

Active Substance(s): **DEXLANSOPRAZOLE SESQUIHYDRATE**

3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>	TRUE COPY OF THE ORIGINAL QUOD ATTESTOR 12 SEP 2019
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>	
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>	

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Active Substance(s): DEXTROPROPOXYPHENE HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, milling</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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Active Substance(s): DICLOFENAC EPOLAMINE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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Active Substance(s): **EMPAGLIFLOZIN**

3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

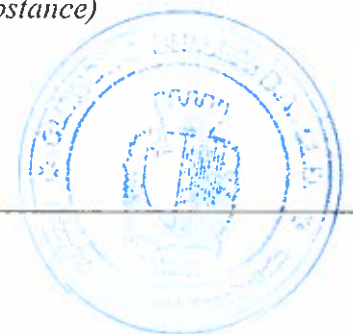
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Active Substance(s): **FESOTERODINE FUMARATE**

3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: micronisation, sieving</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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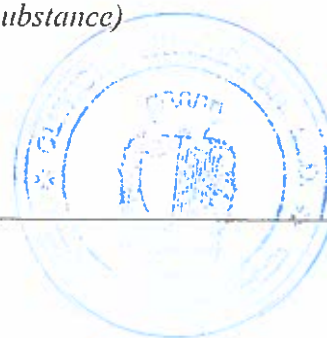


Active Substance(s): FEXOFENADINE HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>
Active Substance(s): FOSINOPRIL SODIUM	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, milling</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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Active Substance(s): GRANISETRON HYDROCHLORIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

Active Substance(s): MIGLUSTAT	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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12 SEP 2019

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Notary Public & Commissioner for Oaths
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clinto@clinto-legal.com.mt12th June 2019
Dr. Mark Cilia

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Active Substance(s): NITISINONE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, sieving</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>
Active Substance(s): PALIPERIDONE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: micronisation, sieving</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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OF THE ORIGINAL
QUOD ATTESTOR

12 SEP 2019

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12th June 2019

Dr. Mark Cilia

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Active Substance(s): PRAMIPEXOLE BASE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, sieving</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

Active Substance(s): **PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE**

3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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12 SEP 2019

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12th June 2019

Dr. Mark Cilia



Active Substance(s): RABEPRAZOLE SODIUM	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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Active Substance(s): RABEPRAZOLE SODIUM (from hydroxy intermediate)		12 SEP 2019
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>	 CLINTON J. BENIZZI LTD. Notary Public & Commissioner for Oaths 55C, O'HEARN STREET, VALLETTA, MALTA TEL 2127451/208 7200000 clinton.j.benizzi@notary.mt
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, milling</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>	
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>	

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Active Substance(s): **RASAGILINE MESYLATE**

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: 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*

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Active Substance(s): **RASAGILINE TARTARATE**

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: 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*

12 SEP 2019

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12th June 2019

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Active Substance(s): RIVAROXABAN	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i> <i>3.6.2 Microbiological testing (excluding sterility testing)</i>
Active Substance(s): RUFINAMIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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Dr. Mark Cilia

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Active Substance(s): **SAPROPTERINE DIHYDROCHLORIDE**

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: 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

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Active Substance(s): SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE

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3.1 Manufacture of Active Substance by Chemical Synthesis

3.1.3 Salt formation/Purification steps : crystallisation

3.5 General Finishing Steps

3.5.1 Physical processing steps: drying, milling, 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

12th June 2019

Dr. Mark Cilia



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Active Substance(s): **SITAGLIPTIN SULPHATE****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: drying, milling, 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*TRUE COPY
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QUOD ATTESTORActive Substance(s): **SITAGLIPTIN TARTARATE HEMIHYDRATE****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**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)*

12 SEP 2019

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Dr. Mark Cilia

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Active Substance(s): **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: drying*
- 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*

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Active Substance(s): **TERBINAFINE 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

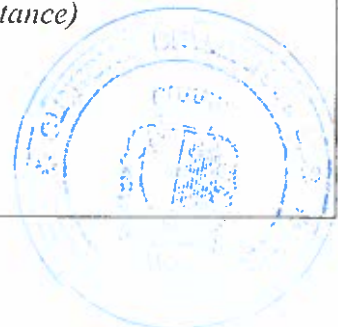
- 3.5.1 Physical processing steps: drying, micronisation*
- 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)*
- 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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*

12 SEP 2019

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12th June 2019

Dr. Mark Cilia

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Active Substance(s): TOLTERODINE TARTRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying, micronisation</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>
Active Substance(s): VORTIOXETINE HYDROBROMIDE MONOHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: drying</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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12 SEP 2019

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12th June 2019

Dr. Mark Cilia



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Active Substance(s): ZIPRASIDONE HYDROCHLORIDE ANHYDROUS	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: milling</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>
Active Substance(s): ZIPRASIDONE HYDROCHLORIDE MONOHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis <i>3.1.1 Manufacture of active substance intermediates</i> <i>3.1.2 Manufacture of crude active substance</i> <i>3.1.3 Salt formation/Purification steps : crystallisation</i>
3.5	General Finishing Steps <i>3.5.1 Physical processing steps: milling, sieving</i> <i>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</i> <i>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)</i>
3.6	Quality Control Testing <i>3.6.1 Physical/Chemical testing</i>

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12 SEP 2019

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clintonj@clintonj.com.mt12th June 2019**Dr. Mark Cilia****Director Inspectorate and Enforcement Directorate
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