

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER: 16MPP048HVFR02

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

Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of France confirms the following:

The manufacturer: FINORGA

Site address: Dynamic Synthesis Finorga, avenue du Lac, BP 30, MOURENX, 64150, France

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

2001/83/EC and Art. 80(1) of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2016-06-23, it is considered that it complies with:

• The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and Article 51 of Directive 2001/82/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.



The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

 $^{^2}$ Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³ These requirements fulfil the GMP recommendations of WHO.



Part 2

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

AMISULPRIDE(en)

BETAHISTINE DIHYDROCHLORIDE(en)

BETAXOLOL HYDROCHLORIDE(en)

DILTIAZEM HYDROCHLORIDE(en)

METOCLOPRAMIDE(en)

METOCLOPRAMIDE HYDROCHLORIDE(en)

PINAVERIUM BROMIDE(en)

SULPIRIDE(en)

TIAPRIDE HYDROCHLORIDE(en)

EICOSAPENTAENOIC ACID ETHYL ESTER(en)

LACOSAMIDE(en)

SAXAGLIPTIN HYDROCHLORIDE(en)

SERTRALINE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : AMISULPRIDE

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:

Crystallization

3.5 General Finishing Steps

- 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: BETAHISTINE 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:

Crystallization

3.5 General Finishing Steps

- 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



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3.5 General Finishing Steps	100
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3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging mat	aterial
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	identification or traceability (lot numbering) of the active substance)
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	3.6.1 Physical / Chemical testing
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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 :
	Crystallization
3.5	General Finishing Steps
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3.5	General Finishing Steps
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	which is in direct contact with the substance)
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	e Substance : TIAPRIDE 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 :
	Crystallization
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material or container. This also includes any labelling of the material which could be used for
	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	ve Substance: EICOSAPENTAENOIC ACID ETHYL ESTER
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: Chromatography
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: Chromatography
	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: Chromatography Extraction of Active Substance from Natural Sources
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: Chromatography Extraction of Active Substance from Natural Sources 3.2.2 Extraction of substance from animal source General Finishing Steps
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: Chromatography Extraction of Active Substance from Natural Sources 3.2.2 Extraction of substance from animal source General Finishing Steps 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
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.5	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.2 3.5	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.5	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:



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



Clarifying remarks (for public users)

Period of validity of the certificate extended to 19 June 2020; SERTRALINE: Limited to the manufacturing of intermediate 4S-Tetralone; SAXAGLIPTIN HYDROCHLORIDE: Limited to the manufacturing of intermediate (3-Hydroxy-tricyclo [3.3.1.1(3,7)] decan-1-yl) oxo acetic acid; The intermediate Clomesac of the Active Substance METOCLOPRAMIDE is isolated and marketed. / Signatory: Mrs Linda Gallais, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2019-11-18

Online EudraGMDP, Ref key: 62079

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

Confidential French National Agency for Medicines and Health Products Safety

Tel: Confidential
Fax: Confidential

Issuance Date: 2019-11-18 Signatory: Confidential Page

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