



National Agency For The Safety Of Medicine And Health Products

CERTIFICATE NUMBER: 23MPP001HFR01

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 France confirms the following:

The manufacturer: **Siegfried St. Vulbas SAS**

Site address: **Parc Industriel De La Plaine De L Ain, 530 Allée De La Luye, St Vulbas, 01150, France**

OMS Organisation Id. / OMS Location Id.: **ORG-100012160 / LOC-100019562**

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-01-13**, it is considered that it complies with:

- 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. 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.

¹ The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.

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

³ These requirements fulfil the GMP recommendations of WHO.



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Part 2

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

DAPAGLIFLOZIN(en)

APIXABAN(en)

ATAZANAVIR SULFATE(en)

FOSINOPRIL SODIUM(en)

LACOSAMIDE(en)

CYCLIZINE(en)

CYCLIZINE HYDROCHLORIDE(en)

TOFOGLIFLOZIN(en)

TROSPIMUM CHLORIDE(en)

ARTICAINE HYDROCHLORIDE(en)

BAMBUTEROL HYDROCHLORIDE(en)

FERRIC CITRATE(en)

METHYLPHENIDATE HYDROCHLORIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:DAPAGLIFLOZIN

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)

3.6 Quality Control Testing

3.6.1 Physical / Chemical testing

Active Substance:APIXABAN

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

3.5.2 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:ATAZANAVIR SULFATE

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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: /
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:FOSINOPRIL SODIUM

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)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance:LACOSAMIDE

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)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance:CYCLIZINE

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
	3.5.2 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

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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
Active Substance:CYCLIZINE 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: /
3.5	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:TOFOGLIFLOZIN	
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)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance:TROSPIMUM CHLORIDE	
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
	3.5.2 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:ARTICAINE 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:
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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:BAMBUTEROL 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:
/

3.5 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:FERRIC CITRATE

3.1 Manufacture of Active Substance by Chemical Synthesis

- 3.1.3 Salt formation / Purification steps:
/

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

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Active Substance: METHYLPHENIDATE 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)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

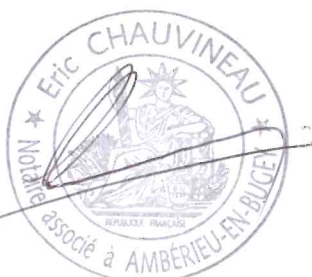
Dapagliflozin: manufacturing limited to the BMS-27-tetracycl intermediate /// Fosinopril sodium: manufacturing limited to the BMS-30-pyrrolidine intermediate /// Lacosamide: manufacturing limited to the SPM 20200 RAC intermediate /// Methylphenidate hydrochloride: manufacturing limited to the phenidacide intermediate /// Tofogliflozin: manufacturing limited to the CHU-12-tetracarbonate intermediate. // Signatory : Mrs Linda Gallais, head of starting materials inspection department --- The ANSM does not issue hard copies of good practices certificates

2023-03-10

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

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CHILI

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. République française

Le présent acte public

2. a été signé par **Eric Chauvineau**

3. agissant en qualité **de notaire associé**

4. est revêtu du sceau/timbre de **Son étude à Ambérieu en Bugey**

Attesté

5. à **LYON**

6. le **09 Janvier 2024**

7. par le Procureur Général près la Cour d'appel de Lyon

8. sous le n° **202** (7 pages)

9. Sceau

10. Signature

Jean-François PISCIONE

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le contenu du document est correct ou que la République française approuve son contenu."

