Agence nationale de sécurité du médicament et des produits de santé

CERTIFICATE NUMBER: 19MPP082HFR01

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of France confirms the following:

The manufacturer: GIVAUDAN - LAVIROTTE

Site address: 56 rue Paul Cazeneuve, BP 8344, LYON, 69008, France

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 2019-09-27, it is considered that it complies with:

• The principles of GMP for active substances ³ referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Online EudraGMDP, Ref key: 70919 Issuance Date: 2020-01-17 Signatory: Confidential Page 1 of 1

¹ 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:

MAGNESIUM GLUCOHEPTONATE(en)

FERROUS GLUCOHEPTONATE(en)

GLUCOHEPTONIC ACID 50%(en)

COPPER GLUCONATE(en)

FERROUS GLUCONATE(en)

GLYCEROPHOSPHORIC ACID 50%(en)

MAGNESIUM GLUCONATE(en)

MAGNESIUM GLYCEROPHOSPHATE(en)

MAGNESIUM GLYCEROPHOSPHATE 50%(en)

SODIUM GLYCEROPHOSPHATE 50%(en)

SODIUM GLYCEROPHOSPHATE 65%(en)

ZINC UNDECYLENATE(en)

CALCIUM GLUCOHEPTONATE(en)

CALCIUM GLUCONOGLUCOHEPTONATE(en)

CALCIUM GLYCEROPHOSPHATE(en)

CALCIUM GLYCEROPHOSPHATE 50% (en)

LITHIUM GLUCONATE(en)

MANGANESE GLUCONATE(en)

POTASSIUM GLYCEROPHOSPHATE 50%(en)

POTASSIUM GLYCEROPHOSPHATE 75%(en)

ZINC GLUCONATE(en)

CALCIUM GLUCONOLACTATE(en)

ZINC L-ASPARTATE(en)

ZINC GLUCOHEPTONATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: MAGNESIUM GLUCOHEPTONATE

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 :	
	Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	

	2.6.2 Migraphia logical testing avaluding starility testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	Active Substance : FERROUS GLUCOHEPTONATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
	Filtration		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	Spray 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		
Active Substance : GLUCOHEPTONIC ACID 50%			
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:		
	Ion exchange		
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		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	e Substance : COPPER GLUCONATE		
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 :		
	Filtration		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	Spray drying		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		

Issuance Date: 2020-01-17

	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				
	3.6.1 Physical / Chemical testing			
	3.6.2 Microbiological testing excluding sterility testing			
Activ	Active Substance : FERROUS GLUCONATE			
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 :			
0.5	Filtration			
3.5	General Finishing Steps			
	3.5.1 Physical processing steps:			
	Spray drying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material			
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)			
	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				
	3.6.1 Physical / Chemical testing			
	3.6.2 Microbiological testing excluding sterility testing			
Active	e Substance : GLYCEROPHOSPHORIC ACID 50%			
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 :			
	Ion exchange and filtration			
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			
	3.6.2 Microbiological testing excluding sterility testing			
Activo	e Substance : MAGNESIUM GLUCONATE			
3.1	Manufacture of Active Substance by Chemical Synthesis			
	3.1.2 Manufacture of crude active substance			
	3.1.3 Salt formation / Purification steps :			
	Filtration			

3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing	
	3.6.1 Physical / Chemical testing	
	3.6.2 Microbiological testing excluding sterility testing	
Active	e Substance : MAGNESIUM GLYCEROPHOSPHATE	
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	Filtration Capacal Finishing Stone	
3.3	General Finishing Steps	
	3.5.1 Physical processing steps : Spray drying	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	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		
	3.6.1 Physical / Chemical testing	
	3.6.2 Microbiological testing excluding sterility testing	
A otiv	e Substance : MAGNESIUM GLYCEROPHOSPHATE 50%	
3.1	Manufacture of Active Substance by Chemical Synthesis	
3.1		
	3.1.1 Manufacture of active substance intermediates3.1.2 Manufacture of crude active substance	
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:	
	Filtration	
3.5		
	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	
	3.6.2 Microbiological testing excluding sterility testing	
Activo	e Substance : SODIUM GLYCEROPHOSPHATE 50%	
	draGMDP, Ref key: 70919 Issuance Date: 2020-01-17 Signatory: Confidential Page 5 of 11	

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 : Filtration	
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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance : SODIUM GLYCEROPHOSPHATE 65%	
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 : Filtration	
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	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance : ZINC UNDECYLENATE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.2 Manufacture of crude active substance	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Flaking and 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 scaled primary package within an outer packaging	
3.5.3 Secondary Packaging (placing the sealed primary package within an outer packagin material or container. This also includes any labelling of the material which could be used		
	identification or traceability (lot numbering) of the active substance)	
3.6		
	3.6.1 Physical / Chemical testing	
Activ	e Substance : CALCIUM GLUCOHEPTONATE	
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 :	
	Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	
	CALCHIM CLUCONOCLUCOUEDTONATE	
	e Substance : CALCIUM GLUCONOGLUCOHEPTONATE	
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:	
	Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	Spray 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	
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing	
3.0		
	3.6.1 Physical / Chemical testing3.6.2 Microbiological testing excluding sterility testing	
	5.6.2 Wherobiological testing excluding stermty testing	
Activo	e Substance : CALCIUM GLYCEROPHOSPHATE	
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 :	
	Filtration	
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	
Online Fu	draGMDP, Ref key: 70919 Issuance Date: 2020-01-17 Signatory: Confidential Page 7 of 11	

Signatory: Confidential

	material or container. This also includes any labelling of the material which could be used for		
2.6	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	e Substance : CALCIUM GLYCEROPHOSPHATE 50%		
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 :		
	Filtration		
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		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	Active Substance : LITHIUM GLUCONATE		
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:		
	Cristallization and filtration		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	Drying		
	Drying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	Drying 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)		
	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		
	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		
3.6	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		
3.6	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) Quality Control Testing		
3.6	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) Quality Control Testing		
3.6	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) Quality Control Testing 3.6.1 Physical / Chemical testing		
	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) Quality Control Testing 3.6.1 Physical / Chemical testing		
	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) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing		
Activ	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) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance: MANGANESE GLUCONATE		
Activ	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) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance: MANGANESE GLUCONATE Manufacture of Active Substance by Chemical Synthesis		
Activ	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) Quality Control Testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing e Substance: MANGANESE GLUCONATE Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates		

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3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	Spray 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		
3.6	identification or traceability (lot numbering) of the active substance) Quality Control Testing		
3.0			
	3.6.1 Physical / Chemical testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	e Substance : POTASSIUM GLYCEROPHOSPHATE 50%		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.1 Manufacture of active substance intermediates		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
2.5	Filtration		
3.5	General Finishing Steps		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
2.6	which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	Active Substance : POTASSIUM GLYCEROPHOSPHATE 75%		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.1 Manufacture of active substance intermediates		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
2.5	Filtration		
3.5	General Finishing Steps		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
2.6	which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing evaluding starility testing		
	3.6.2 Microbiological testing excluding sterility testing		
Activ	re Substance : ZINC GLUCONATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.2 Manufacture of crude active substance		
	3.1.3 Salt formation / Purification steps :		
	Filtration		

Issuance Date: 2020-01-17

3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	
Activ	e Substance : CALCIUM GLUCONOLACTATE	
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 :	
	Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	Spray 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	
A ativ	e Substance : ZINC L-ASPARTATE	
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 : Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	
	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)	

3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
	3.6.2 Microbiological testing excluding sterility testing	
Activ	e Substance : ZINC GLUCOHEPTONATE	
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 :	
	Filtration	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	Spray 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	

Clarifying remarks (for public users)

Signatory: Mr Guillaume Renaud, Deputy Director of inspection division --- The ANSM does not issue hard copies of good practices certificates

2020-01-17	Name and signature of the authorised person of the Competent Authority of France
	Confidential
	French National Agency for Medicines and Health
	Products Safety
	Tel: <i>Confidential</i>
	Fax: Confidential

Issuance Date: 2020-01-17