National Agency For The Safety Of Medicine And Health Products

Report No: ***22MPP077NCR***

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer[1]

Part 1

Issued following an inspection in accordance with
Art. 94(2) of Regulation (EU) 2019/6 as amended
Art. 111(7) 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, Lyon, 69008, France***
OMS Organisation Id. / OMS Location Id.: ***ORG-100019365*** / ***LOC-100028130***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-10-21***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

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- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC. and Article 93(2) of Regulation (EU) 2019/6
- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC.

Note to receiving authorities: Please contact the issuing authority within 20 working days in case there are critical(2) medicinal products potentially affected by this statement.
Manufacturing Authorisation Holders directly affected by this statement have failed to comply with their obligations under Art. 46 of Directive 2001/83/EC or Art. 93(1)(j) to (l) of Regulation (EU) 2019/6 and as a consequence the Qualified Person referred to in Art. 48 of Directive 2001/83/EC and Art. 97(1) of Regulation (EU) 2019/6 is unable to perform the batch certification referred to in Art. 51 of Directive 2001/83/EC and Art. 97 (6) and (7) of Regulation (EU) 2019/6.
In exceptional circumstances there may be no objection to the Qualified Person certifying affected batches thereby allowing their release provided all of the following conditions are fulfilled:

1. Batch certification is performed in order to maintain supply of critical medicinal products only.
2. A documented risk assessment has been performed by, or on behalf of, the Qualified Person and additional actions have been implemented by the manufacturing and/or batch release site to mitigate the risks posed by the non-compliance. Note: Repeated testing alone is not normally sufficient risk mitigation but, together with other actions, can form part of a strategy commensurate with the nature and the level of risk.
3. A thorough risk-benefit evaluation has been performed for the acceptance of risk and a report prepared

that takes full account of the nature of the non-compliance with the involvement of:

- The Manufacturing Authorisation Holder and the Qualified Person of the site responsible for batch certification.
- The manufacturing site subject to this Statement of Non-Compliance, if different from the above.
- The relevant Marketing Authorisation Holder(s).

The report has been shared with the National Competent Authorities of the countries in which distribution of the affected batches is anticipated and that any comments from those authorities have been taken into account.

4. Written confirmation has been obtained from the National Competent Authorities in whose territories the affected batches are intended to be distributed that the product is considered critical on its territory, and that there is no objection to distribution.
5. The Supervisory Authority has been informed, if different from the above, and it has not suspended or revoked the relevant Manufacturing Authorisation.
6. The affected Marketing Authorisations have not been revoked or suspended.
7. Any further conditions imposed by the Supervisory Authority and other involved National Competent Authorities are met.

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[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and Art. 94(2) of Regulation (EU) 2019/6, as amended, is also applicable to importers.*

[2] *See Appendix 3 of the relevant procedure in the Compilation of Union Procedures.*

Part 2

Human Medicinal Products
Veterinary Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS

Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;

1.4	Other products or manufacturing activity
	1.4.1 Manufacture of 1.4.1.3 Other: Active substances(en)

Manufacture of active substance. Names of substances subject to non-compliant:
MAGNESIUM GLUCOHEPTONATE(en)
GLYCEROPHOSPHORIC ACID 50%(en)
MAGNESIUM GLUCONATE(en)
MAGNESIUM GLYCEROPHOSPHATE 50%(en)
SODIUM GLYCEROPHOSPHATE 50%(en)
SODIUM GLYCEROPHOSPHATE 65%(en)
CALCIUM GLYCEROPHOSPHATE 50%(en)
POTASSIUM GLYCEROPHOSPHATE 50%(en)
POTASSIUM GLYCEROPHOSPHATE 75%(en)
ZINC GLUCOHEPTONATE(en)
BENZYL NICOTINATE(en)
CALCIUM GLUCOHEPTONATE(en)
CALCIUM LACTATE GLUCONATE(en)
CALCIUM GLYCEROPHOSPHATE(en)
COPPER GLUCONATE(en)
ETHYL NICOTINATE(en)
IRON GLUCOHEPTONATE(en)
FERROUS GLUCONATE(en)
MANGANESE GLUCONATE(en)
CALCIUM GLUCONOGLUCOHEPTONATE(en)
HEXYL NICOTINATE(en)
LITHIUM GLUCONATE(en)
MAGNESIUM GLYCEROPHOSPHATE(en)
METHYL NICOTINATE(en)
NICOTINAMIDE(en)
UNDECYLENIC ACID(en)
ZINC GLUCONATE(en)
ZINC UNDECYLENATE(en)

3. NON-COMPLIANT 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 3.6.2 Microbiological testing excluding sterility testing

Active 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

Active 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 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:MAGNESIUM 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

Active Substance:SODIUM 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

Active 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

Active 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
Active 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: 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
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: 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
Active 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

Active Substance:BENZYL NICOTINATE

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active Substance:CALCIUM LACTATE 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) 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: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 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: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) 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:ETHYL NICOTINATE

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:IRON 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: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: 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:MANGANESE 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) 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: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 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:HEXYL NICOTINATE

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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 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: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: 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:METHYL NICOTINATE

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:NICOTINAMIDE

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:UNDECYLENIC ACID

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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
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: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 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

Clarifying remarks (for public users)

Calcium glucoheptonate : not intended for use in injectable forms / Iron glucoheptonate : not intended for use in injectable forms / Magnesium glucoheptonate : not intended for use in injectable forms / Zinc glucoheptonate : not intended for use in injectable forms / Calcium gluconoglucoheptonate : not intended for use in injectable forms / Zinc gluconate : not intended for use in injectable forms / Magnesium gluconate : not intended for use in injectable forms / Ferrous gluconate : not intended for use in injectable forms / Copper gluconate : not intended for use in injectable forms / Manganese gluconate : not intended for use in injectable forms

Part 3

1.Nature of non-compliance:

During this inspection, 15 deficiencies were observed, out of which 10 were classified as major // E1[Major] : failures related to deviation management // E2[Major] : insufficient documentation of the quality risk related to the temporary cessation of the company's activities between April 10th, 2022 and July 29th, 2022 // E3[Major] : insufficient quantity of staff, particularly concerning Quality Assurance and Qualification-Validation activities // E4[Major] & E5[Major] : major defects in the design and maintenance of all the facilities inspected // E7[Major] : multiple and repeated failures in the cleaning of equipment used for the manufacture of starting materials for pharmaceutical use, concerning all inspected workshops // E8[Major] : failures concerning traceability of the operations performed on equipment // E9[Major] : multiple and repeated deficiencies in the upkeep and maintenance of equipment used for the manufacture of starting materials for pharmaceutical use // E12[Major] : repeated weaknesses in the correction of anomalies related to equipment qualifications // E15[Major] : shortcomings in the management of cross-contamination risks, highlighted by deficiencies in the verification of the effectiveness of the cleaning methods applied in the multi-product workshops

Action taken/proposed by the NCA

Prohibition of supply
After issuance of the non-compliance report and as long as it remains active, the site should not be authorized to distribute starting materials for pharmaceutical use

Suspension or voiding of CEP (action to be taken by EDQM)
EDQM to consider the suspension of several CEPs : CEP 2016-127 (Calcium glucoheptonate) // CEP 1996-106 (Calcium glycerophosphate) // CEP 1999-164 (Ferrous gluconate hydrate) // CEP 2012-221 (Zinc gluconate)

Additional comments
The validity date of the last GMP certificates (21MPP011HVFR01 and 21MPP011VFR01) and GDP certificate 21MPP011D01 is February 28th, 2023 // No recall of products should be considered. // Where such a MA exists, the addition of an alternative supplier to the MA should be considered using quality risk management (QRM) principles // A sanitary police decision was issued by ANSM on July 3rd, 2023 to suspend manufacturing, importation and distribution activities, including those for export, concerning active substances and manufacturing, packaging, marketing, distribution and exportation activities concerning excipients manufactured by the company GIVAUDAN-LAVIROTTE on the site of Lyon (France), and intended for use in the composition of medicinal products. The decision has been published on the ANSM website on July 10th, 2023. As part of the contradictory procedure, the sanitary police decision has already been communicated to the identified Givaudan-Lavirotte customers in the field of human medicines which contains ingredients manufactured by this site (in France and outside France)

2023-07-11

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

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National Agency For The Safety Of Medicine And Health Products
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