EudraGMDP

French National Agency for Medicines and Health Products Safety

CERTIFICATE NUMBER :***17MPP081HVFR01***

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

The competent authority of France confirms the following:

The manufacturer :***ROQUETTE FRERES***

Site address : ***1 rue de la Haute Loge, LESTREM, 62136, 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 ***2017-11-10*** , 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 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.

(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 :
[FR00640]SORBITOL(en)
[FR17150]GLUCOSE MONOHYDRATE(en)
[FR03011]MANNITOL(en)
[FR]ISOSORBIDE(en)
HYDROXYPROPYLBETADEX(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance :SORBITOL	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.5 Modification of extracted substance Plant 3.2.6 Purification of extracted substance Plant
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Grinding 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 :GLUCOSE MONOHYDRATE	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Plant
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

	3.6.2 Microbiological testing excluding sterility testing

Active Substance :MANNITOL

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.5 Modification of extracted substance Plant 3.2.6 Purification of extracted substance Plant
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 3.6.2 Microbiological testing excluding sterility testing

Active Substance :ISOSORBIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Purification : Crystallization, Activated carbon
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Flaking 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 :HYDROXYPROPYLBETADEX

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Purification
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) :

SORBITOL: Marketed with the trade name « NEOSORB® PF » (Pyrogen free grade); GLUCOSE MONOHYDRATE: Marketed with the trade name « LYCADEX® PF » (Pyrogen free grade); MANNITOL: Marketed with the trade name « PEARLITOL® PF » (Pyrogen free grade); HYDROXYPROPYLBETADEX : Marketed with the trade names « KLEPTOSE® HPB », « KLEPTOSE® HP » (Parenteral grades); ISOSORBIDE: Marketed with the trade name « ISOSORBIDE C PHARMA »

2018-03-12

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

Confidential

French National Agency for Medicines and Health Products Safety

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