Agenzia Italiana del Farmaco

CERTIFICATE NUMBER: ***IT-API/75/H/2021***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Italy confirms the following:
The manufacturer: ***SUANFARMA ITALIA S.P.A.***
Site address: ***Corso Verona, 165, ROVERETO, 38068, Italy***

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 ***2021-03-03***, 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.

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[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.*

Manufacture of active substance. Names of substances subject to inspection:
POTASSIUM CLAVULANATE(en)
MYCOPHENOLIC ACID(en)
POTASSIUM CLAVULANATE DILUTED(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:POTASSIUM CLAVULANATE

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.3 Isolation / Purification 3.3.1 Fermentation
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

Active Substance:MYCOPHENOLIC ACID

3.3	**Manufacturing of Active Substance using Biological Processes**
	3.3.3 Isolation / Purification 3.3.1 Fermentation
3.5	**General Finishing Steps**
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: Drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:POTASSIUM CLAVULANATE DILUTED

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: blending 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)

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 48 months from the latest general GMP inspection conducted on 2019/05/09, except for AIFA¿s re-evaluation of the risk profile.

2021-07-05

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

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Confidential
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