Regierung Von Oberbayern

CERTIFICATE NUMBER: ***DE_BY_04_GMP_2020_0079***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Germany confirms the following:
The manufacturer: ***Pharmazell (India) Private Limited***
Site address: ***Plot no. B5 & B6, A1 & A2 MEPZ, Chennai-600 045, Tambaram, India***

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 ***2020-02-21***, 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.

[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:
L-Cysteine Hydrochloride Monohydrate(en)
L-Cystine(en)
Carbocisteine(en)
L-Cysteine Hydrochloride anhydrous(en)
Zinc Orotate Dihydrate(en)
Magnesium Orotate Dihydrate(en)
6-Methyl Uracil(en)
L-Lysine-S-Carboxymethyl-L-Cysteine Salt(en)
Propafenone Hydrochloride(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:L-Cysteine Hydrochloride Monohydrate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving 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:L-Cystine

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving, 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

Active Substance:Carbocisteine

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving, 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

Active Substance:L-Cysteine Hydrochloride anhydrous

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving 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:Zinc Orotate Dihydrate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving, 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

Active Substance:Magnesium Orotate Dihydrate

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, Blending, Sieving, 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

Active Substance:6-Methyl Uracil

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

Active Substance:L-Lysine-S-Carboxymethyl-L-Cysteine Salt

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

Active Substance:Propafenone 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: Treatment with activated carbon Crystallization
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: Drying, 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)

For the production of the active substances: Carbocisteine L-Cystine L-Cysteine-Hydrochlorid Monohydrate L-Cysteine-Hydrochlorid anhydrous L-Lysine-S-Carboxymethyl-L-Cysteine Salt are used animal extracted products

2020-09-03

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

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Confidential
Regierung Von Oberbayern
Tel:***Confidential***
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