Italian Medicines Agency

CERTIFICATE NUMBER: ***IT/E/API/01/2023***

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

The competent authority of Italy confirms the following:
The manufacturer: ***Supriya Lifescience Limited***
Site address: ***A 5/2 Lote Parshuram Industrial Area M I D C, Khed, Maharashtra, 415722, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100015796 / LOC-100024571***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-05-13***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [3]
- 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 Art. 111(5) of Directive 2001/83/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:
CHLORPHENAMINE MALEATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:CHLORPHENAMINE MALEATE	
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: distillation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, 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 3.6.2 Microbiological testing excluding sterility testing

Any restrictions related to the scope of this certificate:

Building	Room	Line/equipment	QC testing	Products
BB, AC, AB				***confidential***

Clarifying remarks (for public users)

Due to the restriction caused by COVID-19, it was verified by distant assessment that the Chlorphenamine maleate production is performed according to GMP. Inspection performed in the framework of the EDQM inspection programme.

2023-01-16

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

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Confidential
Italian Medicines Agency
Tel:***Confidential***
Fax:***Confidential***