Institute For State Control Of Veterinary Biologicals And Medicines

CERTIFICATE NUMBER: ***018/2022/API***

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

Part 1

Issued following an inspection in accordance with :
Art. 94(1) of Regulation (EU) 2019/6 as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***Cayman Pharma s.r.o.***
Site address: ***Prace 657, Neratovice, 277 11, Czechia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100013822*** / ***LOC-100019767***

Is an active substance manufacturer that has been inspected in accordance with Art. 123(6) of Regulation (EU) 2019/6.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-04-12***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in .

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. 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:
CLOPROSTENOL SODIUM(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance:CLOPROSTENOL SODIUM	
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: crystallisation, chromatographic purification
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

4. Other Activities - Active Substances:
Producing Na (+/-) Clprostenolum, producing Na (+) cloprostenolum

2022-06-08

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

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