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Malta Medicine Authority

CERTIFICATE NUMBER: ***MT/057HM/2022***

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 Malta confirms the following:
The manufacturer: ***Aurobindo Pharma Limited***
Site address: ***Unit XV Plot No 17a, E Bonangi Village Parawada Mandal, Anakapalli District, Anakapalli, 531021, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011510*** / ***LOC-100042747***
DUNS Number: ***65-078-1284***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-06-15***, 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]

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 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

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: oral powder in unit dose forms (sachets)(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: oral powder in unit dosage forms (sachets)(en) 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

-This inspection covered Block A (main block) and new block, Block B (consists of only packaging material and finished products` storage areas, sampling and dispensing booths and blister primary and secondary packaging lines) at this site. -Future expansion area on the first and second floor of Block B were not included in the scope of this inspection. -This certificate is limited in scope to products intended for the EU/EEA markets. -A variation to change company`s address (the district name was modified from `Visakhapatnam` to `Anakapalli`) is also included in this certificate.

2022-12-02

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

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Confidential
Medicines Authority
Tel:***Confidential***
Fax:***Confidential***