

## ***National Authority Of Medicines And Health Products***

CERTIFICATE NUMBER: **FT078/MH/001/2020**

# **CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**<sup>1,2</sup>

### **Part 1**

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Portugal confirms the following:

The manufacturer: ***Athena Drug Delivery Solutions Private Limited***

Site address: ***A1 - A5 Chemical Zone, MID C Road, Ambarnath, Maharashtra, 421501, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100023957 / LOC-100033126***

DUNS Number: ***86-003-7813***

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 ***2019-10-18***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.<sup>3</sup>

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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (<http://eudragmdp.ema.europa.eu/>). 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.

<sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

<sup>2</sup>Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

<sup>3</sup>These requirements fulfil the GMP recommendations of WHO.

## Part 2

Human Medicinal Products	
<b>1 MANUFACTURING OPERATIONS</b>	
<b>1.2</b>	<b>Non-sterile products</b>
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Sachets(en) 1.2.1.13 Tablets 1.2.1.17 Other: Granules and pellets for further processing(en)
<b>1.5</b>	<b>Packaging</b>
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Sachets(en) 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>
<b>1.6</b>	<b>Quality control testing</b>
	<i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

***The following manufacturing areas are out of the scope of the present certificate: Pellet coating-1, Pellet coating-2, Pellet coating-3. - Based on the outcome of the inspection to performed from 05th to 08th of December 2023, and in order to conclude the inspection process, this GMP certificate is valid until 30th June 2024.***

2023-12-13

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

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**National Authority Of Medicines And Health Products**  
Tel: **Confidential**

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