

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: FT055/MH/001/2018

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 Portugal confirms the following:

The manufacturer: ***Eugia Pharma Specialities Limited***

Site address: ***Survey No 550 551 And 552, Kolthur Village Shameerpet Mandal, Medchal Malkajgiri District, Medchal, Hyderabad, 500101, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100031553 / LOC-100049449***

DUNS Number: ***87-220-1704***

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 ***2022-11-25***, 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	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.1 Large volume liquids Special Requirements 7 Other: cytotoxic(en) 1.1.1.2 Lyophilisates Special Requirements 7 Other: cytotoxic(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: hormones, cytotoxic(en)
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids Special Requirements 7 Other: cytotoxic(en)
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: cytotoxic(en) 1.2.1.2 Capsules, soft shell Special Requirements 7 Other: hormones, cytotoxic(en) 1.2.1.13 Tablets Special Requirements 7 Other: cytotoxic(en)

1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: cytotoxic(en) 1.5.1.2 Capsules, soft shell Special Requirements 7 Other: hormones, cytotoxic(en) 1.5.1.13 Tablets Special Requirements 7 Other: cytotoxic(en)
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

Oncology Block - 1.1.1.1 Lines 1 and 2; 1.1.1.2 Line 1; 1.1.1.4 Lines 1 and 2; 1.1.2.3 Lines 1 and 2.
Hormone Block - 1.1.1.4 Vial and pre-filled syringe. - The complete address is Survey No 550 551 And 552, Kolthur Village Shamirpet Mandal, Medchal Malkajgiri District, Hyderabad, Telangana, 500101 – India. - Following the inspection of 21st to 25th November 2022, this GMP Certificate is valid until the end of 2023, until reception and assessment of CAPA plan.

2023-01-30

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

Confidential
National Authority of Medicines and Health Products,
I.P.
 Tel: **Confidential**
 Fax: **Confidential**