

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

CERTIFICATE NUMBER: **FI042/MH/001/2017**

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: ***Venus Remedies, Limited***

Site address: ***Hill Top Industrial Estate, Jharmajri, EPIP Phase-I (Extn), Bhatoli Kalan, Baddi, Distt. Solan, Himachal Pradesh, 173205, India***

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 transposed in the following national legislation:

Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2017-05-26**, it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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 111(5) of Directive 2001/83/EC and 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

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Other(en)
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
1.6	Quality control testing
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

Clarifying remarks (for public users)

1.1.1.6 Other aseptically prepared products: powders, cephalosporins and carbapenems, and cytostatics products lyophilisates 1.1.2.3 terminally sterilized, small volume liquids cytostatics. - Considering the COVID-19 pandemic that has affected and/or prevented the conduct of on-site GMP inspections, the validity of this GMP certificate is extended until the end of 2021. Nevertheless, if necessary, inspections (including distant assessments) may be launched at any time and, in case of non-compliance, the issuing/supervisory authority can take any action that affects the validity of the certificate and/or appropriate regulatory actions will be triggered. Routine on-site inspection will resume as soon as COVID-19 restrictions are lifted, according to risk based inspection planning taking into account the date of the last inspection.

2020-05-12

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***