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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 EstateJharmajri EPIP Phase- I Extension Bhatoli KalanBarotiwala, Solan, 173205, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100031277*** / ***LOC-100049070***

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/EC [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.

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[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**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Other(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate:

1.1.1.6 Other aseptically prepared products: powders, cephalosporins and carbepenems, and cytostatics products lyophilisates 1.1.2.3 terminally sterilized, small volume liquids cytostatics. - Due to the restrictions caused by 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 2023. 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 inspections will be conduted when possible, according to risk-based inspection planning, taking into account any restrictions due to COVID-19.

Clarifying remarks (for public users)

1.1.1.6 Other aseptically prepared products: powders, cephalosporins and carbepenems, and cytostatics products lyophilisates 1.1.2.3 terminally sterilized, small volume liquids cytostatics. - Due to the restrictions caused by 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 2023. 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 inspections will be conduted when possible, according to risk-based inspection planning, taking into account any restrictions due to COVID-19.

2022-10-06

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

Maria Fernanda Ralha

Assinado de forma digital por Maria Fernanda Ralha
Dados: 2022.10.22 20:01:17 +01'00'

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