REPÚBLICA PORTUGUESA
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Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

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

CERTIFICATE NUMBER: ***FI042/MII/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

PHD Chamber of Commerce and Industry
28 SEP 2018
Chandigarh-160031

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 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.*

VENUS REMEDIES LIMITED INDIA

CERTIFIED TO BE TRUE COPY
OF THE ORIGINAL
093089
20 SEP 2018
ATTESTED
SULEKH CHAND
NOTARY PANCHKULA

NOTARY
SULEKH CHAND
PANCHKULA
Regd No.3429
Commission
Expires on
11/08/2021
GOVT. OF INDIA

Fernanda Ralha
Directora da Direcção
Inspecção e Licenciamentos

PRADEEP RATTAN
Additional Resident Director
PHD Chamber of Commerce and Industry
PHD House, Sector 31-A, Chandigarh

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
1.6	**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.

PHD Chamber of Commerce and Industry
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Chandigarh-160031

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.

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VENUS REMEDIES LIMITED INDIA

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Regd No.3429
Commission
Expires on
11/06/2021
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ATTESTED
28 SEP 2018
PRADEEP RATTAN
Additional Resident Director
PHD Chamber of Commerce and Industry
PHD House, Sector 31-A, Chandigarh

Fernanda Ralha
Directora da Direcção
Inspecção e Licenciamentos

REPÚBLICA PORTUGUESA
SAÚDE

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Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

2017-07-28

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

Ms. Maria Fernanda Ralha Henriques Matos
National Authority of Medicines and Health Products, I.P.
Tel: *+351 21 7987278*
Fax: *+351 21 7987257*

Fernanda Ralha
Directora da Direcção
Inspecção e Licenciamentos

PHD Chamber of Commerce and Industry
28 SEP 2018
Chandigarh-160031

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PANCHKULA
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VENUS REMEDIES LIMITED
INDIA

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PRADEEP RATTAN
Additional Resident Director
PHD Chamber of Commerce and Industry
PHD House, Sector 31-A, Chandigarh

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OF THE ORIGINAL

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NOTARY PANCHKULA

20 SEP 2018

SGS

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country **INDIA**

This public document of the type

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

is issued to VENUS REMEDIES LIMITED

has been signed by PRADEEP RATTAN

with the seal / stamp of ADDITIONAL RESIDENT DIRECTOR

Certified By

RPO, MINISTRY OF EXTERNAL AFFAIRS, CHANDIGARH

on 17-OCT-2018 *at* CHANDIGARH, INDIA

with reference no. 9000859681801

seal / stamp

MINISTRY OF EXTERNAL AFFAIRS CHANDIGARH REGIONAL PASS PORT OFFICE

signature

सेहदेव कौशिक/Sehdev Kaushik
अधीक्षक/Superintendent
क्षेत्रीय पारपत्र कार्यालय
...ional Passport Office
चण्डीगढ़/Chandigarh

8,5 9 6 8 1 8 0 1

REPÚBLICA PORTUGUESA
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Infarmed

Traducción fiel al original

Autoridad Nacional de Medicinas y Productos para la Salud, I.P.

CERTIFICADO NÚMERO: ***F1042/MH/001/2017***

CERTIFICADO DE CUMPLIMIENTO BPM DEL FABRICANTE [1 . 2]

Por Vania Silva a las 11:50:15, 22-10-2018

Parte 1

Emitido seguido de una inspección de acuerdo con:
Art. 111(5) de Directiva 2001/83/EC enmendado

La autoridad competente de Portugal confirma lo siguiente:
El fabricante: ***Venus Remedies, Limited***
Dirección del sitio: ***Hill Top Industrial Estate, Jharmajri, EPIP Phase-I (Extn), Bhatoli Kalan, Baddi, Distt Solan, Himachal Pradesh, 173205, India***

Ha sido inspeccionado en conexión con autorización(es) de mercadeo de fabricantes listados localizados fuera del Área Económica Europea de acuerdo con el Art. 111(4) de Directiva 2001/83/EC transpuesto en la siguiente legislación nacional:
Art. 176.º n.º 4 de Decreto de Ley n.º 176/2006, 30 de Agosto.

PHD Chamber of Commerce and Industry
28 SEP 2018
Chandigarh-160031

Del conocimiento obtenido durante la inspección de este fabricante, la última que fue realizada el **26-05-2017**, se considera que cumple con:

- Los principios y guías de las Buenas Prácticas de Manufactura establecido en la Directiva 2003/94/EC [3]

Este certificado refleja el estado del sitio de fabricación al momento de la inspección anotada anteriormente y no se debe confiar en esta para reflejar el estado de cumplimiento si más de tres años han pasado desde la fecha de la inspección. Sin embargo, este período de validez puede ser reducido o extendido usando los principios de administración de riesgo regulatorio por un ingreso en el campo de Restricciones o Notas aclaratorias. Este certificado es válido solo cuando es presentado con todas sus páginas y ambas Partes 1 y 2. La autenticidad de este certificado puede ser verificada en EudraGMDP. Si no aparece, por favor contacte a la autoridad emisora.

[1] El certificado referido en el párrafo 111(5) de Directiva 2001/83/EC y 80(5) de Directiva 2001/82/EC, también será requerido para importaciones provenientes de países terceros a un Estado Miembro.
[2] Guía en la interpretación de este modelo puede encontrarse en el menú de Ayuda de la base de datos de EudarGMDP.
[3] Estos requerimientos cumplen las recomendaciones de BPM de la OMS.

NOTARY SULEKH CHAND PANCHKULA Regd No.3429 Commission Expires on 11/08/2021 GOVT. OF INDIA

VENUS REMEDIES LIMITED INDIA

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093089
20 SEP 2018
ATTESTED SULEKH CHAND NOTARY PANCHKULA

INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque da Saúde de Lisboa - Av. do Brasil, 53
1749-004 Lisboa
Tel.: +351 217 987 100 Fax: 217 987 201 Web: www.infarmed.pt E-mail: infarmed@infarmed.pt

Ref key

Fernanda Ralha
Directora da Direcção Inspecção e Licenciamentos

SURENDER RATTAN
Additional Resident Director
PHD Chamber of Commerce and Industry
PHD House, Sector 31-A, Chandigarh

Parte 2

Productos Medicinales Humanos

1 OPERACIONES DE FABRICACIÓN	
1.1	**Productos estériles**
	1.1.1 Preparados asépticamente (operaciones de proceso para las siguientes formas de dosis) 1.1.1.2 Liofilizados 1.1.1.4 Líquidos de volumen pequeño 1.1.1.6 Otro: Otro (en)
	1.1.2 Esterilizado Terminalmente (operaciones de proceso para las siguientes formas de dosis) 1.1.2.3 Líquidos de volumen pequeño
1.6	**Prueba de control de calidad**
	1.6.1 Microbiológico: estéril *1.6.2 Microbiológico: no estéril* *1.6.3 Químico/Físico*

Cualquier restricción relacionada al ámbito de este certificado:

1.1.1.6 Otros productos preparados asépticamente: polvos, cefalosporinas y carbepenemas, y productos citostáticos liofilizados 1.1.2.3 esterilizado terminalmente, citostáticos líquidos de volumen pequeño.

PHD Chamber of Commerce and Industry
28 SEP 2018
Chandigarh-160031

Notas aclaratorias (para usuarios públicos)

1.1.1.6 Otros productos preparados asépticamente: polvos, cefalosporinas y carbepenemas, y productos citostáticos liofilizados 1.1.2.3 esterilizado terminalmente, citostáticos líquidos de volumen pequeño.

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VENUS REMEDIES LIMITED INDIA

ATTESTED
INFARMED - Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.
Parque de Saúde de Lisboa - Av. do Brasil, 53
Tel.: +351 217 987 100 Fax: +351 217 987 316 Web: www.infarmed.pt e-mail: infarmed@infarmed.pt
28 SEP 2018

Fernanda Ralha
Directora da Direcção
Inspecção e Licenciamentos

Hafeez
SHADEEP PATTAN
Additional Resident Director
PHD Chamber of Commerce and Industry
PHD House, Sector 31-A, Chandigarh.

REPÚBLICA PORTUGUESA
SAÚDE

SNS
SERVIÇO NACIONAL DE SAÚDE

Infarmed

28-07-2017

Nombre y firma de la persona autorizada
de la Autoridad competente de Portugal

Sra. Maria Fernanda Ralha Henriques Matos
Autoridad Nacional de Medicinas y Productos para la Salud, I.P.
Tel: +351 21 7987278
Fax: +351 21 7987257

Fernanda Ralha
Directora da Direcção
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MINISTRY OF EXTERNAL AFFAIRS CHANDIGARH REGIONAL PASS PORT OFFICE

signature

सेहदेव कौशिक/Sehdev Kaushik
अधीक्षक/Superintendent
क्षेत्रीय पारपत्र कार्यालय
Regional Passport Office
चण्डीगढ़/Chandigarh

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

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

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

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Part 2

Human Medicinal Products

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	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 carbepenems, 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

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