MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de medicamentos y productos sanitarios

Certificado Nº / Certificate No: ES/065HV/17

CERTIFICADO DE CUMPLIMIENTO DE NCF[1,2] / *CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*[1,2]

Parte 1 / *Part 1*

Emitido en virtud de una inspección según artículo 111(5) de la Directiva 2001/83/CE . / *Issued following an inspection in accordance with article 111(5) of Directive 2001/83/EC.*

La autoridad competente de España certifica lo siguiente:

The competent authority of Spain confirms the following:

El fabricante **HETERO LABS LIMITED** en su planta ubicada en Unit III Formulation Plot nº 22 - 110 IDA, Jeedimeetla, Hyderabad, 500 055 Telangana India ha sido inspeccionado en relación con los listados de fabricantes incluidos en las autorizaciones de comercialización de medicamentos y localizados fuera del Espacio Económico Europeo de acuerdo con: artículo 111(4) de la Directiva 2001/83/CE incorporada en la siguiente legislación nacional: artículo 108.2c, Real Decreto Legislativo 1/2015, de 24 de julio.

*The manufacturer **HETERO LABS LIMITED** site address Unit III Formulation Plot nº 22 - 110 IDA, Jeedimeetla, Hyderabad, 500 055 Telangana India has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with: article 111(4) of Directive 2001/83/EC transposed in the following national legislation: article 108.2c, Royal Legislative Decree 1/2015, of 24th of July.*

En base a la información obtenida en las visitas de inspección a este fabricante, la última de ellas realizada el 03/03/2017, se considera que el mismo cumple con los principios y directrices de las Normas de Correcta Fabricación establecidas en Directiva 2003/94/CE.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 03/03/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

Este certificado refleja la situación de la planta de fabricación en la fecha en que se efectúa la inspección antes citada, y no puede considerarse que acredite el cumplimiento si han transcurrido más de tres años desde esa fecha de inspección. Sin embargo, este período de validez podrá verse reducido o ampliado mediante el empleo de la herramienta de análisis de riesgos y su inclusión en el correspondiente campo de Restricciones y Aclaraciones.

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.

Este certificado es válido sólo cuando se presente con todas las páginas y las Partes 1 y 2.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

M. SADA SIVA KUMAR REDDY, ADVOCATE, SARASWATHI ENCLAVE, BHAGYANAGAR COLONY, HYDERABAD. NOTARY Regn.No. 198 NOTARIAL

Federation of Indian Micro and Medium Enterprises Chamber of Commerce & Industry FISME No.111(RE-2012)/2009-14 Hyderabad

ATTESTED
Prasuna
B. PRASUNA
Assistant Secretary

[1] El certificado al que se hace referencia en el párrafo 111(5) [illegible] 2C y 80(5) de la Directiva 2001/82/EC, es también aplicable para importadores. / *The certificate referred to in paragrahp 111(5) of Directive 2001/[illegible] 80 [illegible]ive 2001/82/EC, is also applicable to importers.*

[2] La guía para la interpretación de este formulario puede encontrarse en el menú de ayuda de la base de datos EudraGMP. / *Guidance on the interpretation of this template can be found in the help menu of EudraGMP database.*

[3] Estos requisitos cumplen con las recomendaciones GMP de la OMS. / *These requirements fulfil the GMP recommendations of WHO.*

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 17/05/2017

ATTESTED

Localizador: 2SFGE3CCB7

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

24 MAY 2017

M. SADA SIVA KUMAR REDDY, B.Com., B.L.

La autenticidad de este certificado puede ser verificada en EudraGMP. Si no apareciera, por favor contacte con la autoridad emisora.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

Federation of Indian Micro and Small & Medium Enterprises
Chamber of Commerce & Industry
FISME
No.11(RE-2012)/2009-11
Hyderabad

M. SADA SIVA KUMAR REDDY, ADVOCATE
SARASWATHI ENCLAVE, BHAGYANAGAR COLONY
NOTARY
Regn.No. 198.
F-102
KUKATPALLY, HYDERABAD

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 17/05/2017
Localizador: 2SFGE3CCB7

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

Parte 2 / *Part 2*

☑ Medicamentos de Uso Humano / *Human Medicinal Products*

☐ Medicamentos de Uso Veterinario / *Veterinary Medicinal Products*

☐ Medicamentos en Investigación de Uso Humano / *Human Investigational Medicinal Products*

1 - OPERACIONES DE FABRICACIÓN / *1 - MANUFACTURING OPERATIONS*	
1.2	**Productos no estériles / *Non-sterile products***
	1.2.1 Productos No Estériles (operaciones de procesado de las siguientes formas farmacéuticas) / *Non-sterile products (processing operations for the following dosage forms)* 1.2.1.1 Cápsulas duras / *Capsules, hard shell* 1.2.1.6 Líquidos para uso interno / *Liquids for internal use* 1.2.1.13 Comprimidos / *Tablets*
1.5	**Acondicionamiento / *Packaging***
	1.5.1 Acondicionamiento primario / *Primary Packaging* 1.5.1.1 Cápsulas duras / *Capsules, hard shell* 1.5.1.6 Líquidos para uso interno / *Liquids for internal use* 1.5.1.13 Comprimidos / *Tablets* 1.5.2 Acondicionamiento secundario / *Secondary Packaging*
1.6	**Control de calidad / *Quality Control testing***
	1.6.2 Microbiológico: no-esteril / *Microbiological: non-sterility* 1.6.3 Químico/Físico / *Chemical/Physical*

Nombre y firma de la persona autorizada de la Agencia Española de Medicamentos y Productos Sanitarios / *Name and signature of the authorised person of the Competent Authority of Spain*

Madrid, 17 de mayo de 2017

Agencia Española de Medicamentos y Productos Sanitarios

JEFE DE DEPARTAMENTO DE INSPECCIÓN Y CONTROL DE MEDICAMENTOS

P.A.

JEFE DE ÁREA DE CONTROL DE MEDICAMENTOS

agencia española de medicamentos y productos sanitarios
Departamento de Inspección y Control de Medicamentos

Mª Luisa Tarno Fernandez

Federation of Indian Micro and Small & Medium Enterprises ★ Chamber of Commerce & Industry ★ FISME ★ No.11/(RE-2012)/2009-14 ★ Hyderabad ★

M. SASANKA VAKUMAR REDDY, ADVOCATE ★ SARASWATHI ENCLAVE, BHAGYANAGAR COLONY ★ F-102 ★ KUKATPALLY, HYDERABAD ★ NOTARY Regn.No. 198.

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 17/05/2017

Localizador: 2SFGE3CCB7

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

C/ CAMPEZO, 1 - EDIFICIO 8

060415

29 MAY 2017

सं० No. दिनांक Date

वाणिज्य मंडल में पदाधिकारी सचिव उप सचिव/सचिव के हस्ताक्षर सत्यापित किए जाते है ।

The Signature of Asstt. Secretary/Dy. Secretary/Secretary of Chamber of Commerce Attested.

विदेश मंत्रालय इन दस्तावेज के किसी भी विषय वस्तु की जिम्मेदारी नहीं लेता ।

Ministry of External Affairs accepts no responsibility for the contents of this document.

(पुष्पा रंजन)
(PUSHPA RANJAN)
अनुभाग अधिकारी (सत्यापन)
Section Officer (Attestation)

The Ministry of External Affairs accept no responsibility for the genuineness of the above documents

भारत सरकार GOVERNMENT OF INDIA

अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

Country: INDIA

This public document of the type

COMMERCIAL DOCUMENT

is issued to HETERO LABS LTD.

has been signed by B PRASUNA

with the seal / stamp of ASST. SECRETARY, FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES, AP

Certified by

Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 16-Jun-2017 *at* NEW DELHI, INDIA

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmaceutical Quality
Office of Surveillance
Division of Quality Surveillance Assessment
10903 New Hampshire Avenue
Building 51, Room 4316
Silver Spring, MD 20993
TELEPHONE: (301) 796-3254
FAX: (301) 847-8742

04/06/2017

Hetero Labs, Ltd. - Unit III
Rangareddy, Jeedimetla
Plot 22-110, Part II, IDA
Hyderabad, Andhra Pradesh , IN

Reference: Inspection Date(s): 10/17/2016 - 10/26/2016

Location: Hetero Labs, Ltd. - Unit III
Plot 22-110, Part II, IDA
Rangareddy, Jeedimetla
Hyderabad, 500055 , IN

Dear Dr. G. Palleswara Rao,

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 301-796-3197.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Federation of Indian Micro and Small & Medium Enterprises Chamber of Commerce & Industry FISME No.11/RE-2012/2009-14 Hyderabad

06 SEP 2017
ATTESTED
M. SRINIVASA RAO
Deputy Secretary

Sincerely,

Tsedenia Woldehanna -S

Digitally signed by Tsedenia Woldehanna -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2001203833, cn=Tsedenia Woldehanna -S
Date: 2017.04.06 08:45:52 -04'00'

NOTARIAL

FEI: 3005406526

Enclosure: Establishment Inspection Report (EIR)

ATTESTED
06 SEP 2017
M. SADA SIVA KUMAR REDDY, B.Com., B.L.
ADVOCATE & NOTARY
Appointed by Govt. of A.P., India
G.O Ms No.155, Rev (Judl), dt. 11.04.2008
2, Saraswathi Enclave, Vijayanagar Colony,
Hyderabad, AP, India (Ph: 98480 44395)


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
(Convention de La Haye du 5 octobre 1961)
Country
INDIA
This public document of the type
COMMERCIAL DOCUMENT
is issued to HETERO LABS LTD.
has been signed by M SRINIVASA RAO
with the seal / stamp of DY. SECRETARY, FEDERATION OF INDIAN MICRO AND SMALL & MEDIUM ENTERPRISES, AP
Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
on 12-Sep-2017 at NEW DELHI, INDIA
with reference no. APHY0031982917
Seal / Stamp
Signature
(DEBABRATA PAUL)
Section Officer (O.I.)
Ministry of External Affairs
New Delhi