

महाराष्ट्र शासन
आयुक्त
अन्न व औषध प्रशासन, महा. राज्य
३४१, वांद्रे - कुर्ला संकुल, रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.



GOBIERNO DE MAHARASHTRA
COMISIONADO
Administración de Alimentos y Medicamentos (M.S.)
341, Bandra-Kurla Complex,
Opuesto a RBI Buildings,
Bandra (E), Mumbai – 400 051
Tel: 022 – 26592362-65
E-mail: comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/75315/2018/ 3266 /11

दिनांक. 20/9/2018

प्रति,
WANBURY LIMITED
RAIGAD

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजूरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 75315

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/75315 (एकूण प्रमाणपत्रे ।) पाठवीण्यात येत आहेत.

सहआयुक्त, मुख्यालय, मुंबई यांचे मान्यतेने



आमला

(सु.सं मोहिते)

सहायक आयुक्त (मुख्यालय) का क्र.१९
अन्न व औषध प्रशासन, म. राज्य.



TRUE COPY
ATTESTED BY ME

S. M. H. ZAIDI
NOTARY
Government of India
Mumbai & Thane Dist.

10 OCT 2018



Oficina del Comisionado
Administración de Alimentos & Medicamentos, M.S.
Bandra – Kurla Complex
Bandra (E)
Mumbai – 400 051
Fecha: 26 SEP 2018

CERTIFICADO DE BUENAS PRÁCTICAS DE MANUFACTURA

Este certificado está en conformidad al formato recomendado por la Organización Mundial de la Salud
(Se hayan adjuntas Instrucciones Generales y Notas aclaratorias)

Certificado No.: **NEW-WHO-GMP/CERT/KD/75315/2018/11/25070**

En base a la inspección llevada a cabo el **16/08/2018 & 17/08/2018**, certificamos que el sitio indicado en este Certificado cumple con las **Buenas Prácticas de Manufactura** para las formas de dosis, categorías y actividades listadas en la Tabla 1:

1. Nombre de la Firma : **WANBURY LIMITED**
Dirección : **A-15, M.I.D.C. INDUSTRIAL AREA,
PATALGANGA, TAL. KHALAPUR, DIST.
RAIGAD 410220 MAHARASHTRA STATE,
INDIA**
2. Número de Licencia : **KD242 en Forma 25**

Tabla 1

Sr. No.	Forma(s) de Dosis	Categoría(s)	Actividad(es)
1	Ingredientes Farmacéuticos Activos (Medicamentos en Lote)	General (Que no sea Cefalosporinas, Penicilina, Citotóxico, Hormonas)	Producción, Llenado, Empaquetado, Etiquetado, Control de Calidad, Seguro de Calidad
2	Gránulos	General (Que no sea Cefalosporinas, Penicilina, Citotóxico, Hormonas)	Producción, Llenado, Empaquetado, Etiquetado, Control de Calidad, Seguro de Calidad

La responsabilidad por la calidad de los lotes individuales de los productos farmacéuticos fabricados a través de este proceso recae en el fabricante.

Este certificado permanece válido hasta el 22 de septiembre de 2021. Queda invalidado si las actividades y/o categorías certificadas en este son cambiadas o si el sitio deja de ser considerado como en cumplimiento con las BPM.

Dirección de la autoridad certificadora:
Administración de Alimentos & Medicamentos, M.S.
Bandra – Kurla Complex
Bandra (E), Mumbai – 400 051
Maharashtra, INDIA
Tel: +91-22-26592363/64
Fax: +91-22-26591959

Nombre de la persona Autorizada: **A. T. NIKHADE**

Firma :
Timbre y Fecha: Comisionado Adjunto (HQ) & Autoridad
Controladora
Administración de Alimentos & Medicamentos, M.S.
Bandra (E), Mumbai
Maharashtra State, India
Fecha: 26 de septiembre 2018



LISTA DE PRODUCTOS APROBADOS BAJO BPM OMS¹

No. de certificado : NEW-WHO-GMP/CERT/KD/75315/2018/11
/25070

VÁLIDO HASTA: 25 de septiembre 2021

Nombre de la Firma Fabricante: **WANBURY LIMITED**
A-15, M.I.D.C. INDUSTRIAL AREA,
PATALGANGA, TAL. KHALAPUR, DIST. RAIGAD
410220 MAHARASHTRA STATE, INDIA

No. de Licencia del Medicamento: KD242 en Forma 25

Sr.No.	Nombre del Producto	Composición
1	Metformina Clorhidrato BP	1 gm contiene 100% P/P de Metformina Clorhidrato: Metformina Clorhidrato BP 100%
2	Metformina Clorhidrato EP	1 gm contiene 100% P/P de Metformina Clorhidrato: Metformina Clorhidrato EP 100%
3	Metformina Clorhidrato IP	Metformina Clorhidrato IP 100%
4	Metformina Clorhidrato USPP	1 gm contiene 100% P/P de Metformina Clorhidrato: Metformina Clorhidrato USP 100%
5	Metformina Clorhidrato DC Gránulos 90% p/p	1 gm contiene 90% P/P de Metformina Clorhidrato: Metformina Clorhidrato IHS 90% p/p Polivinilpirrolidona K-30 IHS 3,0% Almidón de Maíz IHS 1,2% Estearato de Magnesio IHS 0,4% Aerosil IHS 0,9% Celulosa Micro Cristalina IHS 4,5%
6	Metformina Clorhidrato DC Gránulos 95% p/p	1 gm contiene 95% P/P de Metformina Clorhidrato: Metformina Clorhidrato IHS 95% p/p Polivinilpirrolidona K-30 IHS 2,7% Almidón de Maíz IHS 1,8% Estearato de Magnesio IHS 0,3% Aerosil IHS 0,2%
7	Metformina Clorhidrato DC Gránulos 86,6% p/p	1 gm contiene 86,6% P/P de Metformina Clorhidrato: Metformina Clorhidrato IHS 86,6% p/p Polivinilpirrolidona K-30 IHS 6,94% Almidón de Maíz IHS 1,74% Glicolato de Almidón de Sodio IHS 3,52% Aerosil IHS 1,2%

Dirección de la autoridad certificadora:
Administración de Alimentos & Medicamentos, M.S.
Bandra – Kurla Complex
Bandra (E), Mumbai – 400 051
Maharashtra, INDIA
Tel: +91-22-26592363/64
Fax: +91-22-26591959

Nombre de la persona Autorizada: **A. T. NIKHADE**

Firma :

Timbre y Fecha: Comisionado Adjunto (HQ) & Autoridad
Controladora

Administración de Alimentos & Medicamentos, M.S.
Bandra (E), Mumbai
Maharashtra State, India

Fecha: 26 de septiembre 2018



MR. SANIR PAUL PINTO
ASSISTANT MANAGER
26 SEP 2018

A copy of this document / CERTIFICATE
has been recorded with the Chamber

Authorized Signatory
Bandra Chamber of Commerce and Industry
Regn. No. 8989 Date 10 OCT 2018


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
 (Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
COMMERCIAL DOCUMENT

is issued to **WANBURY LTD.**

has been signed by **SAMIR PAUL PINTO**

with the seal / stamp of **ASSTT. MANAGER, BOMBAY CHAMBER OF COMMERCE AND INDUSTRY**

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
 on **16-Oct-2018** at **NEW DELHI, INDIA**
 with reference no. **MHMC0032421718**

Seal / Stamp: 

Signature: 
(ASHOK KUMAR)
 असोक कुमार (अध्यापक)
 Section Officer (Authentication)
 सी. ए. ओ. विभाग (C.E.O. Division)
 12003 अंतर्देशीय, नई दिल्ली
 Ministry of External Affairs, New Delhi

This document is to be used in the following countries: All

The Signature of Shri. S. M. H. Zaidi
 is hereby certified
 Home Department, Maharashtra accepts
 no responsibility for the contents
 of the document.




Section Officer
Home Department
Government of Maharashtra
Mantralaya, Mumbai

10 OCT 2018

महाराष्ट्र शासन
आयुक्त
अन्न व औषध प्रशासन, महा. राज्य
३४१, वांद्रे - कुर्ला संकुल, रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.



GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/75315/2018/ 3066 /11

दिनांक. २८/१/२०१८

प्रति,
WANBURY LIMITED
RAIGAD

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजूरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 75315

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/75315 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत.

सहआयुक्त, मुख्यालय, मुंबई यांचे मान्यतेने



आमला
(सुसं मोहिते)

सहायक आयुक्त (मुख्यालय) का क्र.११
अन्न व औषध प्रशासन, म. राज्य.



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S. M. H. ZAIDI
NOTARY
Government of India
Mumbai & Thane Dist.

10 OCT 2018



Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra - Kurla Complex,
Bandra (E),
Mumbai - 400 051

Date : 26 SEP 2018

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This Certificate conforms to the format recommended by the World Health Organization.

(General instructions and explanatory notes attached).

Certificate No.: **NEW-WHO-GMP/CERT/KD/75315/2018/11/25070**

On the basis of the inspection carried out on **16/08/2018 & 17/08/2018**, we certify that the site indicated on this Certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1.

1. Name of the Firm : **WANBURY LIMITED**
Address : **A-15, M.I.D.C. INDUSTRIAL AREA,
PATALGANGA, TAL. KHALAPUR, DIST.
RAIGAD 410220 MAHARASHTRA STATE,
INDIA**
2. Licence No. : **KD242 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical Ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	Granules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 25 Sep 2021 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
INAW7997531520180926

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 26 Sep 2018



26 SEP 2018

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/KD/75315/2018/11 VALID UP TO :25 Sep 2021
/25070
Name of Manufacturing Firm : WANBURY LIMITED
A-15, M.I.D.C. INDUSTRIAL AREA,
PATALGANGA, TAL. KHALAPUR, DIST. RAIGAD
410220 MAHARASHTRA STATE, INDIA
Drug License No : KD242 In Form 25

Sr.No.	Name of the Product	Composition
1	Metformin Hydrochloride BP	1 gm contains 100 % W/W Metformin Hydrochloride : Metformin Hydrochloride BP 100 %
2	Metformin Hydrochloride EP	1 gm contains 100 % W/W Metformin Hydrochloride : Metformin Hydrochloride EP 100 %
3	Metformin Hydrochloride IP	Metformin Hydrochloride IP 100 %
4	Metformin Hydrochloride USP	1 gm contains 100 % W/W Metformin Hydrochloride : Metformin Hydrochloride USP 100 %
5	Metformin Hydrochloride DC Granules 90% w/w	1 gm contains 90 % W/W Metformin Hydrochloride : Metformin Hydrochloride IHS 90 % w/w Polyvinylpyrrolidone K-30 IHS 3.0 % Maize Starch IHS 1.2 % Magnesium Stearate IHS 0.4 % Aerosil IHS 0.9 % Microcrystalline Cellulose IHS 4.5 %
6	Metformin Hydrochloride DC Granules 95% w/w	1 gm contains 95 % W/W Metformin Hydrochloride : Metformin Hydrochloride IHS 95 % w/w Polyvinylpyrrolidone K-30 IHS 2.7 % Maize Starch IHS 1.8 % Magnesium Stearate IHS 0.3 % Aerosil IHS 0.2 %
7	Metformin Hydrochloride DC Granules 86.6% w/w	1 gm contains 86.6% W/W Metformin Hydrochloride : Metformin Hydrochloride IHS 86.6 % w/w Polyvinylpyrrolidone K-30 IHS 6.94 % Maize Starch IHS 1.74 % Sodium Starch Glycollate IHS 3.52 % Aerosil IHS 1.2 %

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra, INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1NAW7997531520180926

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:26 Sep 2018

MR. SAMIR PAUL PINTO

ASSISTANT MANAGER

26 SEP 2018

A copy of this document / CERTIFICATE
has been recorded with the Chamber

Authorized Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 8888 10 OCT 2018


भारत सरकार GOVERNMENT OF INDIA
अपोस्टिल / APOSTILLE
 (Convention de La Haye du 5 octobre 1961)
INDIA

This public document of the type
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with the seal / stamp of **ASSTT. MANAGER, BOMBAY CHAMBER OF COMMERCE AND INDUSTRY**

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS
 on **16-Oct-2018** at **NEW DELHI, INDIA**
 with reference no. **MHMC0032421718**

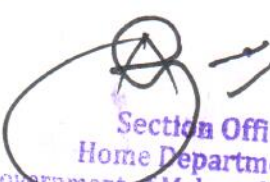
Seal / Stamp  Signature


रमेश कुमार (ASHOK KUMAR)
 अनुमान अधिकारी (सत्यापन)
 Section Officer (Attestation)
 सी. पी. डी. बंगला / C.P.V. Division
 विदेश मंत्रालय, नई दिल्ली
 Ministry of External Affairs, New Delhi



The Signature of Shri. S. M. H. Zaidi
 is hereby certified
 Home Department, Maharashtra accepts
 no responsibility for the contents
 of the document.




Section Officer
Home Department
Government of Maharashtra
Mantralaya, Mumbai

10 OCT 2018

