Certificate No: UK GMP 18593 Insp GMP 18593/11082-0010

MHRA
Regulating Medicines and Medical Devices

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	MEDREICH LIMITED (UNIT 3)
Site address	SURVEY NO 4/3 AVALALHALLI ANJANAPURA POST KANAKUPURA ROAD BANGALORE IN-560-062 INDIA

NOTARY
S.M.H. ZAIDI
Mumbai & Thane Dist.
Regn. No. 3640
GOVT. OF INDIA

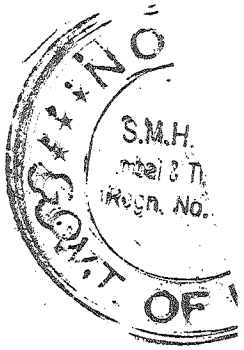
Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art.111(4) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

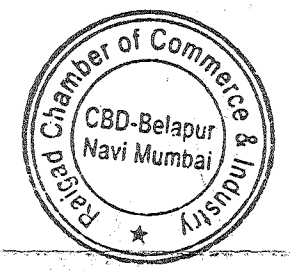
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/10/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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 only valid 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.


S.M.H.
Regn. No.


Raigad Chamber of Commerce & Industry
CBD-Belapur
Navi Mumbai

MHRA
Regulating Medicines and Medical Devices

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ane Dist.
3640
NDIA

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.13 Tablets

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.2 Microbiological: non-sterility
1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

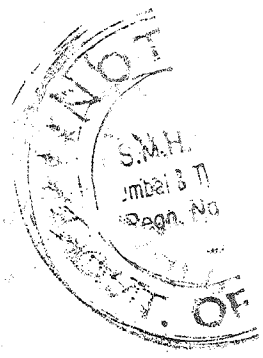
Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

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3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

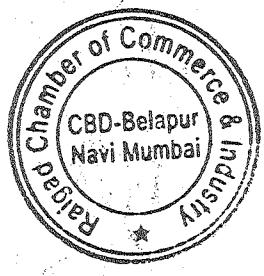
3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised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Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Ian Holloway
GMP Inspector
Ian.Holloway@mhra.gov.uk

Date: 17/02/2018

NOTARIAL NOTARIAL NOTARIAL NOTARIAL NOTARIAL

S.M.H. ZAIDI Mumbai & Thane Dist. Regn. No. 3649

GOVT. OF INDIA

ATTESTED BY ME

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

- 2 AUG 2018

For Raigad Chamber of Commerce & Industry

Sharad Khatre
Secretary

Raigad Chamber of Commerce & Industry
CBD-Belapur
Navi Mumbai

07 AUG 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 MEDREICH LTD.

has been signed by SHARAD KHATRE

with the seal / stamp of SECRETARY, RAIGAD CHAMBER OF COMMERCE & INDUSTRY

Certified by
Section Officer(OI) MINISTRY OF EXTERNAL AFFAIRS

on 09-Aug-2018 *at* NEW DELHI, INDIA

with reference to MHMC0026202018

(DEBABRATA PAL) Signature
Section Officer (OI)
Ministry of External Affairs
New Delhi

Seal / Stamp

Certificado No: UK GMP 18593 Insp GMP 18593/11082-0010

Vania Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA

Agencia Regulatoria de Medicinas y Productos para el Cuidado de la Salud

CERTIFICADO DE CUMPLIMIENTO BPM DE UN FABRICANTE

Parte 1

Emitido seguido a la inspección de acuerdo al Art. 111(5) de Directiva 2001/83/EC.

La autoridad competente del Reino Unido confirma lo siguiente:

El fabricante MEDREICH LIMITED (UNIT 3)
Dirección del sitio SURVEY NO 4-3
AVALALHALLI
ANJANAPURA POST
KANAKUPURA ROAD
BANGALORE
IN-560-062
INDIA

Ha sido inspeccionada en conexión a la autorización de mercadeo de fabricantes listados fuera del Área Económica Europea de acuerdo al Art. 111(4) de Directiva 2001/83/EC transpuesto en la siguiente legislación nacional: Las Regulaciones de Medicinas Humanas 2012 (SI 2012/1916).

Del conocimiento obtenido durante la inspección de este fabricante, la última realizada el 10/10/2017, se considera que cumple con los principios y guías de Buenas Prácticas de Manufactura establecida en la Directiva 2003/94/EC.

Este certificado refleja el estado del sitio de manufactura al momento de la inspección registrado anteriormente y no debe se debe confiar para reflejar el estado si más de tres años han pasado desde la fecha de la inspección. Sn embargo, este período de validez puede ser reducido o extendido usando principios de manejo de riesgos regulatorios por una entrada en el campo de observaciones de Restricciones o Aclaraciones.

Este certificado es solo válido cuando es presentado con todas las 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.


S.M.H.
Regn. No.


Raigad Chamber of Commerce & Industry
CBD-Belapur
Navi Mumbai

Parte 2

Productos Medicinales Humanos

1. OPERACIONES DE MANUFACTURA

1.1 Productos estériles

No Autorizado

1.2 Productos no estériles

1.2.1 Productos no estériles (operaciones de procesamiento para las siguientes formas de dosis)

1.2.1.13 Tabletas

1.3 Productos medicinales biológicos

No Autorizado

1.4 Otros productos o actividad de manufactura

No Autorizado

1.5 Empaquetado

1.5.2 Empaquetado secundario

1.6 Prueba de control de calidad

1.6.2 Microbiológica: no estéril

1.6.3 Química/física

2. IMPORTACIÓN DE PRODUCTOS MEDICINALES

2.1 **Prueba de control de calidad de productos medicinales importados**

No Autorizado

2.2 **Certificación del lote de productos medicinales importados**

No Autorizado

2.3 **Otras actividades de importación**

No Autorizado


S.M.H.
Regn. No


Raigad Chamber of Commerce & Industry
CBD-Belapur
Navi Mumbai

3 OPERACIONES DE MANUFACTURA

3.1 Manufactura de Sustancia Activa por Síntesis Química
No Autorizado

3.2 Actividades de Procesamiento de Sustancia Activa de Fuentes Naturales
No Autorizado

3.3 Manufactura de Sustancia Activa usando Procesos Biológicos
No Autorizado

3.4 Manufactura de Sustancia Activa Estéril
No Autorizado

3.5 Pasos de Finalizado Generales
No Autorizado

3.6 Prueba de Control de Calidad
No Autorizado

4 Otras Actividades
No Autorizado


Raigad Chamber of Commerce & Industry
CBD-Belapur
Navi Mumbai

Cualquier restricción u observación aclaratoria relacionada al alcance de este certificado.

N/A

1. Edificio(s)/Área(s)

   N/A

2. Habitación(es)

   N/A

3. Línea(s) de Equipo(s)

   N/A

4. Prueba QC

   N/A

5. Producto(s) Medicinal(es)/IMP(s)

   N/A

Nombre de la persona autorizada de la Autoridad Competente del Reino Unido

Ian Holloway
Inspector GMP
Ian.Holloway@mhra.gov.uk

Fecha: 17/02/2018

NOTARIAL NOTARIAL NOTARIAL NOTARIAL NOTARIAL

ATTESTED BY ME

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

- 2 AUG 2018

For Raigad Chamber of Commerce & Industry

Sharad Mhatre
Secretary

Raigad Chamber of Commerce & Industry
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