



MHRA
Regulating Medicines and Medical Devices

TRUE COPY

MHRA

151 Buckingham Palace Road
Londres SW1W 9SZ
Reino Unido

mhra.gov.uk

RESTRINGIDO – COMERCIAL

Sr. S. Jaiswal

MACLEODS PHARMACEUTICALS LIMITED

VILLAGE THEDA

POST OFFICE LODHIMAJRA

TEHSIL BADDI

DISTRICT SOLAN

HIMACHAL PRADESH

IN-174101

INDIA

Vania Silva Sepúlveda
Asesor Técnico
Ascend Laboratories SpA

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11 FEB 2019

C. L. SHARMA
C. L. SHARMA M.A. LL.B
NOTARY - GOVT. OF INDIA
Brhan - Mumbai, C - 26, Hiramani
Dadabhai Cross Road - 2,
Andheri (W), Mumbai - 400 058.
Reg. No. 482.



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

Authorized Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 146776, Date 11 FEB 2019

MR. SAMIR PAUL PINTO
ASSISTANT MANAGER



**Medicines and Healthcare
Products Regulatory Agency**

Y2002002



Y2002002

C. L. SHARMA
Ministry of External Affairs
New Delhi
17 JAN 2019

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 **MACLEODS PHARMACEUTICALS 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 19-Feb-2019 at **NEW DELHI, INDIA**

with reference no. **MA/0004028019**

Seal / Stamp

(अशोक कुमार)
(ASHOK KUMAR)
अनुयाय अधिकारी (सहकारण)
Section Officer (Attestation)
श्री. पी. पी. प्रधान / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

मु0568



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

CERTIFICADO DE CUMPLIMIENTO DE BPM DEL FABRICANTE

Parte 1

Se emite seguido de una inspección de acuerdo con el Art. 111(5) de Directiva 2001/83/EC.

La autoridad competente del Reino Unido confirma lo siguiente:

El fabricante: MACLEODS PHARMACEUTICALS LIMITED
Dirección del sitio VILLAGE THEDA
POST OFFICE LODHIMAJRA
TEHSIL BADDI
DISTRICT SOLAN
HIMACHAL PRADESH
IN-174101
INDIA

Ha sido inspeccionado en conexión con autorización(es) de comercialización listadas por el fabricante localizadas fuera del Área Económica Europea en conformidad con el Art. 111(4) de Directiva 2001/83/EC transpuesto en la siguiente legislación nacional: Regulaciones de Medicinas Humanas 2012 (SI 2012/1916).

Del conocimiento obtenido durante la inspección de este fabricante, la última realizada el 27/04/2017, se considera que cumple con los principios y guías de las Buenas Prácticas de Manufactura dispuestas en la Directiva 2003/94/EC.

Este certificado refleja el estado del sitio de manufactura 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 principios de administración de riesgos regulatorios por una entrada en el campo de observaciones de las Restricciones o Clarificaciones.

Este certificado es válido solo cuando sea 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.

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)

1.2.1.1 Cápsulas, cáscara dura

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 esterilidad

1.6.3 Química/física

2. IMPORTACIÓN DE PRODUCTOS MEDICINALES

2.1 Prueba de control de calidad de productos medicinales importados

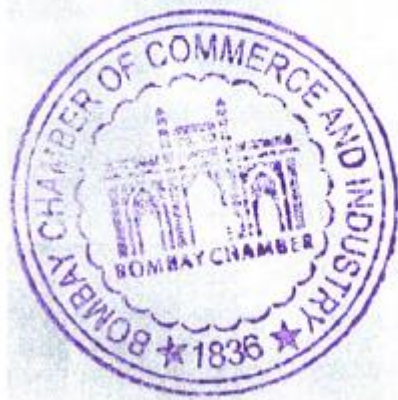
No Autorizado

2.2 Certificación del lote de productos medicinales importados

No Autorizado

2.3 Otras actividades de importación

No Autorizado



3. OPERACIONES DE MANUFACTURA

3.1 Manufactura de la Sustancia Activa por Síntesis Química

No Autorizado

3.2 Actividades de Procesamiento de la Sustancia Activa de Fuentes Naturales

No Autorizado

3.3 Manufactura de la Sustancia Activa usando Procesos Biológicos

No Autorizado

3.4 Manufactura de la sustancia activa estéril

No Autorizado

3.5 Pasos de Terminado Generales

No Autorizado

3.6 Pruebas de Control de Calidad

No Autorizado

4 Otras Actividades

No Autorizado



Cualquier restricción u observación aclaratoria relacionada al ámbito de este certificado:

El Certificado BPM EU es para Tabletas y Cápsulas de Gelatina Dura producidas en Edificio Block N2 (Block General)

1. Edificio(s)/Área(s)

Block N2 solo aprobado.

2. Habitación(es)

N/A

3. Equipo(s) de Línea(s)

N/A

4. Prueba de QC

Para Tabletas y Cápsulas producidas en Block N2.

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

N/A

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

Ian Holloway

Inspector BPM

Ian.Holloway@mhra.gsi.gov.uk

Fecha: 21/08/2017





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Regulating Medicines and Medical Devices

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151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

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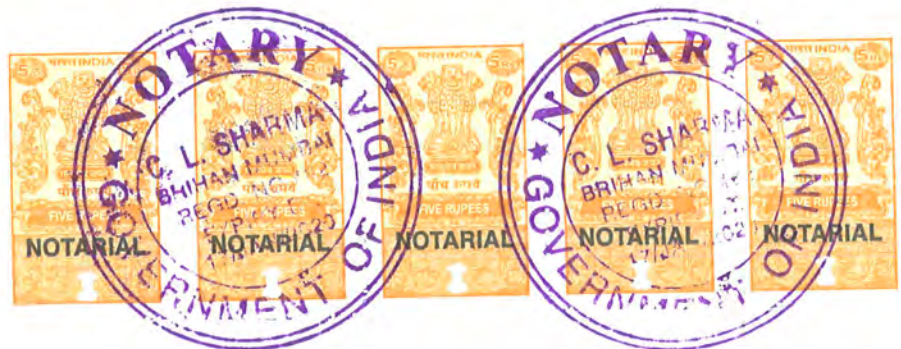
RESTRICTED – COMMERCIAL
Mr S Jaiswal
MACLEODS PHARMACEUTICALS LIMITED
VILLAGE THEDA
POST OFFICE LODHIMAJRA
TEHSIL BADDI
DISTRICT SOLAN
HIMACHAL PRADESH
IN-174101
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MR. SAMIR PAUL PINTO
ASSISTANT MANAGER



Medicines and Healthcare
Products Regulatory Agency

Y 4 0 2 5 3 0 2



CELESTIAL TRUST COMPANY

NOTARY

C. L. SHARMA, N.B.
Notary Public - Government of India
Registration No. 40, Expiry Date 17 JAN 2019
District Court, Mumbai - 400 001
Phone: 829 708 - 829 709
Fax: 829 708


Country: INDIA

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

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मु 0568
GOVT. OF INDIA, NEW DELHI

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Ministry of External Affairs, New Delhi

The Ministry of External Affairs
has no responsibility for the
contents of the above documents



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	MACLEODS PHARMACEUTICALS LIMITED
Site address	VILLAGE THEDA POST OFFICE LODHIMAJRA TEHSIL BADDI DISTRICT SOLAN HIMACHAL PRADESH IN-174101 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).

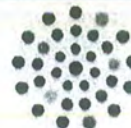
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27/04/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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.





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)

1.2.1.1 Capsules, hard shell

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

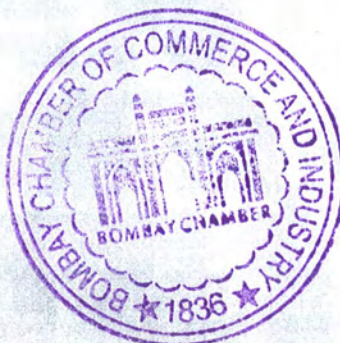
Not Authorised

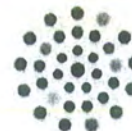
2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

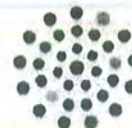




3. MANUFACTURING OPERATIONS

- 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





Any restrictions or clarifying remarks related to the scope of this certificate:

The EU GMP Certificate is for Tablets and Hard Gelatin Capsules produced in Building Block N2 (General Block)

1. Building(s)/Area(s)

Block N2 approved only.

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

For Tablets and Capsules produced in Block N2.

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.gsi.gov.uk

Date: 21/08/2017

