



Bahagian Regulatori Farmasi Negara
National Pharmaceutical Regulatory Agency
KEMENTERIAN KESIHATAN MALAYSIA
MINISTRY OF HEALTH MALAYSIA

36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia

Tel : +603-78835400
Fax: +603-79562924 / 79581312
<http://nptra.moh.gov.my>

GMP Certificate No. M029/19

Our Ref. : KKM/NPRA.PKP/600-2/5 (17) 2019
Date : 27 September 2019

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confirms the following:

The Manufacturer : **FDC Limited**
Site Address : **B-8, M.I.D.C., Industrial Area,
Waluj, Aurangabad - 431136,
Maharashtra,
India.**



Has been inspected in accordance with Malaysian Control of Drugs and Cosmetics Regulations 1984 and Malaysian Drug Registration Guidance Document (DRGD).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **8-12 April 2019**, it is considered that it complies with the principles and guidelines of the current Pharmaceutical Inspection Co-Operation Scheme (PIC/S) GMP Guides.

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, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts I and II.

The authenticity of this certificate may be verified with the issuing authority.


(MUHAMMAD LUKMANI IBRAHIM) RPh. 1046
Head of Centre for Compliance and Licensing



A copy of this document/CERTIFICATE
has been recorded with the Chamber
Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 30549 Date **20 JAN 2020**

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Certified to ISO 9001: 2008
Cert. No. AR 2293



Member of
Pharmaceutical Inspection
Cooperation Scheme



Non Member Adherence to
Mutual Acceptance of
Data for GLP



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

Country **REPUBLIC OF INDIA**

This public document
COMMERCIAL DOCUMENT

has been signed by N/A

acting in the capacity of N/A

bears the seal/stamp of **BOMBAY CHAMBER OF COMMERCE AND INDUSTRY**

Certified
at **NEW DELHI, INDIA** the **27-Jan-2020**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **MHMC0002459320**

Seal / Stamp is issued to **FDC LTD.**

Signature 



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. डी. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs New Delhi



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Part II

✓ Human Medicinal Products

1. MANUFACTURING OPERATIONS – MEDICINAL PRODUCTS

1.1	Sterile Products
	1.1.1 Aseptically prepared (processing operations for the following dosage forms)
	1.1.1.6 Other aseptically prepared products - Eye drops
	1.1.3 Batch certification
1.5	Packaging
	1.5.2 Secondary packing
1.6	Quality Control Testing
	1.6.1 Microbiological: sterility
	1.6.3 Chemical/Physical

Any restrictions or clarifying remarks related to the scope of this certificate: -None-

----- End of pages -----



ATTESTED BY ME

N. S. BHAI SARE
20/01/2020
N. S. BHAI SARE
NOTARY
GOVT. OF INDIA



Muhammad Lukmani Ibrahim
(MUHAMMAD LUKMANI IBRAHIM) RPh. 1046
Head of Centre for Compliance and Licensing

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Agencia Reguladora Farmacéutica Nacional
KEMENTERIAN KESIHATAN MALAYSIA

MINISTERIO DE SALUD DE MALASIA

36, Jalan Universiti, 46200 Petaling Jaya, Selangor, Malaysia

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Certificado BPM No. M029/19

Nuestra Ref. : KKM/NPRA.PKP/600-2/5 (17) 2019

Fecha : 27 de septiembre de 2019

Traducción fiel
al original

CERTIFICADO DE CUMPLIMIENTO DE UN FABRICANTE

Parte I

La Agencia Reguladora Farmacéutica Nacional, Ministerio de Salud de Malasia, confirma lo siguiente:

El Fabricante : **FDC LIMITED**

Dirección del Sitio : **B-8, M.I.D.C., Industrial Area,
Waluj, Aurangabad – 431136,
Maharashtra,
India.**



Ha sido inspeccionado de acuerdo con las Regulaciones de Control de Medicamentos y Cosméticos de Malasia 1984 y el Documento de Guías de Registro de Medicamentos de Malasia (DRGD).

Del conocimiento obtenido durante la inspección de este fabricante, la última realizada el **8-12 de abril de 2019**, se considera que cumple con los principios y directrices de las actuales guías BPM Esquema de Co-Operación de Inspección Farmacéutica (PIC/S).

Este certificado refleja el estado del sitio de manufactura al momento de la inspección anotado anteriormente y no se debe confiar en este para reflejar el estado de cumplimiento si más de tres años han pasado desde la fecha de inspección. Luego de este tiempo la autoridad emisora debe ser consultada.

Este certificado es válido solo cuando sea presentado con todas sus páginas y ambas Partes I y II.

La autenticidad de este certificado puede ser verificada con la autoridad emisora.


(MUHAMMAD LUKMANI IBRAHIM) RPh. 1046

Jefe del Centro de Cumplimiento y Licencias



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

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 30549 Date

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Ministry of External Affairs New Delhi

Ministry of External Affairs
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contents of the above documents.



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Parte II

✓ Productos Medicinales para Humanos

1. OPERACIONES DE MANUFACTURA – PRODUCTOS MEDICINALES

1.1	Productos Estériles
1.1.1	Preparados asépticamente (operaciones de procesamiento para las siguientes formas de dosis)
1.1.1.6	Otros productos preparados asépticamente – Gotas para los ojos
1.1.3	Certificación de lote
1.5	Empaquetado
1.5.2	Empaquetado secundario
1.6	Prueba de Control de Calidad
1.6.1	Microbiológico: esterilidad
1.6.3	Químico/Físico

Cualquier restricción u observación aclaratoria relacionada al alcance de este certificado: -Ninguna-

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[Signature]
N. S. BHUISARE
NOTARY
GOVT. OF INDIA



20 JAN 2020

[Signature]
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