



#### 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://npra.moh.gov.my

THAME

GMP Certificate No. M029/19

Our Ref.

: KKM/NPRA.PKP/600-2/5 ( 17 ) 2 LD9

: 27 September 2019 Date

# CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

#### Part I

The National Pharmaceutical Regulatory Agency, Ministry of Health Malaysia confidence 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 is document/CERTIFICATE ded with the Chamber

Authorised Signatory

Bombay Chamber of Commerce and Industry

Regn. No.30.549 ... Date

20 JAN 2020

Page 1 of 2

(MUHAMMAD LUKMANI IBRAHIM) RPh. 1046

Head of Centre for Compliance and Licensing

Certified to ISO 9001: 2008

Cert. No. AR 2293



Mutual Acceptance of Data for GLP





# भारत सरकार GOVERNMENT OF INDIA अपोस्टिल / APOSTILLE

(Convention de La Haye du 5 octobre 1961)

# REPUBLIC OF INDIA linistry of External Affairs accepts no responsibility for the

This public document

COMMERCIAL DOCUMENT has been signed by

acting in the capacity of N/A

N/A

contents of the above documents bears the seel/stamp of BOMBAY CHAMBER OF COMMERCE AND

#### Certified

NEW DELHI, INDIA the 27-Jan-2020

SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS

Seal / Stamp

is issued to FDC LTD.



(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई) \
Section Officer (OI)
सी. पी. पी. प्रभाग / C.P.V. Divie ( )
विवेश मञ्जालग, नई दिल्ली

Ministry of External Affairs New





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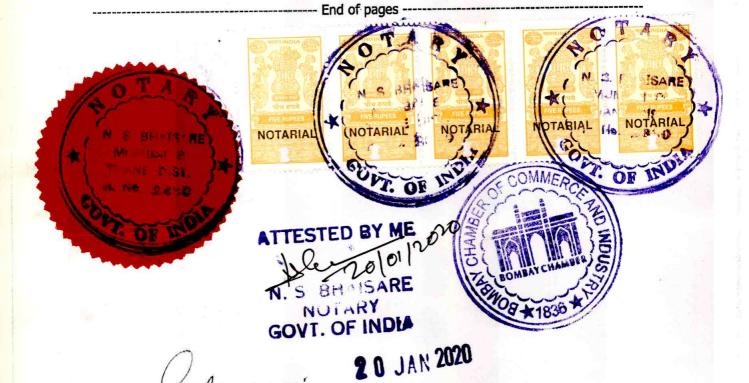
SMP Certificate No. M029/19

#### Part II

√ Human Medicinal Products

1. MA	NUFACTURING 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-



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

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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



Certificado BPM No. M029/19



#### Bahagian Regulatori Farmasi Negara

Agencia Reguladora Farmacéutica Nacional KEMENTERIAN KESIHATAN MALAYSIA

MINISTERIO DE SALUD DE MALASIA

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

Nuestra Ref.

: KKM/NPRA.PKP/600-2/5 ( 1) ) JUST

Tel: +603-78835400

http://npra.moh.gov.my

Fax: +603-79562924 / 79581312

**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, confi

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. TA CODY OF THIS document/CERTIFICATE

uthorised Signatory

Bombay Chamber of Commerce and Industry

ded with the Chamber

Regn. No.30.549 Date

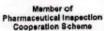
20 JAN 2020

(MUHAMMAD LUKMANI IBRAHIM) RPh. Jefe del Centro de Cumplimiento y Licencias

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(स्मील चनाय) (SUNIL CHANAP) अनुमान अधिकारी (ओ आई) Section Officer (OI) जी. के. के. क्यान / C.P.V. Divis 1 : विवेश संज्ञानत, गई विल्ली क्र Ministry of External Atlairs New





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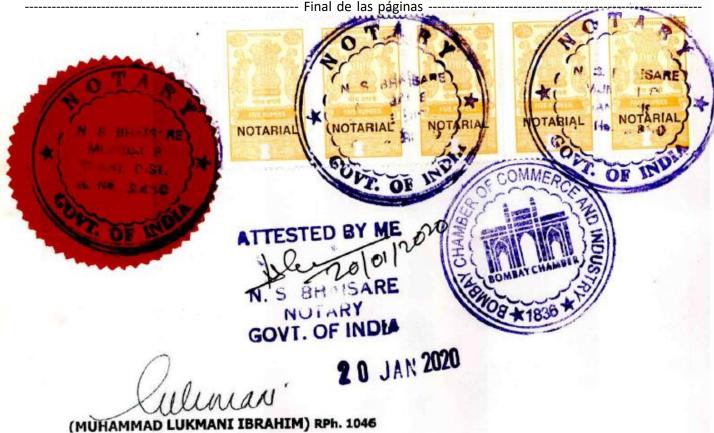
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#### Parte II

**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-



Jefe del Centro de Cumplimiento y Licencias

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