

L.Dis.No:81754/TS/2022

Dated:31/05/2022
Valid until:29/05/2025

Sub: Drugs and Cosmetics Act, 1940 and Rules made thereunder – Issue of World Health Organisation G.M.P. Certificate –
Regarding

Ref: 1. Your letter dated: **09/02/2022**.
2. Joint Inspection report .

-X-X-X-X-

With reference to your application cited, I forward herewith **World Health Organisation GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Telangana State & Drugs Inspector, CDSCO, Hyderabad vide reference 2nd cited.



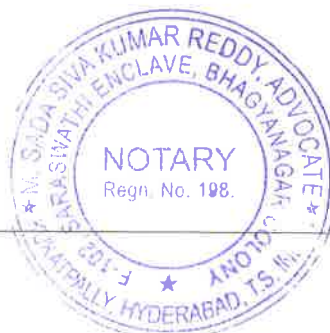
Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:31-05-2022 15:46:06 PM

L.Dis.No:81754/TS/2022

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LIST OF PRODUCTS APPROVED UNDER WHO-GMP
CERTIFICATION SCHEME FOR EXPORT PURPOSE

S.No	Generic Name	Brand Name	Composition	PackSize	Market
1	Cefdinir JP/USP/CP				Domestic & Export
2	Cefditoren Pivoxil JP/In-house				Domestic & Export
3	Cefixime USP/BP/JP/Ph.Eur				Domestic & Export
4	Cefpodoxime Proxetil USP/Ph.Eur/CP/JP				Domestic & Export
5	Cefprozil USP/Ph.Eur				Domestic & Export
6	Ceftibuten Hydrate JP/In-house				Domestic & Export







**DRUGS CONTROL ADMINISTRATION
Government of Telangana**



- 7 Cefuroxime Axetil
(Amorphous /
Crystalline)
USP/BP/Ph.Eur/CP/IP
- 8 Cefuroxime Axetil DC
grade (Each gram
contains Cefuroxime
Axetil IP/USP 714 mg
Equivalent to
Cefuroxime 580 mg)
USP

Domestic &
Export

Domestic &
Export

Manufacturer: M/S M/s COVALENT LABORATORIES PVT. LTD.,
SURVEY.374,GUNDLA MACHANOR VILLAGE,HATHNOOR
MANDAL,SANGAREDDY DIST, TELANGANA , INDIA -502296, GUNDLA
MACHNUR VILLAGE, HATHNOORA MANDAL, SANGAREDDY
DISTRICT,PINCODE 502296,TELANGANA STATE,INDIA

Drug License No: 07/MD/AP/2003/B/R,
Dated:24/02/2013 Under Form 28 ,valid upto 23/02/2023

When applicable Placing the product on the market as detailed below.

The Unit M/S M/s COVALENT LABORATORIES PVT. LTD., SURVEY.374,GUNDLA MACHANOR VILLAGE,HATHNOOR
MANDAL,SANGAREDDY DIST, TELANGANA , INDIA -502296, GUNDLA MACHNUR VILLAGE, HATHNOORA MANDAL,
SANGAREDDY DISTRICT,PINCODE 502296,TELANGANA STATE,INDIA Telangana State,India was inspected jointly by

It is certified that:

- i. The above products had been authorized to be placed on the market for use in the country and exported countries
- ii. The manufacturing plant in which the product is produced is subject to inspection at suitable intervals.
- iii. The manufacturer conforms to requirements for Good Manufacturing Practices in the manufacture and Quality Control (As recommended by the World Health Organisation) in respect of products to be sold or distributed with in the Country of origin (or to be exported).

Digitally Signed By
RAMDHAN GUGULOTH
Deputy Director and Certifying Authority
DRUGS CONTROL ADMINISTRATION
TELANGANA STATE
Date:31-05-2022 15:46:06 PM

This Document is Digitally Signed. Signature is not required



ATTESTED
G. Dayanand
G. DAYANAND
Asst. Secretary
Andhra Chamber of Commerce
Secunderabad-500 003 (India)

ATTESTED

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W/AD

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

Country
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by **RAMDHAN GUGULOTH**
acting in the capacity of **DY. DIRECTOR**
bears the seal/stamp of **ANDHRA CHAMBER OF COMMERCE SEC BAD**

Certified
at **NEW DELHI, INDIA** the **29-Jun-2022**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **APHY0007410222**

Seal / Stamp
01 253692
is issued to **COVALENT LABORATORIES PVT. LTD.**

Signature
ef



(सुनील चणप)
(SUNIL CHANAP)
अनुभाग अधिकारी (सत्यापन / ओ.आई.)
Section Officer (Attestation/O.I.)
सी.पी.ओ. अनुभाग / C.P.O. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

L. Dis. No: 81754/TS/2022

Fecha: 31/05/2022

Válido hasta: 29/05/2025

Asunto: Acta de Medicamentos y Cosméticos de 1940 y Reglas subsecuentes – Respecto a – Emisión de Certificado de B.P.M. de la Organización Mundial de la Salud

Ref: 1. Su carta con fecha: **09/02/2022**.

2. Informe de inspección conjunto.

-X-X-X-X

En referencia a su solicitud citada, hacemos envío del Certificado de **BUENAS PRÁCTICAS DE MANUFACTURA de la Organización Mundial de la Salud** para los productos mencionados en el Informe de Inspección Conjunta de los Oficiales de la Administración de Control de Medicamentos, estado de Telangana & Inspector de Medicamentos, CDSCO, Hyderabad véase la segunda referencia citada.



Firmado digitalmente por

RAMDHAN GUGULOTH

Director Adjunto y Autoridad Certificadora

ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS

ESTADO DE TELANGANA

Fecha: 31-05-2022 15:46:06 PM

L. Dis. No: 81754/TS/2022

Fecha: 31/05/2022

Válido hasta: 29/05/2025

LISTA DE PRODUCTOS APROBADOS BAJO EL ESQUEMA DE
CERTIFICACIÓN OMS-BPM PARA LA EXPORTACIÓN

S.No.	Nombre genérico	Nombre de marca	Composición	Tamaño del paquete	Mercado
1	Cefdinir JP/USP/CP				Doméstico & Exportación
2	Cefditoren Pivoxil JP/Interno				Doméstico & Exportación
3	Cefixima USP/BP/JP/Ph.Eur				Doméstico & Exportación
4	Cefpodoxima Proxetil USP/Ph.Eur/CP/JP				Doméstico & Exportación
5	Cefprozil USP/Ph.Eur				Doméstico & Exportación
6	Ceftibuten Hidrato JP/Interno				Doméstico & Exportación



CHAMBER
OF
COMMERCE



ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS
Gobierno de Telangana



- | | | |
|---|--|----------------------------|
| 7 | Cefuroxima Axetil
(Amorfo /
Cristalino)
USP/BP/Ph.Eur/CP/JP | Doméstico &
Exportación |
| 8 | Cefuroxima Axetil
grado DC (Cada gramo
contiene Cefuroxima
Axetil IP/USP 714 mg
Equivalente a
Cefuroxima 580 mg)
USP | Doméstico &
Exportación |

Fabricante: M/S M/s COVALENT LABORATORIES PVT. LTD.,
SURVEY. 374, GUNDLA MACHANOR VILLAGE, HATHNOOR
MANDAL, SANGAREDDY DIST, TELANGANA, INDIA – 502296, GUNDLA
MACHNUR VILLAGE, HATHNOORA MANDAL, SANGAREDDY
DISTRICT, PINCODE 502296, TELANGANA STATE, INDIA

No. de licencia de medicamento: 07/MD/AP/2003/B/R,

Fecha: 24/02/2013 En la Forma 28, válida hasta el 23/02/2023

Cuando aplique: Colocar el producto en el mercado como se indica a continuación.

La Unidad M/S M/s COVALENT LABORATORIES PVT. LTD., SURVEY. 374, GUNDLA MACHANOR VILLAGE, HATHNOOR MANDAL, SANGAREDDY DIST, TELANGANA, INDIA – 502296, GUNDLA MACHNUR VILLAGE, HATHNOORA MANDAL, SANGAREDDY DISTRICT, PINCODE 502296, TELANGANA STATE, INDIA Telangana State, India fue inspeccionada en conjunto por:

Se certifica que:

- i. Los productos anteriores han sido autorizados para ser colocados en el mercado para su uso en el país y los países de exportación.
- ii. La planta de manufactura en la cual el producto de producido está sujeta a inspección a intervalos adecuados.
- iii. El fabricante está conforme a los requisitos para las Buenas Prácticas de Manufactura en la fabricación y control de calidad (como lo recomienda la Organización Mundial de la Salud) con respecto a los productos para ser vendidos o distribuidos en el país de origen (o para ser exportados)

Firmado digitalmente por

RAMDHAN GUGULOTH

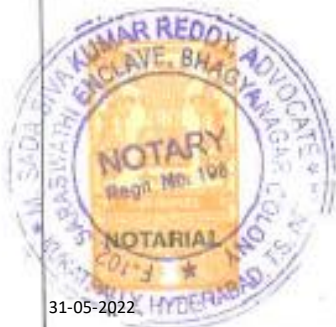
Director Adjunto y Autoridad Certificadora

ADMINISTRACIÓN DE CONTROL DE MEDICAMENTOS

ESTADO DE TELANGANA

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Este documento está firmado digitalmente. No requiere firma.



ATTESTED
G. Dayanand
G. DAYANAND
Asst. Secretary
Andhra Chamber of Commerce
Secunderabad-500 003 (India)

31-05-2022

ATTESTED

Página 2 / 2

<https://www.odls.telangana.gov.in>

M. SADA SIVA KUMAR REDDY, B.Com., B.A.
ADVOCATE & NOTARY
Appointed by Govt. India
G.O. Ms. No. 198, Rev (Regn-II), dt. 11.04.2000
102, Saraswathi Enclave, Bhagyanagar Colony,
Hyderabad T.S. India. (Ph: 98480 44395)

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N/A

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

128 Ministry of External Affairs
responsible for the
issuance of apostilles

Country
REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by **RAMDHAN GUGULOTH**
acting in the capacity of **DY. DIRECTOR**
bears the seal/stamp of **ANDHRA CHAMBER OF COMMERCE SEC. S&O**

Certified
at **NEW DELHI, INDIA** on **25-Jun-2022**
by **SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS**
No. **APHY0007410222**

Seal / Stamp
01 253692

is issued to **COVALENT LABORATORIES PVT. LTD.**

Signature
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(सुनील चणप)
(SUNIL CHANAP)
अनुभाग अधिकारी (सहसाधन / ओ. आ. 1)
Section Officer (Attestation/O.I.)
की. नी. प्रमाण - C.O.V. Division
विदेश संचालन एवं विकास
Ministry of External Affairs, New Delhi