Office of The Commissioner
Food and Drug Administration
Maharashtra State
2nd floor, Survey No. 341,
Bandra - Kurla Complex,
Bandra (East)
Mumbai - 400 501

Date : 12/6/2012

CERTIFICATE OF GOOD MANUFACTURING PRACTICES

This certificate conforms to the format recommended by the World Health Organization (general instructions and explanatory notes attached).

Certificate No.: WHO-GMP/CERT/NKD-NEW-169-2011/1013/11.

On the basis of the inspection carried out on 29/08/2011, 30/08/2011 and 11/11/2011 we certify that the site indicated on this certificate complies with **Good Manufacturing Practices** for the dosage forms, categories and activities listed in Table 1

1. Name and address of site:
   FDC Limited,
   PLOT NO. G - 1, MIDC,
   MALEGAON, SINNAR – 422 103,
   DIST. NASHIK,
   MAHARASHTRA STATE, INDIA

2. Manufacturer's license No. : **NKD / 42 in Form 25**

3. Table 1.

Sr. No.	Pharmaceutical Product (s)[1]	Category (ies)	Activity (ies)
	Dosage Form(s)		
1.	**ORAL POWDER**	General (Other than Hormones, Cytotoxic, Cefalosporin and Penicillin)	Production, Packaging, Labelling, Quality Control
	As per Annexure		

The responsibility for the quality of the individual batches of the Pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until – 7. JUN 2014 It becomes invalid if the activities and/ or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Name of the authorized person: **O. S. SADHWANI**

Signature:

Stamp and Date:
Joint Commissioner (Law)
Food and Drug Administration,
Maharashtra State, Bandra
Mumbai, INDIA

– 8. JUN 2012

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY *1836*

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

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 25630 Date 11 NOV 2013

SERVICIO CONSULAR 2013 10 10 US$ CHILE US$

SERVICIO CONSULAR 2013 2 2 US$ CHILE US$

CONSULADO DE CHILE EN
NUEVA DELHI, INDIA

El Conul de Chile que suscribe, certifica la autenticidad de la firma de don. GEORGE LAKRA funcionario para asuntos consulares del Ministerio de Relaciones Exteriores de India.
Actuacion No. 3319 Arancel Art No. 4/10
Derechos percibidos: US $ 12
NUEVA DELHI 20 de NOV de 2013

EMBAJADA DE CHILE EN INDIA SECCION CONSULAR

DERECHOS PAGADOS 12
COMPROB.DE PAGO No.
ACT. No. 3319 ART. 4 No. 10

Renato Gómez
Cónsul de Chile

Legalizada en el Ministerio de Relaciones Exteriores de Chile
Firma del Señor
RENATO GOMEZ
4 NOV 2013
MIGUEL REYES VARGAS
Oficial de Legalizaciones

सख्या 155569 दिनांक 18 NOV 2013
No. Date
वाणिज्य विभाग में सहायक सचिव/उप सचिव/
सचिव के हस्ताक्षर सत्यापित किए जाते है।
The Signature of Asstt. Secretary/
Dy. Secretary/Secretary of Chamber
of Commerce Attested.

विदेश मंत्रालय Ministry of External Affairs Govt. of India New Delhi मु०568

(जार्ज लाकरा)
(GEORGE LAKRA)
अनुभाग अधिकारी (सत्यापन)
Section Officer (Attestation)
सी.पी.वी. प्रभाग/C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs
New Delhi

Explanatory Notes

1. This certificate, which is in the format recommended by WHO, certifies the status of the site listed in point 1 of the certificate.

2. The certification number should be traceable within the regulatory authority issuing the certificate.

3. Where the regulatory authority issues a license for the site, this number should be specified. Record "not applicable" in cases where there is no legal framework for the issuing of a license.

4. Table 1

List the dosage forms, starting materials, categories and activities. Examples are given below:

Example 1

Pharmaceutical Product (s)[1]	**Category (ies)**	**Activity (ies)**
Dosage form (s)		
Tablets	Cytotoxic	Packaging
	Harmone	Production, Packaging, Quality Control
	Penicillin	Repackaging and labelling
Injectables	Cefalosporin	Aseptic preparation, Packaging, labelling

Example 2

Pharmaceutical Product (s)[1]	**Category (ies)**	**Activity (ies)**
Starting Material (s)[2]		
Paracetamol	Analgesic	Synthesis, Purification, Packing, labelling

Use, whenever available, International Nonproprietary Names (INNs) or otherwise national Nonproprietary names.

5. The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

6. The requirements for good practices the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999. World Health Organization, Geneva and subsequent updates.

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1836