

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-169-2011/1018/11.

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		

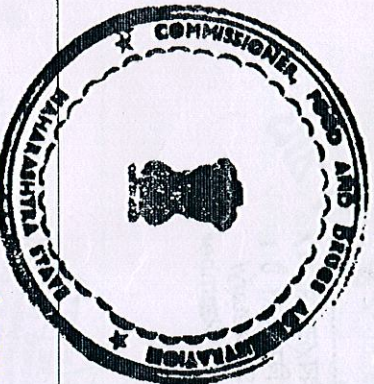
The responsibility for the quality of the individual batches of the Pharmaceutical products manufactured through this process lies with the manufacturer.

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

Name of the authorized person: O. S. SADHWANI

Signature: 

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



A copy of this document/CERTIFICATE **- 8. JUN 2012**
has been recorded with the Chamber

S. A. A. A.

Authorized Signatory

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



CONSULADO DE CHILE EN
NUEVA DELHI, INDIA



El Consul de Chile que suscribe, certifica la
autenticidad de la firma de don. CAE. RAUL AYALA
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



Renato Gómez
Cónsul de Chile

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

Legalizada en el Ministerio de
Relaciones Exteriores de Chile
Firma del Señor CAE. RAUL AYALA
4 NOV 2013
MIGUEL REYES VARGAS
Oficial de Legalizaciones

No. 155563 Date 18 NOV 2013
वर्णन : जिसे में सहस्रक सचिव/उप सचिव
सचिव से हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Assst. Secretary/
Dy. Secretary/Secretary of Chamber
of Commerce Attested.



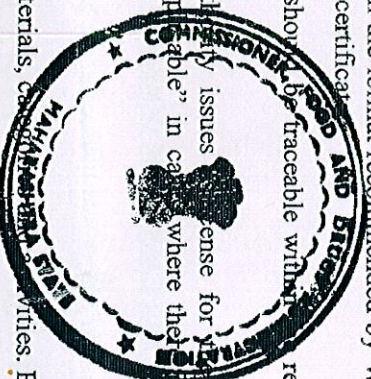
(सचिव सचिव)
(GEORGE LAKRA)
Section Officer (Attestation)
Dy. Secy. Secy./C.P.V. Division
Ministry of External Affairs
New Delhi

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 a 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
	Hormone	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.

