FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date :

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.: **NEW-WHO-GMP/CERT/KD/72769/2018/11/26252**

On the basis of the inspection carried out on **23/07/2018 & 24/07/2018** ,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 of the Firm : **BEC CHEMICALS PVT. LTD.**
   Address : **24, MIDC, DHATAV, ROHA, DIST-RAIGAD RAIGAD 402116 MAHARASHTRA STATE, INDIA**
2. Licence No. : **618 In Form 25**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Active Pharmaceutical ingredients (Bulk Drugs)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Synthesis, Purification, Packing, Labelling, Quality Control, Quality Assurance

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 17 Dec 2021 . 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.

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1CEB7757276920181218

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**18 Dec 2018**

18 DEC 2018

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 licence for the site , this number should be specified record "not applicable" in cases where there is no legal framework for the issuing of a licence.

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.
Injectables	Penicillin	Repackaging & Labelling.
	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.

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/72769/2018/11 /26252 **VALID UP TO :17 Dec 2021**

Name of Manufactring Firm : BEC CHEMICALS PVT. LTD.
24, MIDC, DHATAV, ROHA, DIST-RAIGAD
RAIGAD 402116 MAHARASHTRA STATE, INDIA

Drug License No : 618 In Form 25

Sr.No.	Name of the Product	Composition
1	Ketoprofen BP	N.A.
2	Ketoprofen EP	N.A.
3	Ketoprofen IP	N.A.
4	Ketoprofen USP	N.A.
5	Mesalamine USP	N.A.
6	Mesalazine BP	N.A.
7	Mesalazine EP	N.A.
8	Mesalazine IP	N.A.

1 2

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1CEB7757276920181218

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**18 Dec 2018**

18 DEC 2018

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/72769/2018/11 /26252 **VALID UP TO :17 Dec 2021**

Name of Manufactring Firm : BEC CHEMICALS PVT. LTD.
24, MIDC, DHATAV, ROHA, DIST-RAIGAD
RAIGAD 402116 MAHARASHTRA STATE, INDIA

Drug License No : 618 In Form 25

Sr.No.	Name of the Product	Composition
9	Dexketoprofen Trometamol	NA
10	Ketoprofen Lysine/ Ketoprofen Lysinate	N.A
1 2		

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1CEB7757276920181218

Name of the Authorised person : **A. T. NIKHADE**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**18 Dec 2018**

18 DEC 2018

महाराष्ट्र शासन
आयुक्त
अन्न वा औषध प्रशासन , महा. राज्य
३४१ , वांद्रे - कुर्ला संकुल , रिजर्व बँक
समोर, वांद्रे (पूर्व)
मुंबई - ४०० ०५१.

सत्यमेव जयते
FDA MAHARASHTRA
FOOD AND DRUG ADMINISTRATION

GOVERNMENT OF MAHARASHTRA
COMMISSIONER
Food and Drugs Administration (M.S.)
341, Bandra-Kurla Complex,
Opposite of RBI Buildings,
BAndra (E), Mumbai - 400 051
Tel : 022 - 26592362-65
E-Mail : comm.fda-mah@nic.in

क्र. NEW-WHO-GMP/CERT/KD/72769/2018/ 4345 /11 दिनांक. 21/12/2018

प्रति,
BEC CHEMICALS PVT. LTD.
RAIGAD

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 72769

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ KD/72769 (एकूण प्रमाणपत्रे 1) पाठवीण्यात येत आहेत

आपला

(जे बी मंत्री)
सह आयुक्त (मुख्यालय) करीता
अन्न व औषध प्रशासन , म. राज्य.