GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

No : DCD/SPCL/CR405/21-22
GSC No: DD008S210000038

Office of the Drugs Controller
For the State of Karnataka
P.B. No. 5377 ,Palace Road,
Bangalore - 560001
Date:13/07/2021

WHO GMP CERTIFICATE

This one page certificate conforms to the format recommended by the World Health Organization

(General Instructions and explanatory notes are attached)

On the basis of the inspection carried out on **09/04/2021** we certify that the site indicated on this certificate complies with Good Manufacturing Practices(GMP) for the dosage form categories and activities listed on Table 1

01.Name and Address of the site : KARNATAKA ANTIBIOTICS PHARMACEUTICALS LTD. ,
PLOT NO.14, II PHASE, PEENYA INDUSTRIAL AREA, BENGALURU 560058
INDIA..

A copy of this document/certificate
has been kept on record with the chamber.
A. Bhatnagar
Authorised Signatory
GLOBAL EXPORTS CHAMBER OF COMMERCE
R. No. 2656 Date 26 AUG 2021

02.Manufacturers Licence Numbers :SP-96/84 & NB-152/84.

03.Table 1:

S. No.	Pharmaceutical Products / Dosage forms	Category(ies)	Activity(ies)
1.	CAPSULES	ANTACIDS	PRODUCTION, PACKING & QUALITY CONTROL
2.	DRY POWDER INJECTIONS	PENICILLIN'S	PRODUCTION, ASEPTIC FILLING, PACKING & QUALITY CONTROL
3.	DRY POWDER INJECTIONS	CEPHALOSPORINS	PRODUCTION, ASEPTIC FILLING, PACKING & QUALITY CONTROL
4.	LIQUID INJECTIONS	ANTIOBIOTIC	PRODUCTION, ASEPTIC FILLING, PACKING & QUALITY CONTROL
5.	LIQUID ORALS	ANTIPARASITIC	PRODUCTION, PACKING & QUALITY CONTROL
6.	TABLETS	ANTHELMINITIC	PRODUCTION, PACKING & QUALITY CONTROL

The responsibility for the quality of the individual batches of the Pharmaceutical products manufactured through

this process lies with manufacturer.

This certificate remains valid upto **08/04/2024** . It become invalid if the activities and or categories certified herewith are changed or if the site is on longer considered to be in compliance with GMP.

This certificate is issued as per WHO TRS No.908 of 2003

Address of Certifying authority :Office of the Drugs Controller, For the State of Karnataka ,

Palace Road,Bangalore - 560001,INDIA.

Name of the Authorized Person:Amaresh Tumbagi.

Phone/Fax no:TEL:91-080-22264760,Fax:091-080-22286492.

Email:dckarnataka@gmail.com

Signature
Stamp & Date

Signature valid
Digitally signed by Signer Name
Date: 2021.08.07 13:00 IST
Amaresh Tumbagi
ADDITIONAL DRUGS
CONTROLLER &
LICENCING AUTHORITY

ATTESTED BY ME
CHANDRAKALA, M.A., LL.B.,
ADVOCATE & NOTARY
GOVT. OF INDIA
Indiranagar, Bangalore,
BENGALURU - 560 010.

NOTARY GOVT. OF INDIA

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

Country REPUBLIC OF INDIA

This public document
COMMERCIAL DOCUMENT
has been signed by AMARESH TUMBAGI
acting in the capacity of LICENSING AUTHORITY
bears the seal/stamp of GLOBAL EXPORTS CHAMBER OF COMMERCE, NEW DELHI

Certified

at NEW DELHI, INDIA *the* 26-Aug-2021
by SO (OI/Attestation) MINISTRY OF EXTERNAL AFFAIRS
No. DLND0001096121

Seal / Stamp *Signature*

is issued to KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD.

(सुनील चनप)
(SUNIL CHANAP)
Section Officer (Attestation/OI)
Ministry of External Affairs, New Delhi

Explanatory notes:

(1) This certificate, which is in the format recommeded 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 casewhere there is no legal framework for the issuing of a licence.
(4) Table 1
List the dosage forms, starting materials, categories and activities.
Examples give below.

Pharmaceutical	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)2	Category(ies)	Activity(ies)
Starting material(s):3		
Paracetamol	Analgesic	Synthesis, purification,packing, labelling

2 Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

3 Starting Materials: Any substance of a defined quality used in the production of alpharmaceutical product, but excluding packaging materials.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 in 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.

NOTARY GOVT. OF INDIA

EXPORTS CHAMBER OF COMMERCE & GLOBAL NEW DELHI

कर्नाटक एंटीबायोटिक्स एण्ड फार्मास्युटिकल्स लिमिटेड
(भारत सरकार का उद्यम)
KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED
(A Government of India Enterprise)

August 18, 2022

TO WHOMSOEVER IT MAY CONCERN

DECLARATION LETTER

Subject:
Error in the name of the company in the WHO-GMP Certificate

Currently, with effect from November 09, 2020, an application for obtaining the WHO-GMP certificate has been made as an online process by the Government of Karnataka through a common citizen service portal/facility known as the Seva Sindhu Portal to provide government related services and other information in one place to save time and money.

The name of the firm is mentioned as '**KARNATAKA ANTIBIOTICS PHARMACEUTICALS LTD'** in the WHO GMP Certificate instead of "M/s. KARNATAKA ANTIBIOTICS **AND** PHARMACEUTICALS LIMITED" due to the constraints in the space provided.

This is the first time that an application for the WHO-GMP certificate has been made as an online process and we have brought this issue to the notice of the Drug Control Department and the software is being upgraded to address the issue.

We request you to kindly consider the WHO-GMP Certificate that has been submitted to your good office.

Thanking you,

For M/s. Karnataka Antibiotics And Pharmaceuticals Limited,

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LTD.
FACTORY:
PLOT No. 14
2nd PHASE
PEENYA INDUSTRIAL
AREA
BANGALORE-58

B. U. Kamath
General Manager – Plant
Head of:
Quality Assurance,
Quality Control,
Formulation Development and
Regulatory Affairs (Domestic)