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/ND/83543/2019/ 2525 /11 दिनांक. 19/07/2019

प्रति,
SNEHAL PHARMA & SURGICALS PVT. LTD
NAGPUR

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 83543

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ ND/83543 (एकूण प्रमाणपत्रे १) पाठवीण्यात येत आहेत

आपला

(जे. बी. मंत्री)
सहाय्यक आयुक्त (मुख्यालय) (डेस्क ११)
अन्न व औषध प्रशासन , म. राज्य.

FDA MAHARASHTRA

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

19 JUL 2019

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/ND/83543/2019/11/28832**

On the basis of the inspection carried out on **24/05/2019, 25/05/2019 and 02/07/2019** ,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 : **SNEHAL PHARMA & SURGICALS PVT. LTD**
   Address : **PLOT NO B-1/11, M.I.D.C. BUTIBORI, NAGPUR NAGPUR 441108 MAHARASHTRA STATE, INDIA**
2. Licence No. : **ND56 In Form 25, ND55 In Form 28**

Table 1

Sr.No.	Dosage Form(s)	Categor(ies)	Activity(ies)
1	Capsules	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
2	External Preparation (Ointments / Creams / Lotion/Gel)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	External Preparation (Ointments / Creams / Lotion/Gel/Ear drop/Nasal drop/Spray)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	Liquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
5	Oral Powders / Granules / Pellets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
6	Tablets	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, 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 18 Jul 2022 . 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
1ENS7278354320190719
SNEHAL PHARMA & SURGICALS PVT. LTD
NEW-WHO-GMP/CERT/ND/83543/2019/11
/28832

Name of the Authorised person : **A. T. NIKHADE**
Signature :
Stamp and Date :

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION ★ MAHARASHTRA STATE

Joint Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai
Maharashtra State, India
Date:19 Jul 2019

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/ND/83543/2019/11 /28832 **VALID UP TO :18 Jul 2022**

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NAGPUR 441108 MAHARASHTRA STATE, INDIA

Drug License No : ND56 In Form 25, ND55 In Form 28

Sr.No.	Name of the Product	Composition
1	Ambroxol HCL, Terbutline sulphate, Guaiphenesin and Menthol syrup	Each 5 ml Contains Ambroxol HCL IP 15.0 mg Terbutaline Suphate IP 1.25 mg Guaiphenesin IP 50.0 mg Menthol IP 2.5 mg Colour:Ponceau-4R
2	Amlodipine Tablets I.P. 5 mg	Each Uncoated Tablet Contains: Amlodipine Besylate Eq. Amlodipine IP 5 mg
3	Atorvastatin Tablet I.P. 10 mg	Each Film Coated Tablet Contains Atorvastatin Calcium Eq. to Atorvastatin IP 10 mg Colour:Titanium Dioxide I.P.
4	Atorvastatin Tablet I.P. 20 mg	Each Film Coated Tablet Contains Atorvastain Calcium Eq. to Atorvastatin IP 20 mg Colour:Titanium Dioxide I.P.
5	Atorvastatin Tablets I.P.40 mg	Each Film Coated Tablet Contains Atorvastatin Calcium Eq to Atorvastatin IP 40 mg
6	Azithromycin Tablet I.P. 500 mg	Each Tablet Contains: Azithromycin IP 500 mg
7	Ciprofloxacin hydrochloride Tablet IP 250 mg	Each Film Coated Tablet Contains Ciprofloxacine Hydrochloride Eq. to Ciprofloxacin IP 250.0 mg Colour:Lake Sunset Yellow FCF & Titanium Dioxide I.P.
8	Diclofenac 1% Gel	Composition: Diclofenac Diethylamine Eq Diclofenac Sodium BP 1 % w/w Methyl Salisylate IP 10 % w/w Menthol IP 5 % w/w Linseed Oil BP 3 % w/w

1 2 3

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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:19 Jul 2019

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION
MAHARASHTRA STATE

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Drug License No : ND56 In Form 25, ND55
In Form 28

Sr.No.	Name of the Product	Composition
9	Diclofenac Sodium & Paracetamol Tablet	Each Uncoated Tablet Contains Paracetamol IP 325 mg Diclofenac Sodium IP 50.0 mg
10	Diclofenac Tablets I.P. Film Coated	Each Film Coated Tablet Contains Diclofenac Sodium IP 50 mg Colour:Sunset Yellow and Titaniun Dioxide
11	Fluconazole Capsules 200 mg (For Export Only)	Each Empty Hard Gelatin Capsule Contains Fluconazole BP 200 mg Approved Colours used in Capsules Shell Colour:Approved Coloured used in Capsule Shell
12	Folic Acid Tablet IP 5 mg	Each Uncoated Tablet Contains Folic Acid IP 5.0 mg
13	Metformin Hydrochloride Sustained Release Tablet IP 500mg	Each Sustained Released Tablet Contains Metformin Hydrochloride IP 500 mg Colour:Titanium Dioxide IP
14	Omeprazole capsule IP 20mg	Each Hard Gelatin Capsule Contains Omeprazole (as enteric coated granules) IP 20.0 mg Approved Colours used in Capsules Shell
15	Oral Rehydration Salt IP Orange Flavour	Each Sachet of 21 gms Contains Sodium Chloride IP 2.60 gm Dextrose Anhydrous IP 13.50 gm Potassium Chloride IP 1.50 gm Sodium Citrate IP 2.90 gm
16	Pantaprazole Tablet IP 40 mg	Each Enteric Coated Tablet Contains Pantoprazole Sodium Eq. Pantoprazole IP 40.0 mg Colour:Yellow Oxide of Iron & Titanium Dioxide IP

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NAGPUR 441108 MAHARASHTRA STATE, INDIA

Drug License No : ND56 In Form 25, ND55 In Form 28

Sr.No.	Name of the Product	Composition
17	Pantoprazole 40 mg and Domperidone 30 mg Capsule	Each Empty Hard Gelatin Capsule Contains Pantoprazole Sodium Sesquihydrate I.P. Eq. to Pantoprazole (as Enteric Coated Pellets) IP 40 mg Domperidone (as Sustained Released Pellets) IP 30 mg Colour:Approved Coloured used in Capsule Shell
18	Paracetamol oral suspention I.P.	Each 5 ml Contains Paracetamol IP 250 mg In a flavoured Syrupy base Colour:Carmosine
19	Paracetamol syrup I.P.	Each 5 ml Contains Paracetamol IP 125 mg In a flavoured Syrupy base Colour:Quinoline Yelow W5
20	Paracetamol Tablet IP 500 mg	Each Uncoated Tablet Contains Paracetamol IP 500.0 mg
21	surgical Denatured spirit	Each 100ml Contains Ethyl Alcohol IP 94 ml In a aqueous base Purified Water 0 q.s. up to 100 ml In a aqueous base Colour:Crystal Violet
22	Vitamin C Chewable Tablet IP 500 mg	Each uncoated Chewable Tablet Contains Ascorbic Acid IP 500 mg Colour:Quinonline Yellow WS & Brilliant Blue

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