FDA MAHARASHTRA

Office of The Commissioner,
Food & Drugs Administration M.S.
Bandra – Kurla Complex,
Bandra (E),
Mumbai – 400 051
Date : 24/1/2018

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/59499/2017/11/19876**

On the basis of the inspection carried out on **12/04/2017, 13/04/2017 and 18/05/2017** ,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 : **SGPHARMA PVT. LTD.**
   Address : **542, 3/10, BHUTA NIWAS, DR. AMBEDKAR ROAD, MATUNGA (EAST), MUMBAI 400019**
   Manufacturing At : **PLOT NO. 9, 10, 11 & 20, SURVEY NO. 53, MANOR ROAD, NEAR RAILWAY BRIDGE, PALGHAR (E), THANE 401404 MAHARASHTRA STATE, INDIA**
2. Licence No. : **KD2074A In Form 25A, KD2351A In Form 28A**

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/Ear drop/Nasal drop/Spray)	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
3	Liquid Orals	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labelling, Quality Control, Quality Assurance
4	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 12 Jun 2019 . 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/
Fax: +91-22-26591955

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:23 Jan 2018

23 JAN 2018

Digitally signed by Harea Ştefan
Date: 2019.01.25 10:02:12 EET
Reason: MoldSign Signature
Location: Moldova

LIST OF PRODUCT APPROVED UNDER WHO GMP[1]

No. of certificate : NEW-WHO-GMP/CERT/KD/59499/2017/11 /19876 **VALID UP TO :12 Jun 2019**

Name of Manufactring Firm : SGPHARMA PVT. LTD.
542, 3/10, BHUTA NIWAS, DR. AMBEDKAR ROAD, MATUNGA (EAST), MUMBAI 400019

Manufacturing At : PLOT NO. 9, 10, 11 & 20, SURVEY NO. 53, MANOR ROAD, NEAR RAILWAY BRIDGE, PALGHAR (E), THANE 401404 MAHARASHTRA STATE, INDIA

Drug License No : KD2074A In Form 25A,
KD2351A In Form 28A

Sr.No.	Name of the Product	Composition
25	Chlorpromazine Hydrochloride Tablets USP 25 mg	Each film coated tablet contains : Chlorpromazine Hydrochloride USP 25 mg Excipients qs Colours : Red Ferric Oxide NF, Yellow Ferric Oxide NF
26	Clindamycin Hydrochloride Capsules USP 150 mg	Each hard gelatin capsule contains : Clindamycin Hydrochloride USP equivalent to Clindamycin 150 mg Excipients qs Approved Colours used in empty capsule shells.
27	Clindamycin Hydrochloride Capsules USP 300 mg	Each hard gelatin capsule contains : Clindamycin Hydrochloride USP equivalent to Clindamycin 300 mg Excipients qs Approved Colours used in empty capsule shells.
28	Clomifene Tablets B.P.	Each uncoated tablet contains : Clomifene Citrate BP 50 mg Excipients . qs
29	Clomipramine Tablets 50 mg	Each film coated tablet contains : Clomipramine Hydrochloride BP 50 mg Excipients . qs Colour : Titanium Dioxide B.P.
30	Cycloserine Tablets I.P.	Each film coated tablet contains : Cycloserine IP 250 mg Excipients . qs Colour : Titanium Dioxide I.P.
31	Cyproheptadine Hydrochloride Oral Solution USP	Each 5 ml contains : Cyproheptadine HCl USP equivalent to anhydrous Cyproheptadine HCl 2 mg Flavoured Syrupy base . qs
32	Dapsone Tablets USP	Each uncoated tablet contains : Dapsone USP 50 mg Excipients . qs

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COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

Address of certifying authority :
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Bandra-kurla Complex,
Bandra (E), Mumbai – 400 051.
Maharashtra,INDIA.
Tel: +91-22-26592363/64
Fax: +91-22-26591959
1PGS2165949920170703

Name of the Authorised person : **O S SADHWANI**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date:**03 Jul 2017**

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