

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



**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/PD/124470/2023/ 1135-11

दिनांक. 31/3/2023

प्रति,  
**SURGE PHARMACEUTICALS PVT. LTD.**  
**PUNE**

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजूरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 124470

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी ( सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग ) स्टेटस प्रमाणपत्र  
क्रमांक डब्लूएचओ - जीएमपी/ PD/124470 ( एकूण प्रमाणपत्रे 1 ) पाठवीण्यात येत आहेत

आपला

( डॉ. सं. ने. कळते ) ( पत्र. ५११-५१२१२ )

सहाय्यक आयुक्त ( मुख्यालय ) ( डेस्क ११ )

अन्न व औषध प्रशासन, म. राज्य.





Office of The Commissioner,  
Food & Drugs Administration M.S.  
Bandra – Kurla Complex,  
Bandra (E),  
Mumbai – 400 051  
Date :-31 Mar 2023

## 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/PD/124470/2023/11/44681**

On the basis of the inspection carried out on **10/02/2023** and **11/02/2023**, 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.

- Name of the Firm : **SURGE PHARMACEUTICALS PVT. LTD.**  
Address : **PLOT NO. C-78 & C-79 ADDITIONAL M.I.D.C.  
JEJURI PUNE 412303 MAHARASHTRA  
STATE, INDIA**
- Licence No. : **MH103234 In Form  
25, MH103235 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	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.

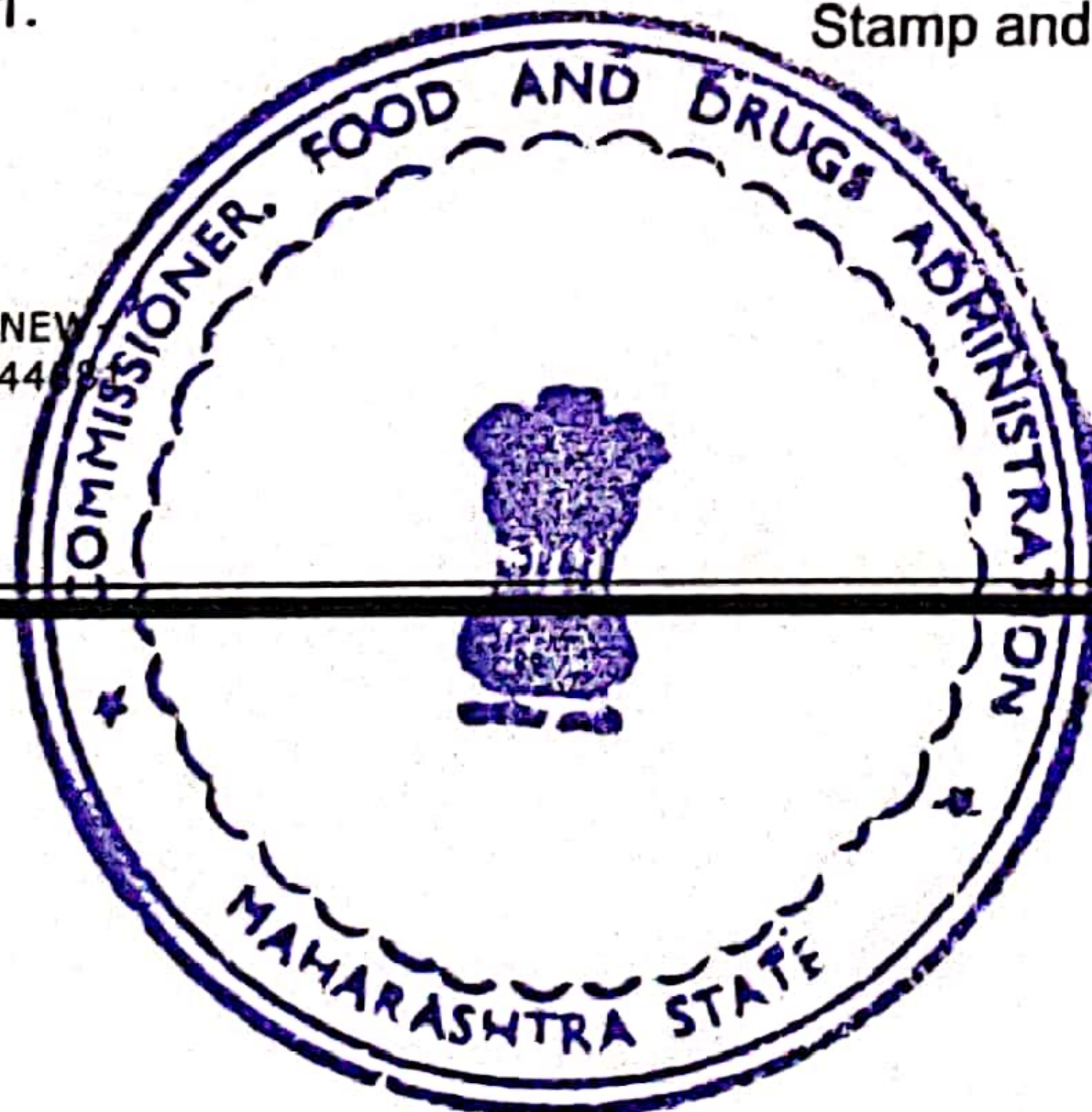
This certificate remains valid until 30 Mar 2026 . It becomes invalid if the activities and / or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

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  
1RUS32112447020230331  
SURGE PHARMACEUTICALS PVT. LTD. - NEW  
WHO-GMP/CERT/PD/124470/2023/11/44681

Name of the Authorised person : **MR BHUSHAN PATIL , J.C**

Signature :

Stamp and Date : **Joint Commissioner (HQ) & Controlling  
Authority  
Food & Drug Administration, M.S.  
Bandra (E), Mumbai.  
Maharashtra State, India  
Date:31 Mar 2023**





**LIST OF PRODUCT APPROVED UNDER WHO GMP<sup>1</sup>**

**No. of certificate** : NEW-WHO-GMP/CERT/PD/124470/2023/11 /44681 **VALID UP TO :30 Mar 2026**  
**Name of Manufacturing Firm** : SURGE PHARMACEUTICALS PVT. LTD.  
PLOT NO. C-78 & C-79 ADDITIONAL M.I.D.C.  
JEJURI PUNE 412303 MAHARASHTRA STATE,  
INDIA  
**Drug License No** : MH103234 In Form 25,  
MH103235 In Form 28

Sr.No.	Name of the Product	Composition
1	Betahistine Dihydrochloride Tablets IP 16 mg	Each uncoated Tablet contains Betahistine Dihydrochloride IP 16 mg Excipients IP qs
2	Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules IP	Each hard gelatin capsule contains Pantoprazole Sodiurn Gastro-resistant IP 40 mg Domperidone maleate Prolonged release IP 30 mg Excipients IP qs

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SURGE PHARMACEUTICALS PVT. LTD. - NEW-  
WHO-GMP/CERT/PD/124470/2023/11/44681

Name of the Authorised person : MR BHUSHAN PATIL , J.C

Signature :  
Stamp and Date : **Joint Commissioner (HQ) & Controlling Authority**  
**Food & Drug Administration, M.S.**  
**Bandra (E), Mumbai.**  
**Maharashtra State, India**  
**Date:31 Mar 2023**

