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. WHO-GMP/CERT/AD/84622/2019/ 2061 /11

दिनांक. 14/06/2019

प्रति,
HARMAN FINOCHEM LTD.
AURANGABAD

विषय - डब्लूएचओ - जीएमपी प्रमाणपत्र मंजुरीबाबत

संदर्भ - आपला प्रस्ताव क्रमांक 84622

महोदय,

सोबत डब्लूएचओ - जीएमपी प्रमाणपत्र / सीओपीपी (सर्टिफिकेट ऑफ फार्मास्युटिकल्स प्रॉडक्ट्स / स्टेटमेंट ऑफ लायसन्सिंग) स्टेटस प्रमाणपत्र क्रमांक डब्लूएचओ - जीएमपी/ AD/84622 (एकूण प्रमाणपत्रे 1) 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 : 14 JUN 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.: **WHO-GMP/CERT/AD/84622/2019/11/28413**

On the basis of the inspection carried out on **30/09/2016 and 14/12/2016** ,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 : HARMAN FINOCHEM LTD.
   Address : **PLOT NO. E-9, E-7, E-8 MIDC CHIKALTHANA, AURANGABAD AURANGABAD 431006 MAHARASHTRA STATE, INDIA**
2. Licence No. : **849 In Form 25, AD001 In Form 25F, 722 In Form 28**

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.

The Certificate was valid upto 04 Apr 2019. The validity of this certificate has been extended for the period of six months and now the validity of this Certificate remains 04 Oct 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: +91-22-26592363/64
Fax: +91-22-26591959
HARMAN FINOCHEM LTD. - WHO-GMP/CERT/AD/84622/2019/11/28413

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:13 Jun 2019

COMMISSIONER, FOOD AND DRUGS ADMINISTRATION MAHARASHTRA STATE

13 JUN 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 : WHO-GMP/CERT/AD/84622/2019/11/28413 VALID UP TO :04 Oct 2019

Name of Manufactring Firm : HARMAN FINOCHEM LTD.
PLOT NO. E-9, E-7, E-8 MIDC CHIKALTHANA,
AURANGABAD AURANGABAD 431006
MAHARASHTRA STATE, INDIA

Drug License No : 849 In Form 25, AD001 In Form 25F, 722 In Form 28

Sr.No.	Name of the Product	Composition
1	ALLOPRINOL USP -	
2	ALLOPURINOL BP -	
3	Allopurinol EP --	
4	Allopurinol IP --	
5	Allopurinol JP --	
6	Aripiperazole --	
7	BISOPROLOL FUMARATE USP -	
8	Choline Fenofibrate (Choline Salt of Fenofibric Acid) --	

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HARMAN FINOCHEM LTD. - WHO-GMP/CERT /AD/84622/2019/11/28413

Name of the Authorised person : A. T. NIKHADE

Signature :

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
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MAHARASHTRA STATE, INDIA

Drug License No : 849 In Form 25, AD001 In
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Sr.No.	Name of the Product	Composition
9	Colchicine EP --	
10	Cyclobenzaprine Hydrochloride USP --	
11	Fenofibric Acid --	
12	Glycopyrrolate USP --	
13	Glycopyrronium Bromide (Glycopyrronii Bromidum)EP --	
14	Lidocaine EP --	
15	Lidocaine Hydrochloride EP --	
16	MEPHOBARBITAL USP -	

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MAHARASHTRA STATE, INDIA

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Sr.No.	Name of the Product	Composition
17	Metformin Hydrochloride BP --	
18	Metformin Hydrochloride EP --	
19	Metformin Hydrochloride IP --	
20	Metformin Hydrochloride JP --	
21	Metformin Hydrochloride USP --	
22	Metformin Hydrochloride with 0.50% Aerosil --	
23	Metformin Hydrochloride with 1.0% Aerosil --	
24	Methadone Hydrochloride BP --	

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MAHARASHTRA STATE, INDIA

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Sr.No.	Name of the Product	Composition
25	Methadone Hydrochloride EP --	
26	Methadone Hydrochloride USP --	
27	Methyl Phenidate Hydrochloride EP --	
28	Methyl Phenidate Hydrochloride USP --	
29	METHYLPHENOBARBITAL BP -	
30	METHYLPHENOBARBITAL EP -	
31	Oxiconazole Nitrate --	
32	OXYBUTYNIN HYDROCHLORIDE BP -	

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Drug License No : 849 In Form 25, AD001 In Form 25F, 722 In Form 28

Sr.No.	Name of the Product	Composition
33	Oxybutynin Hydrochloride EP --	
34	Phenobarbital EP --	
35	Phenobarbital Sodium EP ---	
36	Phenobarbitone (Phenobarbital)BP --	
37	Phenobarbitone IP --	
38	PHENOBARBITONE(PHENOBARBITAL)USP -	
39	Phenytoin Sodium BP --	
40	Phenytoin Sodium EP --	

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Drug License No : 849 In Form 25, AD001 In Form 25F, 722 In Form 28

Sr.No.	Name of the Product	Composition
41	Phenytoin Sodium USP	
42	Propofol EP	
43	Riboflavin 5 Phosphate Sodium BP --	
44	Riboflavin Sodium Phosphate EP --	
45	RIBOFLAVIN SODIUM PHOSPHATE USP -	
46	Sitagliptin Phosphate Monohydrate	
47	Torasemide EP --	
48	Xipamide --	

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