



Office of The Commissioner,
Food & Drug Administration M.S.
Bandra - Kurla Complex,
Bandra (E),
Mumbai - 400 051
Date 16/9/2013

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/2380/2013/11/4230

On the basis of the inspection carried out on 8th & 9th July 2013 & Compliance Inspection on 31/08/2013, 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 | : | ADORE PHARMACEUTICALS PVT. LTD. |
| | Address | : | S.S. KHOKHAN INDL. COMPLEX NO. 2, NEAR SAI
TEMPLE SATIVALI, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA |
| 2 | Licence No. | : | KD 424 In Form 25.
KD867 In Form 28 |

Table 1

Sr.No.	Dosage Form(s)	Category(ies)	Activity(ies)
1	Injectables	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labeling, 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, labeling, Quality Control, Quality Assurance
3	Eye / Ear Drops	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labeling, Quality Control, Quality Assurance
4	Eye Drops / Ophthalmic Preparations	General (Other than Cephalosporins, Penicillin, Cytotoxic, Hormones)	Production, Filling, Packing, labeling, 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 Sep 2015. 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: +91-22-26591859
LODAR 1892760/0130900753

Name of the Authorized 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 13 Sep 2013



13 SEP 2013

LIST OF PRODUCT APPROVED UNDER WHO-GMP¹

VALID UP TO: 12 Sep 2015

No. of certificate

NEW-WHO-GMPCERT/KD/2380
/2013/11/4230

Name of Manufacturing Firm

ADORE PHARMACEUTICALS PVT. LTD
5/6, KHOKHANE INDL. COMPLEX NO. 2, NEAR SAI
TEMPLE SATTVALI, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA
KD 424 in Para 23,
KD867 in Para 28

Drug License No

Sr.No.	Name of the Product	Composition
1	CHLORAMPHENICOL EAR DROPS BP 5.0% W/V	Each ml contains Chloramphenicol BP 5.0 % w/v Phenyl Mercuric Nitrate BP 0.002 % w/v Propylene Glycol BP q.s.
2	CHLORAMPHENICOL EYE DROPS BP 0.5% W/V	Each ml contains Chloramphenicol BP 0.5 % w/v Phenyl Mercuric Nitrate(as preservative) BP 0.002 % w/v Water For Injection BP q.s.
3	DEXAMETHASONE SODIUM PHOSPHATE OPHTHALMIC SOLUTION USP	Each ml contains Dexamethasone Sodium Phosphate USP eq. to Dexamethasone Phosphate 0.1 % w/v Phenyl Mercuric Nitrate BP 0.001 % w/v Water for Injection q.s.
4	DIAZEPAM INJECTION BP	EACH ML CONTAINS Diazepam IP 5 mg Benzyl Alcohol IP 5.0 mg Water for Injection IP q.s.
5	ERGOMETRINE MALEATE INJECTION BP	EACH ML CONTAINS Ergometrine Maleate BP 0.5 mg Sodium Chloride BP 0.5 % Maleic Acid BP 0.0108 % Water for Injection IP q.s.
6	FENITRONE INJECTION BP	EACH ML CONTAINS Fenitron BP 1 % w/v Sodium Chloride Sodium Hydroxide
7	GENTAMICIN EYE DROPS BP 0.3%	Each ml contains Gentamicin Sulphate BP eq. to Gentamicin base 0.3 % w/v Sodium Acid Phosphate BP 0.11 % w/v Disodium Phosphate BP 0.2 % w/v Sodium Chloride IP 0.733 % w/v Water for Injection BP q.s.
8	Metoclopramide Hydrochloride Injection IP -5mg/ml	EACH ML CONTAINS Metoclopramide Hydrochloride IP eq. to Metoclopramide 5 mg Disodium EDTA BP 0.05 % w/v Sodium Metabisulphite IP 0.1 % w/v Water for Injection IP q.s. Sodium Acetate IP 0.271 % w/v Glacial Acetic Acid IP 0.33 % w/v

123456

Address of certifying authority:
Food & Drug Administration, M.S.
Bandra-Kurla Complex,
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Tel: +91-22-260628384
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E-mail: fda@maharashtra.gov.in

Name of the Authorized person : O.S. BACHWANE

Signature

Stamp and Date: 08/09/2013 Commissioner (F&D) & Controlling Authority

Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 13 Sep 2013



13 SEP 2013

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

VALID UP TO: 12 Sep 2015

No. of certificate :

NEW-WHO-GMP/CERT/KD/2380
2013/11/4230

Name of Manufacturing Firm :

ADORE PHARMACEUTICALS PVT. LTD.
5,6, KHOKHANI INEL. COMPLEX NO. 2, NEAR SAI
TEMPLE SATTWALL, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA
KD 424 In Form 25,
KD867 In Form 28

Drug License No :

Sr.No.	Name of the Product	Composition
9	ONDANSETRON INJECTION USP	EACH ML CONTAINS Ondansetron Hydrochloride USP eq. to Ondansetron 2 mg Water for Injection IP qs
10	Piroxicam Injection IM -1ml	EACH ML CONTAINS Piroxicam BP 20 mg Benzyl Alcohol IP 20.0 mg Alcohol IP 13.34 % v/v Water for Injection IP qs
11	Prednisolone Sodium Phosphate Injection USP	EACH ML CONTAINS Prednisolone Sodium Phosphate USP eq. to Prednisolone Phosphate 30 mg Water for Injection IP qs
12	PROMETHAZINE HYDROCHLORIDE INJECTION IP	EACH ML CONTAINS Promethazine Hydrochloride IP 25 mg Water for Injection IP qs
13	STERILE WATER FOR INJECTION IP 10ML	Each ml contains Water for Injection IP
14	TIMOLOL MALEATE OPHTHALMIC SOLUTION BP 0.25%	Each ml contains Timolol Maleate BP eq. to Timolol BP 0.25 % w/v Benzalkonium Chloride (as preservative) BP 0.02 % w/v Water for Injection IP . qs Disodium Hydrogen Phosphate IP Monobasic Sodium Phosphate IP Sodium Hydroxide IP
15	TIMOLOL MALEATE OPHTHALMIC SOLUTION BP 0.5%	Each ml contains Timolol Maleate BP eq. to Timolol 0.5 % w/v Benzalkonium Chloride (as preservative) BP 0.02 % w/v Water for Injection IP . qs Disodium Hydrogen Phosphate IP Monobasic Sodium Phosphate IP
16	TRAMADOL HYDROCHLORIDE INJECTION	EACH ML CONTAINS Tramadol Hydrochloride 50 mg Water for Injection IP qs

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Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-Kurla Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA
Tel: +91-22-25540300
Fax: +91-22-25540300
100A/MS/1/2013/11/4230

Name of the Authorized 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: 12 Sep 2013



13 SEP 2013

No. of certificate

LIST OF PRODUCT APPROVED UNDER WHO GMP

NEW WHO-GMP/CERT/KD/2380

VALID UP TO: 12 Sep 2015

Name of Manufacturing Firm

ADORE PHARMACEUTICALS PVT. LTD.
S.A. KIRKURAM INDL. COMPLEX NO. 2, NEAR SAJ
TEMPLE BATTALI, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA
KD-434 in Para 25,
EDM-7 in Para 25

Drug License No.

Sr.No.	Name of the Product	Composition
17	Gentamicin Injection Gentamicin Injection IP 10ml vial	EACH ML CONTAINS Gentamicin Sulphate IP eq. to Gentamicin base 40 mg Methyl Paraben IP 0.18 % w/v Propyl Paraben IP 0.02 % w/v Water for Injection IP - qs Disodium EDTA IP 0.01 % w/v Sodium Metabisulphate IP 0.32 % w/v
18	BETAMETH EYE/EAR DROPS (Dexamethasone and Hydroxypropyl Methyl Cellulose Eye/Ear Drops)	Each ml contains Dexamethasone Sodium Phosphate IP 0.1 % w/v Hydroxypropyl Methyl Cellulose IP 0.25 % w/v
19	BETAMETH-II EYE/EAR DROPS (Dexamethasone, Neomycin and Hydroxypropyl Methyl Cellulose Eye/Ear drops)	Each ml contains Dexamethasone Sodium Phosphate IP 0.1 % w/v Neomycin Sulphate IP 0.5 % w/v Hydroxypropyl Methyl Cellulose IP 0.25 % w/v
20	CARBON EYE DROPS	Each ml contains Potassium Iodide IP 3.3 % w/v Sodium Chloride IP 0.83 % w/v Calcium Chloride Dihydrate IP 1 % w/v Sodium Methyl Hydroxybenzoate IP eq. to Methyl Hydroxybenzoate (as preservative) 0.022 % w/v Sodium Propyl Hydroxybenzoate IP Eq. to Propyl Hydroxybenzoate (as preservative) 0.011 % w/v In sterile buffered base qs
21	CHLOROQUINE PHOSPHATE INJECTION BP	EACH ML CONTAINS Chloroquine Phosphate BP eq. to Chloroquine base 40 mg Benzyl Alcohol BP 1.5 % w/v Water for Injection BP qs
22	CIPROMAX Ciprofloxacin Ophthalmic Solution USP	Each ml contains Ciprofloxacin Hydrochloride BP eq. to Ciprofloxacin 0.3 % w/v Benzalkonium Chloride Solution IP 0.02 % w/v Disodium EDTA IP 0.05 % w/v Sodium Chloride IP 0.9 % w/v Hydrochloric Acid IP qs Water for Injection IP qs
23	DETIRM Droperidone Hydrochloride 20mg	Each ml contains Droperidone Hydrochloride 20 mg Sodium Metabisulphate IP 1.0 mg Absolute Alcohol IP 8.0 % w/v Water for Injection IP qs
24	DEXACORAL INJECTION 4MG/ML Dexamethasone Sodium Phosphate Injection IP 4mg/ml	EACH ML CONTAINS Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 4 mg Methyl Paraben IP 0.15 % w/v Propyl Paraben (as preservative) IP 0.02 % w/v Water for Injection IP - qs Sodium Metabisulphate IP Sodium Citrate Hydrate IP

123456

Address of certifying authority

Food & Drug Administration, Maharashtra

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E-mail: fda@mah.gov.in

Name of the Authorized person: O.B. Bhatnagar

Signature

Stamp and Date

Joint Commissioner (HQ) & Controlling Authority

Food & Drug Administration, M.S.

Bandra (E), Mumbai

Maharashtra State, India

Date: 13 Sep 2013



13 SEP 2013

No. of certificates

Name of Manufacturing Firm

Drug License No.

LIST OF PRODUCT APPROVED UNDER WHO GMP

NEW WHO-GMP/CERT/00/2380

VALID UP TO: 12 Sep 2015

/2013/114230

ADORE PHARMACEUTICALS PVT. LTD
5/6, KHORCHANE INDL. COMPLEX NO. 2, NEAR SAJ
TEMPLE SATTVALI, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA
ED 424 in Form 25,
KDB67 in Form 28

Sr. No.	Name of the Product	Composition
25	DEXLY-G EYE/EAR DROPS Gentamicin Sulphate & Dexamethasone Sodium Phosphate Eye Drops	Each ml contains Gentamicin Sulphate IP eq. to Gentamicin base 0.3 % w/v Dexamethasone Phosphate (as Dexamethasone Sodium Phosphate) IP 0.1 % w/v Benzalkonium Chloride Solution (as preservative) IP 0.02 % w/v Water for Injection IP q.s.
26	DEXLY-N EYE/EAR DROPS Neomycin Sulphate & Dexamethasone Sodium Phosphate Ophthalmic Solution USP	Each ml contains Neomycin Sulphate IP eq. to Neomycin base 0.5 % w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1 % w/v Phenyl Mercuric Nitrate IP 0.002 % w/v Water for Injection IP q.s.
27	DOFEC INJECTION 25MG/ML DICLOFENAC SODIUM INJECTION IP 25MG/ML	EACH ML CONTAINS DICLOFENAC SODIUM IP 25 mg Benzyl Alcohol IP 4 % w/v Mannitol IP Sodium Metabisulphite IP Propylene Glycol IP Sodium Hydroxide IP
28	FALPAR INJECTION Alpha Beta Actinether	Each ml contains Amino-ether 75 mg Ascorbic Oil IP q.s.
29	INJ DICORT 40 Triamcinolone Acetonide Injection IP 40mg/ml (for use only)	Each ml contains Triamcinolone Acetonide IP 40 mg Benzyl Alcohol IP 0.9 % w/v Water for Injection IP q.s.
30	Intac Injection 25 mg/ml Ranitidine Hydrochloride Injection IP 25mg/ml	EACH ML CONTAINS Ranitidine Hydrochloride IP Equivalent to Ranitidine 25 mg
31	LYMON EYE/EAR DROPS Dexamethasone & Chloramphenicol Ophthalmic Solution	Each ml contains Chloramphenicol IP 0.5 % w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1 % w/v Phenyl Mercuric Nitrate (as preservative) IP 0.002 % w/v Water for Injection IP q.s.
32	METHYLERGOMETRINE MALEATE INJECTION IP 10ML	EACH ML CONTAINS Methylethergometrine Maleate IP 0.2 mg Maleic Acid IP 0.0086 % EDTA Disodium IP 0.01 % Water for Injection q.s.

122456

Address of certifying authority:
Food & Drug Administration, M.B.
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E-MAIL: fda@mah.gov.in

Name of the Authorized person: O.S. SACHIN

Signature

Stamp and Date: Joint Commissioner (MC) & Controlling Authority
Food & Drug Administration, M.B.
Bandra (E), Mumbai
Maharashtra State, India
Date: 12 Sep 2013



13 SEP 2013

LIST OF PRODUCT APPROVED UNDER WHO GMP

No. of certificate

NEW-WHO-GMP-CERT/KD/2380

VALID UP TO (12 Sep 2015)

Name of Manufacturing Firm

ADORE PHARMACEUTICALS PVT. LTD.
S/O, KHORHANI INDL. COMPLEX NO. 2, NEAR SAI
TEMPLE SATTVALL, VASAI (EAST), THANE 401208
MAHARASHTRA STATE, INDIA
KD 404 in Form 25.
ED 867 in Form 28

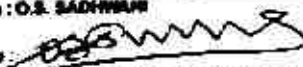

Drug License No

Sr.No.	Name of the Product	Composition
33	PROPLY EYE DROPS Norfloxacin Eye Drops BP	Each ml contains Norfloxacin IP 0.3 % w/v Benzalkonium Chloride solution (as preservative) IP 0.02 % w/v Water for Injection IP qs
34	OFLOMAX Ofloxacin Ophthalmic Solution LSP	EACH ML CONTAINS Ofloxacin USP 3 mg Benzalkonium Chloride Solution IP 0.02 % w/v Water for Injection IP . qs
35	OMEFLON-DX Ofloxacin & Dexamethasone Ophthalmic Solution	Each ml contains Ofloxacin USP 0.3 % w/v Dexamethasone IP 0.1 % w/v Benzalkonium Chloride solution (as preservative) IP 0.02 % w/v Sterile Aqueous vehicle qs
36	OMEPREO EYE/EAR DROPS Prednisolone acetate plus Ofloxacin Ophthalmic Suspension	Each ml contains Prednisolone acetate USP 10 mg Ofloxacin USP 3 mg Benzalkonium Chloride solution IP 0.02 % w/v Sterile aqueous base qs
37	PREDSON EYE DROPS Prednisolone Acetate Ophthalmic Suspension USP	Each ml contains Prednisolone Acetate USP 10 mg Benzalkonium Chloride solution (as preservative) IP 0.02 % w/v Sterile aqueous vehicle qs
38	PREMYON 250 AMIKACIN SULPHATE INJECTION IP 250MG/2ML	Each 2ml vial contains Amikacin Sulphate IP eq. to Amikacin IP 250 mg Methyl Paraben IP 0.08 % w/v Propyl Paraben IP 0.02 % w/v Sodium Metabisulphite IP 0.33 % w/v Sodium Chloride dihydrate IP 1.425 % w/v Water for Injection IP qs
39	PREMYON 500 AMIKACIN SULPHATE INJECTION IP 500MG/2ML	Each 2ml vial Contains Amikacin Sulphate IP eq. to Amikacin IP 500 mg Methyl Paraben IP 0.04 % w/v Propyl Paraben IP 0.01 % w/v Sodium Metabisulphite IP 0.33 % w/v Sodium Chloride dihydrate IP 7.85 % w/v Water for Injection IP qs
40	TOBRA-D EYE DROPS Tobramycin & Dexamethasone Eye drops	Each ml contains Tobramycin Sulphate USP eq. to Tobramycin 0.3 % w/v Dexamethasone Sodium Phosphate USP eq. to Dexamethasone Phosphate 0.1 % w/v Water For Injection BP qs Benzalkonium Chloride Solution (As preservative) BP 0.02 % w/v

1 2 3 4 5 6

Address of certifying authority :
Food & Drug Administration, M.S.
Bandra-Burda Complex,
Bandra (E), Mumbai - 400 051
Maharashtra, INDIA
Tel: +91-22-2662283/84
Fax: +91-22-26691809
LC00062360701 3091 3153

Name of the Authorized person : O.S. SACHINRAM

Signature: 
Stamp and Date: 
Commissioner (HQ) & Controlling Authority
Food & Drug Administration, M.S.
Bandra (E), Mumbai.
Maharashtra State, India
Date: 13 Sep 2013

13 SEP 2013

LIST OF PRODUCT APPROVED UNDER WHO GMP¹

No. of certificate : NEW-WHO-GMP/CERT/KD/2380
 /2013/11/4230
 Name of Manufacturing Firm : ADORE PHARMACEUTICALS PVT. LTD.
 1,6, KHOKHANI IND. COMPLEX NO. 2, NEAR SAI
 TEMPLE SATTVALI, VASAI (EAST), THANE 401208
 MAHARASHTRA STATE, INDIA
 Drug License No : KD 424 1a Form 25,
 KD867 1a Form 28

VALID UP TO: 12 Sep 2015

Sr.No.	Name of the Product	Composition
41	VITAMED INJECTION	Each 2ml contains Thiamine Hydrochloride BP 20 mg Riboflavin Sodium Phosphate BP 4 mg Pyridoxine Hydrochloride BP 4 mg Nicotinamide BP 200 mg Cyanocobalamin BP 8 mcg D-panthenol BP 6 mg Benzyl Alcohol (As preservative) BP 0.9 % w/v Water for Injection BP qs

1 2 3 4 5 6

Address of certifying authority :
 Food & Drug Administration, M.S.
 Bandra-kurla Complex,
 Bandra (E), Mumbai - 400 051.
 Maharashtra, INDIA.
 Tel: +91-22-26562363/64
 Fax: +91-22-26561958
 100A368238020130913153

Name of the Authorized person : O.S. SACHINANI

Signature : 

Stamp and Date : Joint Commissioner (HQ) & Controlling Authority
 Food & Drug Administration, M.S.
 Bandra (E), Mumbai
 Maharashtra State, India
 Date: 13 Sep 2013



13 SEP 2013