



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

Date : 22/1/2016

### 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/31137/2016/11/13619**

On the basis of the inspection carried out on **15/10/2015** and **05/12/2015**, 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 : **5,6, KHOKHANI 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)                             | Categor(ies)   | Activity(ies)   |
|--------|--|--|---|
| 1      | External Preparation (Ear drop/Nasal drop) | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 2      | Eye Drops / Ophthalmic Preparations        | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 3      | Liquid Injection ( SVP )                   | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 4      | Nasal Drop/Spray                           | General ( Other than Cephalosporins, Penicillin, Cytotoxic, Hormones ) | Production, Filling, Packing, labelling, Quality Control, Quality Assurance |
| 5      | Eye / Ear Drops                            | 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 21 Jan 2018 . 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  
10DA3893113720160122041

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: 22 Jan 2016**



22 JAN 2016

### 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) <sup>1</sup> | 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) <sup>1</sup> | Category (ies) | Activity (ies)                               |
|---|----------------|--|
| Starting material (s) <sup>2</sup>      |                |  |
| 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.





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| Sr.No. | Name of the Product  | Composition   |
|--------|--|---|
| 1      | ARTEMETHER INJECTION 80MG/ML                                 | EACH ML CONTAINS<br>Artemether IHS 80 mg<br>Fractionated Coconut oil qs   |
| 2      | CHLORAMPHENICOL EAR DROPS BP<br>5.0% W/V                     | Each ml contains<br>Chloramphenicol BP 5.0 % w/v<br>Phenyl Mercuric Nitrate BP 0.002 % w/v<br>Propylene Glycol BP qs  |
| 3      | CHLORAMPHENICOL EYE DROPS BP<br>0.5% W/V                     | Each ml contains<br>Chloramphenicol BP 0.5 % w/v<br>Phenyl Mercuric Nitrate(as preservative) BP 0.002 % w/v<br>Water For Injection BP qs                                  |
| 4      | CLINDAMYCIN INJECTION USP                                    | Each ml contains<br>Clindamycin Phosphate(Anhydrous) USP equivalent to Clindamycin 150 mg<br>Benzyl Alcohol (as preservative) USP 0.9 % v/v<br>Water for Injections BP qs |
| 5      | DEXAMETHASONE SODIUM<br>PHOSPHATE OPHTHALMIC<br>SOLUTION USP | Each ml contains<br>Dexamethasone Sodium Phosphate USP eq. to Dexamethasone Phosphate<br>0.1 % w/v<br>Phenyl Mercuric Nitrate BP 0.001 % w/v<br>Water for Injection qs    |
| 6      | DIAZEPAM INJECTION IP  | EACH ML CONTAINS<br>Diazepam IP 5 mg<br>Water for Injection IP qs<br>Benzyl Alcohol IP 2 % w/v  |
| 7      | ERGOMETRINE MALEATE INJECTION<br>BP                          | EACH ML CONTAINS<br>Ergometrine Maleate BP 0.5 mg<br>Sodium Chloride BP 0.5 %<br>Maleic Acid BP 0.0108 %<br>Water for Injection IP qs                                     |
| 8      | FRUSEMIDE INJECTION BP                                       | EACH ML CONTAINS<br>Frusemide BP 1 % w/v<br>Sodium Chloride<br>Sodium Hydroxide   |

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 Drug License No : KD 424 In Form 25,  
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| Sr.No. | Name of the Product                          | Composition  |
|--------|--|--|
| 9      | GENTAMICIN EYE/EAR DROPS BP                  | Each ml contains<br>Gentamicin Sulphate BP equivalent to Gentamicin base BP 3 mg<br>Benzalkonium Chloride solution BP 0.02 % v/v<br>Water for Injections IP qs   |
| 10     | ONDANSETRON INJECTION USP                    | EACH ML CONTAINS<br>Ondansetron Hydrochloride USP eq. to Ondansetron 2 mg<br>Water for Injection IP qs   |
| 11     | Piroxicam Injection IM -1ml                  | EACH ML CONTAINS<br>Piroxicam BP 20 mg<br>Benzyl Alcohol IP 20.0 mg<br>Alcohol IP 13.34 % v/v<br>Water for Injection IP qs   |
| 12     | Prednisolone Sodium Phosphate Injection USP  | EACH ML CONTAINS<br>Prednisolone Sodium Phosphate USP eq. to Prednisolone Phosphate 30 mg<br>Water for Injection IP qs   |
| 13     | PROMETHAZINE HYDROCHLORIDE INJECTION IP      | EACH ML CONTAINS<br>Promethazine Hydrochloride IP 25 mg<br>Water for Injection IP qs   |
| 14     | QUININE DIHYDROCHLORIDE INJECTION            | EACH ML CONTAINS<br>QUININE DIHYDROCHLORIDE BP 300 mg<br>BENZYL ALCOHOL (AS PRESERVATIVE) BP 0.5 % w/v<br>WATER FOR INJECTION (FOR IV USE ONLY) BP qs  |
| 15     | STERILE WATER FOR INJECTION IP 10ML          | Each ml contains<br>Water for Injection IP   |
| 16     | TIMOLOL MALEATE OPHTHALMIC SOLUTION BP 0.25% | Each ml contains<br>Timolol Maleate BP eq. to Timolol BP 0.25 % w/v<br>Water for Injection IP . qs<br>Disodium Hydrogen Phosphate IP<br>Monobasic Sodium Phosphate IP<br>Sodium Hydroxide IP<br>Benzalkonium Chloride (as preservative) BP 0.022 % w/v |

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| Sr.No. | Name of the Product  | Composition  |
|--------|--|--|
| 17     | TIMOLOL MALEATE OPHTHALMIC SOLUTION BP 0.5%  | Each ml contains<br>Timolol Maleate BP eq. to Timolol 0.5 % w/v<br>Water for Injection IP . qs<br>Disodium Hydrogen Phosphate IP<br>Monobasic Sodium Phosphate IP<br>Benzalkonium Chloride (as preservative) BP 0.022 % w/v  |
| 18     | TRAMADOL HYDROCHLORIDE INJECTION   | EACH ML CONTAINS<br>Tramadol Hydrochloride 50 mg<br>Water for Injection IP qs  |
| 19     | TRANEXAMIC ACID INJECTION BP   | Each ml contains<br>Tranexamic Acid BP 100 mg<br>Water for Injections BP qs  |
| 20     | APMOL 500<br>PARACETAMOL INJECTION<br>500MG/5ML                                      | Each ml Contains<br>Paracetamol BP 100 mg<br>Benzyl Alcohol BP 2 % v/v<br>Water for Injection BP qs  |
| 21     | APMOL 600<br>PARACETAMOL INJECTION<br>600MG/5ML                                      | Each ml contains<br>Paracetamol BP 120 mg<br>Benzyl Alcohol BP 2 % v/v<br>Water for Injection BP qs  |
| 22     | BETAMETH EYE/EAR DROPS<br>(Betamethasone and Hypromellose Eye/Ear Drops)             | Each ml contains<br>Betamethasone Sodium Phosphate IP 0.1 % w/v<br>Hydroxypropyl Methyl Cellulose IP 0.25 % w/v  |
| 23     | BETAMETH-N EYE/EAR DROPS<br>(Betamethasone, Neomycin and Hypromellose Eye/Ear drops) | Each ml contains<br>Betamethasone Sodium Phosphate IP 0.1 % w/v<br>Neomycin Sulpha IP 0.5 % w/v<br>Hydroxypropyl Methyl Cellulose IP 0.25 % w/v  |
| 24     | CATAGON EYE DROPS  | Each ml contains<br>Potassium Iodide IP 3.3 % w/v<br>Sodium Chloride IP 0.83 % w/v<br>Calcium Chloride Dihydrate IP 1 % w/v<br>Sodium Methyl Hydroxybenzoate IP eq. to Methyl Hydroxybenzoate (as preservative) 0.023 % w/v<br>Sodium Propyl Hydroxybenzoate IP Eq. to Propyl Hydroxybenzoate (As preservative) 0.011 % w/v<br>In sterile buffered base qs |

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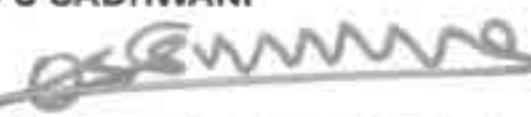
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| Sr.No. | Name of the Product   | Composition   |
|--------|---|---|
| 25     | CHLOROQUINE PHOSPHATE<br>INJECTION BP   | EACH ML CONTAINS<br>Chloroquine Phosphate BP eq. to Chloroquine base 40 mg<br>Benzyl Alcohol BP 1.5 % w/v<br>Water for Injection BP qs  |
| 26     | CIPROLEX<br>CIPROFLOXACIN EYE/EAR DROPS<br>5ML  | EACH VIAL CONTAINS<br>Ciprofloxacin Hydrochloride USP eq. to Ciprofloxacin USP 0.3 % w/v<br>Benzalkonium Chloride Solution (as preservative) USP 0.02 % v/v<br>Sterile Aqueous base 0 qs  |
| 27     | DETRIM<br>Drotaverine Hydrochloride 20mg  | Each ml contains<br>Drotaverine Hydrochloride 20 mg<br>Sodium Metabisulphite IP 1.0 mg<br>Absolute Alcohol IP 8.0 % v/v<br>Water for Injection IP qs  |
| 28     | DEXLY-G EYE/EAR DROPS<br>Gentamicin Sulphate &<br>Dexamethasone Sodium Phosphate<br>Eye Drops)            | Each ml contains<br>Gentamicin Sulphate IP eq. to Gentamicin base 0.3 % w/v<br>Dexamethasone Phosphate (as Dexamethasone Sodium Phosphate) IP 0.1 %<br>w/v<br>Benzalkonium Chloride Solution (as preservative) IP 0.02 % v/v<br>Water for Injection IP qs |
| 29     | DEXLY-N EYE/EAR DROPS<br>Neomycin Sulphate &<br>Dexamethasone Sodium Phosphate<br>Ophthalmic Solution USP | Each ml contains<br>Neomycin Sulphate IP eq. to Neomycin base 0.5 % w/v<br>Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1<br>% w/v<br>Phenyl Mercuric Nitrate IP 0.002 % w/v<br>Water for Injection IP qs                           |
| 30     | FALPAR INJECTION<br>Alpha Beta Arteether  | Each ml contains<br>Arte-ether 75 mg<br>Arachis Oil IP qs   |
| 31     | FLUTIREST NASAL SPRAY<br>FLUTICASONE FUROATE 27.5MCG<br>NASAL SPRAY                                       | EACH SPRAY CONTAINS<br>Fluticasone Furoate 0 27.5 mcg<br>Fluticasone Furoate 0 0.055 % w/v<br>Benzalkonium Chloride (As preservative) IP 0.02 % w/v   |
| 32     | INJ DCORT 40<br>Triamcinolone Acetonide Injection<br>IP-40mg/ml IM use only                               | Each ml contains<br>Triamcinolone Acetonide IP 40 mg<br>Benzyl Alcohol IP 0.9 % v/v<br>Water for Injection IP qs  |

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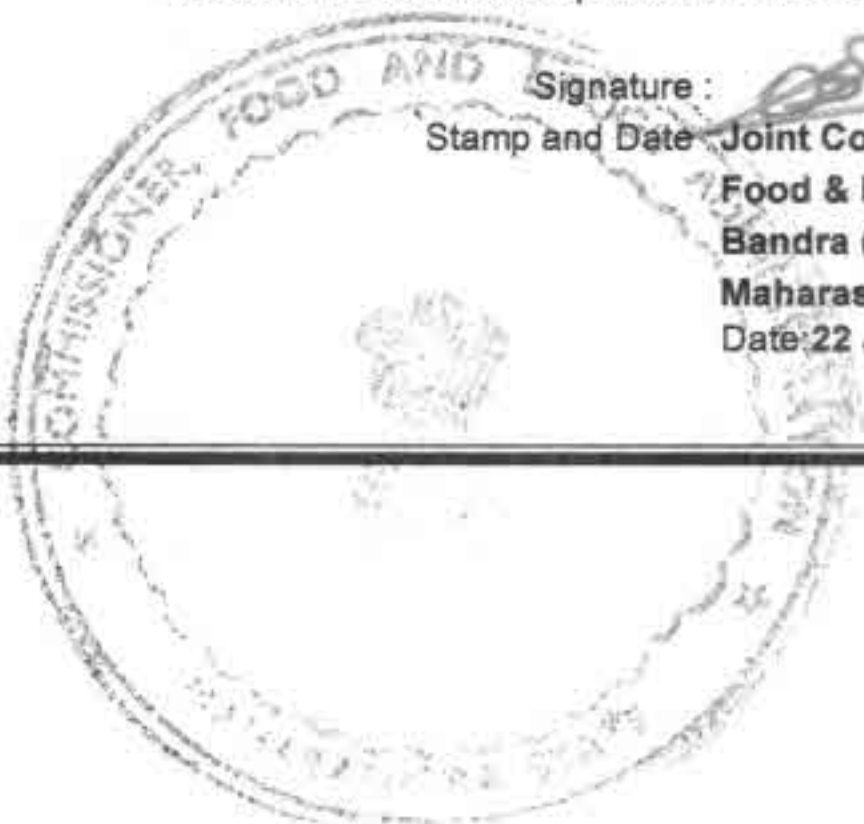
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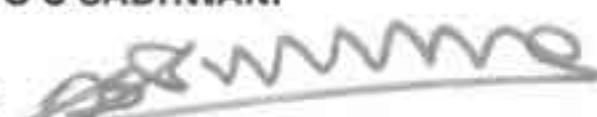
| Sr.No. | Name of the Product   | Composition   |
|--------|---|---|
| 33     | Intac Injection 25 mg/ml<br>Ranitidine Hydrochloride Injection<br>IP 25mg/ml  | EACH ML CONTAINS<br>Ranitidine Hydrochloride IP Equivalent to Ranitidine 25 mg  |
| 34     | LIDOCAINE INJECTION BP 1% W/V   | EACH ML CONTAINS<br>LIDOCAINE HYDROCHLORIDE BP 1 % w/v<br>WATER FOR INJECTIONS BP qs  |
| 35     | LYMON EYE/EAR DROPS<br>Dexamethasone & Chloramphenicol<br>Ophthalmic Solution | Each ml contains<br>Chloramphenicol IP 0.5 % w/v<br>Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1<br>% w/v<br>Phenyl Mercuric Nitrate(as preservative) IP 0.002 % w/v<br>Water for Injection IP qs |
| 36     | METHYLERGOMETRINE MALEATE<br>INJECTION IP 10ML                                | EACH ML CONTAINS<br>Methylergometrine Maleate IP 0.2 mg<br>Maleic Acid IP 0.0086 %<br>EDTA Disodium IP 0.01 %<br>Water for Injection qs   |
| 37     | NEO-HYCOLEX EYE, NOSE & EAR<br>DROPS  | EACH VIAL CONTAINS<br>HYDROCORTISONE ACETATE BP 1.5 % w/v<br>NEOMYCIN SULPHATE BP 0.5 % w/v<br>BENZALKONIUM CHLORIDE SOLUTION (AS PRESERVATIVE) USP 0.02 % v/v<br>STERILE AQUEOUS VEHICLE 0 qs                            |
| 38     | NORLY EYE DROPS<br>Norfloxacin Eye Drops BP                                   | Each ml contains<br>Norfloxacin IP 0.3 % w/v<br>Benzalkonium Chloride solution (as preservative) IP 0.02 % v/v<br>Water for Injection IP qs   |
| 39     | OFLOMAX<br>Ofloxacin Ophthalmic Solution USP                                  | EACH ML CONTAINS<br>Ofloxacin USP 3 mg<br>Benzalkonium Chloride Solution IP 0.02 % w/v<br>Water for Injection IP . qs   |
| 40     | OMEFLOX-DX<br>Ofloxacin & Dexamethasone<br>Ophthalmic Solution                | Each ml contains<br>Ofloxacin USP 0.3 % w/v<br>Dexamethasone IP 0.1 % w/v<br>Benzalkonium Chloride solution (as preservative) IP 0.02 % w/v<br>Sterile Aqueous vehicle qs   |

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| Sr.No. | Name of the Product  | Composition  |
|--------|--|--|
| 41     | OMEPRD EYE/EAR DROPS<br>Prednisolone acetate plus Ofloxacin<br>Ophthalmic Suspension | Each ml contains<br>Prednisolone acetate USP 10 mg<br>Ofloxacin USP 3 mg<br>Benzalkonium Chloride solution IP 0.02 % v/v<br>Sterile aqueous base qs  |
| 42     | PRED SOL EYE DROPS<br>Prednisolone Acetate Ophthalmic<br>Suspension USP              | Each ml contains<br>Prednisolone Acetate USP 10 mg<br>Benzalkonium Chloride solution (as preservative) IP 0.02 % v/v<br>Sterile aqueous vehicle qs   |
| 43     | REMYCIN 250<br>AMIKACIN SULPHATE INJECTION IP<br>250MG/2ML                           | Each 2ml vial contains<br>Amikacin Sulphate IP eq. to Amikacin IP 250 mg<br>Methyl Paraben IP 0.08 % w/v<br>Propyl Paraben IP 0.02 % w/v<br>Sodium Metabisulphite IP 0.33 % w/v<br>Sodium Citrate dihydrate IP 1.425 % w/v<br>Water for Injection IP qs  |
| 44     | SHAYLOK 0.5%<br>Ketorolac Tromethamine 0.5% Eye<br>Drops                             | Each ml contains<br>Ketorolac Tromethamine BP 5 mg<br>Benzalkonium Chloride BP 0.12 mg<br>Sterile Aqueous Vehicle 0 qs   |
| 45     | SHAYLOK INJECTION 1ML<br>Ketorolac Tromethamine Injection<br>USP 30mg/ml             | Each ml Contains<br>Ketorolac Tromethamine USP 30 mg<br>Water for Injections IP qs   |
| 46     | SHIPLIN 100<br>PENTOXIFYLLINE 100 MG/5ML INJ   | Each 5ml contains<br>Pentoxifylline USP 100 mg<br>Water for Injections BP qs   |
| 47     | SHYPED 25<br>PREDNISOLONE SODIUM<br>PHOSPHATE 25MG/ML INJECTION<br>USP               | EACH ML CONTAINS<br>Prednisolone Sodium Phosphate USP eq. to Prednisolone USP 25 mg<br>Water for Injections BP qs  |
| 48     | TOBRA-D EYE DROPS<br>Tobramycin & Dexamethasone Eye<br>drops                         | Each ml contains<br>Tobramycin Sulphate USP eq. to Tobramycin 0.3 % w/v<br>Dexamethasone Sodium Phosphate USP eq. to Dexamethasone Phosphate<br>0.1 % w/v<br>Water For Injection BP qs<br>Benzalkonium Chloride Solution (As preservative) BP 0.02 % v/v |

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| Sr.No. | Name of the Product                         | Composition  |
|--------|---|--|
| 49     | VITAL VIT K1<br>PHYTOMENADIONE INJECTION BP | Each 0.5ml contains<br>Phytomenadione BP 1 mg<br>Water for Injections BP qs  |
| 50     | VITAMED INJECTION                           | Each 2ml contains<br>Thiamine Hydrochloride BP 20 mg<br>Riboflavin Sodium Phosphate BP 4 mg<br>Pyridoxine Hydrochloride BP 4 mg<br>Nicotinamide BP 200 mg<br>Cyanocobalamine BP 8 mcg<br>D-panthenol BP 6 mg<br>Benzyl Alcohol (As preservative) BP 0.9 % w/v<br>Water for Injection BP qs |

1 2 3 4 5 6 7

Address of certifying authority :  
Food & Drug Administration, M.S.  
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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:22 Jan 2016



22 JAN 2016