



Food & Drugs Control Administration

BLOCK NO. 8, 1ST FLOOR, DR. JIVRAJ MEHTA BHAVAN,
GANDHINAGAR, GUJARAT STATE, INDIA PIN: 382010



Certificate No. : **1704005**

On the basis of the inspection carried out on **20-21/02/2017 & 28/03/2017** 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 & Address of site: **APEX HEALTHCARE LTD..**

4710, G.I.D.C. ESTATE,,

City : ANKLESHWAR, Dist : BHARUCH,

GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/1642**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	General	Manufacturer

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 **02/04/2019**. 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

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration,
Block No. 8, 1ST floor, Dr. Jivraj Mehta
Bhavan, Gandhinagar, Gujarat State,
India. - Pin : 382010

Name & function of : **(Dr. H.G. KOSHTIA)**
responsible Person **Commissioner**

Email : **comfdca@gujarat.gov.in**

Phone : **91-79-23253417, Fax : 91-79-232-53400**

Date : **03/04/2017**



LIST OF PRODUCT FOR GRANT OF COPP AS PER WHO GUIDELINES
(FOR EXPORT)

(MANUFACTURING DRUG LICENCE NO. IN FORM 25: G/25/1642)

- 1) MELOXICAM BP/EP/USP
- 2) PIROXICAM BP/EP/USP
- 3) BISACODYL BP/EP/USP
- 4) SODIUM ALENDRONATE BP/EP/USP
- 5) SODIUM PICOSULPHATE BP/EP
- 6) LIDOCAINE HCL BP/EP/USP
- 7) LIDOCAINE BP/EP/USP
- 8) PIROXICAM BETACYCLODEXTRIN
- 9) BENZOCAINE BP/EP/USP
- 10) PRILOCAINE BP/EP/USP
- 11) PRILOCAINE HCL BP/EP/USP
- 12) CETIRIZINE DIHYDROCHLORIDE BP/EP
- 13) PHENYRAMIDOL HYDROCHLORIDE
- 14) LORNOXICAM




For Commissioner
Food & Drugs Control Administration
Gujarat State, Gandhinagar

03 APR 2017 to 02 APR 2019



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