

# MEHTA

## API PVT. LTD.

EU-GMP, TGA, WHO-GMP

*Contributing to Good Health for Good Life*



## **VISION**

To be a leader in healthcare industry by contributing to enhance overall health and wellness of human being globally with high quality product at affordable price.

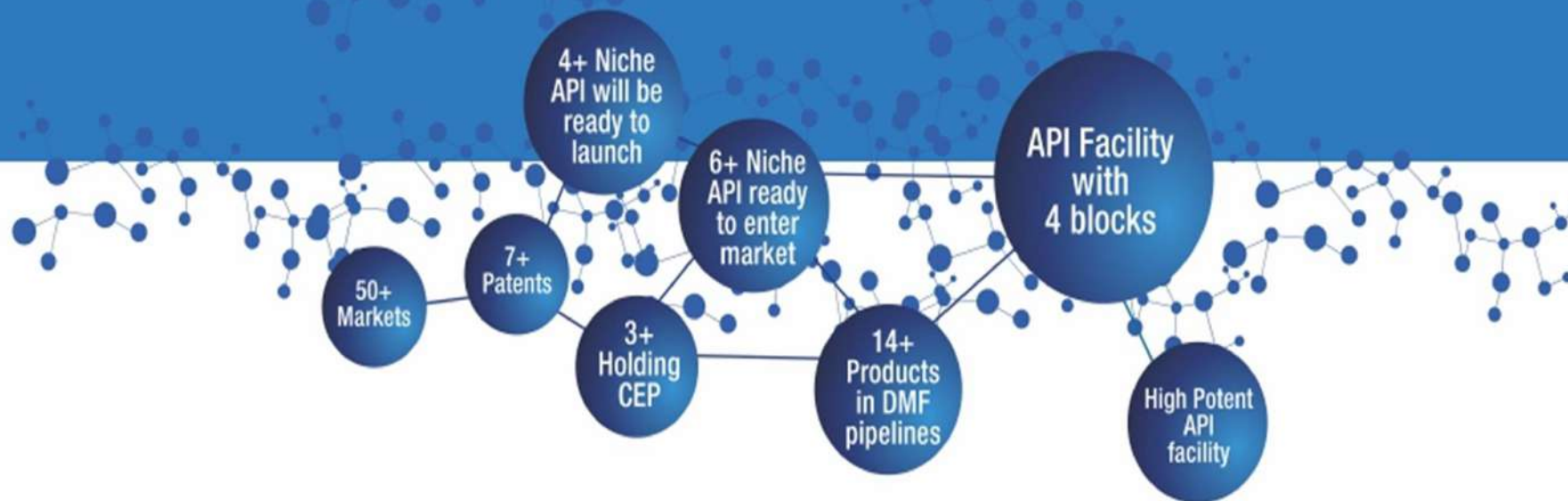
## **OUR COMPETITIVE ADVANTAGES**

- State-of-the-art manufacturing facility and equipment's
- Manufacturing support with strong expertise
- Flexibility: small to medium batch sizes, campaign production
- Company's ability to stay on the edge of innovation and to keep one step ahead of competitions
- Complies as per ICH and other regulatory guidelines
- Moving towards Zero discharge

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# Company Profile



WORKING IN REGULATED MARKETS FOR 15 YEARS  
SEVERAL **CTD DMF** APPROVED MORE THAN 30 COUNTRIES

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# Milestones



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## ASPIRATIONS

We will achieve long-term success by customer centric focus in Global pharmaceutical market, ensuring to stay on the edge of innovation and adapt new technology early in development & manufacturing for sustainable development.



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# Management Team



**Mr. HARSHADRAI MEHTA**, is a **CMD**. He is the founder of Mehta Group. With over five decades of dedicated work and a wealth of experience in the API Manufacturing field. He is the driving force behind MAPL's success & mentoring 2nd generation for successful growth.

He was President of Chemist and Druggist Association, Mumbai from 1992 to 1996

His passion is developing new, complex products for critical illness where there is challenging chemistry



**Mr. DEVENDRA H MEHTA** is a **CEO**. He is Science graduate from Mumbai University and Diploma in Business Management.

Responsibilities are Product Selection, Business Development, Strategic alliances, Intellectual property development and In/Out licensing.

His passion is to build a team and selection of good product and its development with eco friendly technology, and respect for the environment and contributing to the Society.



**Mr. YOGIN H MEHTA** is a **COO**. He is graduate in commerce & computer programming & cost accounting from Mumbai University.

Over a period of 2 decades, he has got vast experience from Plant administration, Regulatory and Legal compliance, Project Management and Accounts and Taxation.

His passion is adopting eco friendly Technology and reducing carbon footprint meeting EHS ( Environment, health and safety norms).

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# Manufacturing Facility



**MEHTA**  
API PVT. LTD.



- BLOCK "A" with Large Volume Products
- BLOCK "B" for Medium Scale Production
- BLOCK "C" with different Facilities and Capabilities for Small Scale Production
- BLOCK "D" is dedicated Production Area for HAPI with isolator.

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# Accreditations



**MEHTA**  
API PVT. LTD.

## CEP BISOPROLOL FUMARATE

**Certificate of Suitability**  
No. RO-CEP 2009-267-Rev 02

**1. Name of the substance:**  
BISOPROLOL

**2. Name of the manufacturer:**  
MEHTA API PVT. LTD.  
Gate No. 54B, SFL, SDA & SBL, Village Kundhwa,  
Taluka, District Rajkot

**3. Address of the manufacturer:**  
See Annex 1

**4. This certificate supersedes the previous certificate:**  
RO-CEP 2009-267-Rev 01

**5. The distribution of the information provided on the manufacturing method and subsequent (intermediate) quality parameters for this substance at the site(s) of production shall, in every way, comply with the quality of the substance as actually controlled by the current version of the monograph BISMOPROLOL in CD of the European Pharmacopoeia, current edition of the substance, only if it is supplemented by the (inter) national data listed in the following paragraphs of this certificate.**

**6. Any analytical quality indicated by the two pharmacopoeial monographs of the substance is limited to not more than 1.0%.**

**7. Test for residue solvents to get chromatography:** (Annex 2)  
Chromatograms: not more than 600 ppm

**8. In the air stage of the synthesis water to used as solvent:** not more than 5000 ppm

**9. The substance is tested as pharmaceuticals, played in a 10% dose.**

**10. The scope of the certificate includes the absence of use of material of human or animal origin in the manufacture of the substance.**

**11. The substance must be updated after any significant change that may affect the quality, safety or efficacy of the substance.**

**12. Provisions of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the scope of this certificate.**

**13. Date:** 14th March 2009  
**14. Validity:** 10 years  
**15. Issued by:** Director General, Directorate General of Medicines and Health Products

## CEP ERYTHROLYCIN

**Certificate of Suitability**  
No. RO-CEP 2013-342-Rev 01

**1. Name of the substance:**  
ERYTHROLYCIN FUMARATE

**2. Name of the manufacturer:**  
MEHTA API PVT. LTD.  
Gate No. 54B, SFL, SDA & SBL, Village Kundhwa,  
Taluka, District Rajkot

**3. Address of the manufacturer:**  
See Annex 1

**4. This certificate supersedes the previous certificate:**  
RO-CEP 2013-342-Rev 00

**5. The distribution of the information provided on the manufacturing method and subsequent (intermediate) quality parameters for this substance at the site(s) of production shall, in every way, comply with the quality of the substance as actually controlled by the current version of the monograph BISMOPROLOL in CD of the European Pharmacopoeia, current edition of the substance, only if it is supplemented by the (inter) national data listed in the following paragraphs of this certificate.**

**6. Any analytical quality indicated by the two pharmacopoeial monographs of the substance is limited to not more than 1.0%.**

**7. Test for residue solvents to get chromatography:** (Annex 2)  
Chromatograms: not more than 600 ppm

**8. In the air stage of the synthesis water to used as solvent:** not more than 5000 ppm

**9. The substance is tested as pharmaceuticals, played in a 10% dose.**

**10. The scope of the certificate includes the absence of use of material of human or animal origin in the manufacture of the substance.**

**11. The substance must be updated after any significant change that may affect the quality, safety or efficacy of the substance.**

**12. Provisions of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the scope of this certificate.**

**13. Date:** 14th March 2013  
**14. Validity:** 10 years  
**15. Issued by:** Director General, Directorate General of Medicines and Health Products

## EU GMP CERTIFICATE (ANSM)

**ANSM**  
Agence Nationale de Sécurité Médicament et Santé Publique

**CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER**

**1. Name of the manufacturer:**  
MEHTA API PVT. LTD.  
Gate No. 54B, SFL, SDA & SBL, Village Kundhwa,  
Taluka, District Rajkot

**2. Address of the manufacturer:**  
See Annex 1

**3. This certificate supersedes the previous certificate:**  
RO-CEP 2013-342-Rev 01

**4. The distribution of the information provided on the manufacturing method and subsequent (intermediate) quality parameters for this substance at the site(s) of production shall, in every way, comply with the quality of the substance as actually controlled by the current version of the monograph BISMOPROLOL in CD of the European Pharmacopoeia, current edition of the substance, only if it is supplemented by the (inter) national data listed in the following paragraphs of this certificate.**

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**12. Date:** 14th March 2013  
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## GLOBAL PRESENCE

AUSTRIA, ARGENTINA, BANGLADESH, BELGIUM, BRAZIL,  
CANADA, CHINA, COLOMBIA, EGYPT, GHANA, GREECE, HONG-KONG,  
IRAN, INDONESIA, IRELAND, JAPAN, JORDAN, KOREA, KENYA, MALAYSIA,  
MEXICO, MOROCCO, NETHERLANDS, PAKISTAN, PHILIPPINES, POLAND,  
ROMANIA, SINGAPORE, SOUTH AFRICA, SPAIN, SUDAN, SLOVENIA,  
TAIWAN, TUNISIA, TURKEY, THAILAND, UK, UAE, VIETNAM, ZIMBABWE



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# THANK YOU FOR YOUR ATTENTION

## MEHTA API PVT LTD (EU-GMP, TGA, WHO-GMP)

### CORPORATE OFFICE

Mehta API Pvt. Limited  
811, The Summit Business Bay,  
Next to Western Express Highway  
Metro station, Andheri Kurla Road,  
Andheri (East), Mumbai - 400093  
Board No: 91-22-40390400  
Fax no : 91-22-26845644  
Email : info@mehtaapi.com

### PLANT LOCATION

TARAPUR PLANT:  
Mehta API Pvt. Limited  
Gut. No. 546, 571, 519 & 520,  
Village Kumbhavali, Tarapur, Boisar,  
Dist : Palghar, Pin - 401 506,  
Maharashtra (INDIA).  
Phone : +91-7030964120-29,  
02525-661108

**“WORKING TOGETHER IS SUCCESS”**

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