

CORPORATE PROFILE



Presented by,

Dr. Bapu Gawade, M.Sc. Ph.D
Founder & Managing Director

Cleanchem Laboratories LLP

Corporate office and R&D

Plot No. A-737/2, TTC Industrial Area, MIDC Khairane, Navi Mumbai, INDIA- 400710

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Email: bapugawade@cleanchemlab.com Website: www.cleanchemlab.com

About Cleanchem

- Cleanchem is registered on 11th May 2015 under Ministry of Commerce, Govt. Of India
- Approved by DIPP, Govt. of India, (Recognition No: DIPP31605)
- Deals in various Products & Services to Pharmaceutical, Agro, Biotech & allied industries
- Independent Reliable Synthesis & Analytical R&D based CRO / CDMO
- Pioneer in Developing Nitrosamine standards in India
- Largest Inventory of Nitrosamines & NDSRI across the globe

Accreditations & Recognition

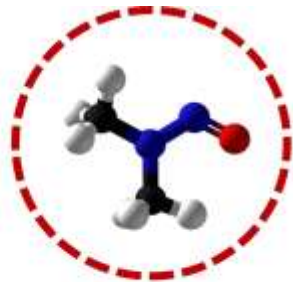


Cleanchem at Glance

- **8+ Yrs** of service to Pharma, Chemical & Allied Industries
- Global Presence **35+ Countries**
- State of Art **World Class R&D** Infrastructure of 22,000 Sq. Ft area
- Team of **100+ Scientists** including Ph.D's & Post Graduates



4000+
Impurities
Ready Stock



500+
Nitrosamines
Ready Stock



400+
Clients
Worldwide



Product
Specific
Packaging



100%
Quick
Delivery

Our Team

❖ **Dr. Bapu Gawade (Managing Director)**

M.Sc. Ph.D - Chemistry (ICT / UDCT Mumbai) Research Experience: 16 years

❖ **Mr. Nitin Bondre (Operational Director)**

M.Sc. Organic Chemistry (Pune University), Pursuing Ph.D Research Experience: 16 years

❖ **Dr. Anil Gawade (R&D Director)**

M.Sc. Ph.D - Chemistry (ICT / UDCT Mumbai) Research Experience: 12 years

Technical Strength with Qualification (Total: 110+)

➤ PhD: 08

➤ Postgraduate: 100

Organogram

Dr. Babu Gawade
Managing Director

Mr. Nitin Bondre
Director- Operations

Administrative Head

Dr. Anil Gawade
Director - R&D

QA

Accounts

Stores &
Material
Management

Purchase & Supply
Chain Management

Maintenance

Business Development

Sales

Finance

HR

Administration

CRD

ARD

Safety

Project
Management

Dr. Bapu Gawade (Managing Director)

Experience

- **Research Exp.- 16 Yrs.**
- **Ph.D Chemistry: 2015**, Institute of Chemical Technology, ICT (Formerly UDCT) Mumbai
- **M.Sc. Organic Chemistry: 2007**, Ahmednagar College, Ahmednagar, Pune University
- **Visiting Researcher**, University of Saskatchewan, Saskatoon, Canada , 2012-2013

Awards, Recognition & Professional Expertise:

- **Junior Research Fellow**, CSIR-NMITLI, 2009
- **Special Meritorious Fellow**, UGC (Green Technology Programme), 2010
- **Commonwealth Fellow**, Govt. of Canada under INDO-CANADA Research and Cultural Exchange Programme, 2012
- **“Healthcare leadership Award”**, ABP News 2018
- **“100 Most Impactful Healthcare Leaders Award”**, World Health & Wellness Congress, 2019
- **“Young Achiever Award”** by UDCT Alumni Association, 2019

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Mr. Nitin Bondre (Director - Operations)

Experience

- **Research Exp.- 16 Yrs.**
- **Ph.D. Chemistry:** Pursuing Institute of Chemical Technology, ICT (Formerly UDCT) Mumbai
- **M.Sc. Organic Chemistry: 2007,** Ahmednagar College, Ahmednagar, Pune University

Patents & Professional Expertise:

- A process for the preparation of Avanafil and its novel intermediates (**W02015177807A1**)
- Filed patent of preparation Apremilast impurities (**Application ID 201621013195**)
- Stability-indicating related substances method of Apremilast by HPLC and synthesis and characterization of related impurities using Mass and NMR spectroscopy
(**International Journal of Current Medical and Pharmaceutical Research February 28, 2017**)
- Synthesis, Characterization, Identification and Quantification of Sertraline HCL Related Impurities
(**European journal of pharmaceutical and medical research October 14, 2016**)

Contact Details



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Dr. Anil Gawade (Director - R&D)

Experience

- **Research Exp.- 12 Yrs.**
- **Ph.D. Chemistry: 2016**, Institute of Chemical Technology, ICT (Formerly UDCT) Mumbai
- **M.Sc. Organic Chemistry: 2011**, Ahmednagar College, Ahmednagar, Pune University

Awards, Recognition & Professional Expertise:

- **Special Meritorious Fellow**, UGC (Green Technology Programme), 2012
- Worked as a **R&D Manager** in **Dharamsi Morarji Chemical Company** (2017-2019)
- Worked as a **Research Scientist** in **Resonance Specialities Ltd.** (2016-2017)
- Worked as a **Research Chemist** in **Ranbaxy Pharmaceuticals Ltd.** (2011-2012)
- Published 5 research papers in international peer-reviewed journals and granted 3 Indian patents

Contact Details



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Mobile: +91-9702598044

R&D Capabilities - Chemical Synthesis

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- **Reaction Scale: Mg to Kg**
- **Reaction Temp Range -80 to 200 °C**
- **Laboratory Fume Hood (20)**
- **Rotary Evaporator (1L to 20L)**
- **Fix Glass Reactors (25L to 50L)**
- **High Pressure & Gas Phase Reaction**
- **Microwave Reactions**
- **Pyrophoric & Moisture Sensitive Rxns**
- **Flow Chemistry**



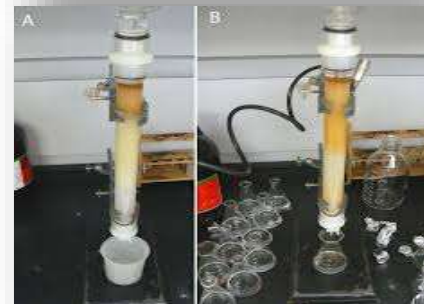
Analytical Instrumentation Facility

- **HPLC with UV & PDA Detector (05)**
- **Gas Chromatography (03)**
- **GC-MS (01)**
- **LCMS-MS -Triple Quadruple (01)**
- **Karl Fischer Titrator**
- **Titrimetric Analysis**
- **Volumetric analysis**
- **Gravimetric Analysis**



Advance Purifications / Bio-processing

- **Chromatographic Purification with Silica & Resin**
- **Preparative HPLC Purification**
- **Flash Chromatography**
- **Lyophilization Facility**
- **Short Path Distillation / Thin Film Evaporation**
- **Steam Distillation**
- **High Vacuum Distillation**
- **Unknown Impurity Identification**



Our Products

- **Impurity Reference Standards**
- **Working standards**
- **Nitrosamines & NDSRI's**
- **Metabolites & Glucuronides**
- **Genotoxic Standards**
- **Isotope Labelled Standards**
- **Peptides & Bile Salts**
- **API, Intermediates & KSM**
- **Catalysts & Nano Materials**



Nitrosamines (Genotoxic Standards)

- Custom Synthesis of **Nitrosamines & NDSRI's**
- **Pioneer** in Development of Nitrosamine Standards
- **Ready stock 500+** Nitrosamines & NDSRI's
- Expertise in synthesis of Product Specific Nitrosamine (**NDSRI's**)
- Nitrosamine **Assessment** in Drug Substance & Drug Products
- Technical Justification Report for Regulatory Authority submission for the Non Formation & Non Stability of Nitrosamines
- A Unique List of **~7000 NDSRI** from various API is ready for publish

500+ Ready Stock Nitrosamines

Nitroso Compound	Abbr.
N-Nitroso Dimethylamine	NDMA
N-Nitroso Diethylamine	NDEA
N-Nitroso-N-methyl-4-aminobutyric Acid	NMBA
N-Nitroso Dibutylamine	NDBA
N-Nitroso Diisopropylmine	NDIPA
N-Nitrosoisopropyl Ethylamine	NEIPA
N-Nitroso Methyl Phenylamine	NMPA
N-Nitroso N Methyl Piperazine	NMP
N-Nitroso N-Methyl Morpholine	NMOR
N-Nitroso Dibenzylamine	NDBZA
Many more.....	

NDSRI's Compound
N-Nitroso Diclofenac
N-Nitroso Dabigatran
N- Nitroso Metoprolol
N- Nitroso Sitagliptin (NTPP)
N- Nitroso Quetiapine
4-Nitroso Hydrochlorothiazide
N- Nitroso Vancomycin
N- Nitroso Azithromycin
N- Nitroso N Desmethyl Metformin
N- Nitroso Sumatriptan
Many more.....

Services Offered

- **Custom Synthesis Services (CRO/ CDMO)**
- **Drug Discovery Support**
- **KSM Synthesis**
- **FTE & FFS based R&D Services**
- **Short Path Distillation (SPDU) & Thin Film Evaporation**
- **High Pressure Reactions on Autoclave (R&D Scale)**
- **Advance Purification Services**
- **Unknown Impurities Identification**

Our Esteemed Clients



International Clients





Thank You