

**YOUR**  
**PRECISION TESTING**  
**PARTNER**



NABL (ISO / IEC 17025 : 2005)



ISO 9001:2008

**MAL** MANISHA  
ANALYTICAL  
LABORATORIES PVT. LTD.

**“ Achieving Excellence Through Analytical Service”**

## THE TRUSTED NAME IN PRECISION TESTING

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Manufacturing companies in India have made enviable progress over the years. Today, a number of them enjoy significant international presence. Everything, from pharmaceutical and petroleum products, to dyes and chemicals, is exported from India to all corners of the globe. The progression has brought with it an added sense of responsibility and accountability. Today, for a product to compete in the international markets, it has to be certified by a approved testing lab. Hence, now more than ever, Indian companies need a precision testing partner they can depend on.

**Manisha Analytical Laboratories Pvt. Ltd. (MALPL)** was founded in 1989 with the sole mission to partner our customers in their analytical testing needs. MALPL have always remained ahead of competition due to prompt & cost effective analysis. MALPL has a team of visionary technocrats who foresaw the growing need for reliable analytical testing more than two decades ago. Ever since, staying ahead of the curve has been a part of MALPL's DNA.



## FROM THE DIRECTOR'S DESK



When we founded **Manisha Analytical Laboratories Pvt. Ltd. (MALPL)** in 1989 our sole aim was to partner our customers in their analytical testing needs. The past two decades have shown us in good light. But we are hardly content. We intend to continue our dominance in analytical testing in India for years to come, and have made a number of significant acquisitions towards this end. The most recent being Bee Pharmo Labs Pvt. Limited and Omega Analytical Laboratories.

We are also on the lookout for an international partner to fortify our reach in the international market. Possibilities of outsourcing the sampling process from pharma giants in USA, Europe & across the globe are also being explored.

At MALPL, we continue to abide by a simple maxim... **"Look back with pride. Look forward with passion!"**

## OUR STRENGTHS

- **MALPL** has a full-fledged marketing team, which reviews the needs of our clients on an ongoing basis, and suggests them the best solutions. They help our clients make informed decisions.
- **MALPL** has a dedicated team of well-trained customer support executives who co-ordinate with our customers and aid them with prompt solutions.
- **MALPL** has a specialized Logistics team for collection of samples and delivery of reports to our customer's premises.
- **MALPL's** 9000 sq. ft. State-of-the-art lab, boasts of a highly competent technical team guided by senior technocrats.
- **MALPL** promises its customers quality, integrity and confidentiality of their critical information. One of the biggest reasons for our customers choosing us as their testing partner is we offer value added service at no extra cost.

At **MALPL** we speak one language – our customer's language. And that's the **language of Quality!**



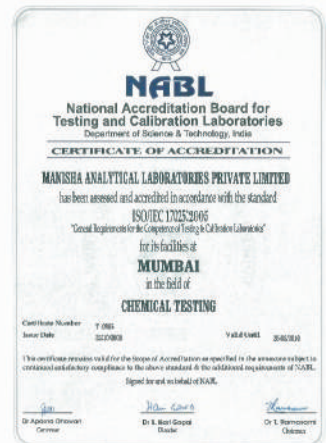
**"Achieving Excellence Through Analytical Service"**

## OUR QUALITY METHODOLOGY

**Manisha Analytical Laboratories Pvt. Ltd.** continues to remain committed to a high standard of service by employing stringent quality measures. Our service reflects planned professionalism through high integrity, dedication and strict confidentiality. Our staff is imparted continuous training by internal as well as external experts, which helps the organization stay abreast of the rapidly changing technological environment. We adhere to SOPs, and our instruments undergo periodic quality checks and calibrations, both by internal as well as external agencies, to maintain precision in the results.



## OUR RECOGNITIONS



MALPL has been bestowed the globally recognised NABL accreditation in accordance with standard **ISO/IEC-17025:2005**.



MALPL's facilities are ISO 9001:2008 certified by BM TRADA.

## PRECISION AT WORK



**Manisha Analytical Laboratories Pvt. Ltd.** is the preferred testing partner for a number of organizations from varied sectors. We undertake analytical testing of:

- **Pharmaceutical Formulations**
- **Fine Chemicals**
- **Raw Materials**
- **Cosmetics**
- **Ayurvedic Preparations**

**MALPL's** state-of-the-art facilities include:

- **A full-fledged R&D Lab with stability studies**
- **Chemical Instrumentation Lab**
- **Microbiological & Sterility Lab**
- **Biological Lab**

**MALPL** adhere to the norms laid down by World health Organisation (WHO), and the GLP norms of the Amended **Schedule 'L-I'** of the Drugs & Cosmetics Act. The lab is fully air-conditioned with air handling systems to ensure that all tests are carried out in a strictly controlled environment.

The laboratories are staffed by FDA-approved skilled professionals and are equipped with the latest instruments to conduct a variety of tests. All lab instruments are under AMC, and are periodically calibrated by an internal as well as external agencies to maintain precision in the test results.



**" Achieving Excellence Through Analytical Service"**

## THE TOOLS OF PRECISION

**Manisha Analytical Laboratories Pvt. Ltd.** Including R&D Lab is equipped with state-of-the-art instruments to ensure precision in a variety of tests. The Lab has often found itself at the leading edge of change in the analytical testing domain.

Here's an overview of the lab facilities:



### PARTICLE SIZE ANALYZER

The particle size analyzer of **Microtrac S3500 (USA)** is based on trilaser system for wet & dry method. The S3500 measures scattered light from particles in a laser beam. The amount of direction of light scattered by the particles measured by optical detector arrays is analysed to determine the particle size distribution. The measuring range is between 0.243 microns to 1408 microns. The particle size analyzer is used in many application requirements for the pharmaceutical products, pigments, bulk drugs, speciality chemicals.

### THE PARTICULATE MATTER

It is based on light obscuration particle count test of subvisible particles of small volume parentals (injections), large volume parentals [infusions] & ophthalmic solutions. The detection range is between 2 microns & 123 microns.



### HIGH PERFORMANCE LIQUID CHROMATOGRAPHY [H.P.L.C.]

**MALPL** employs various H.P.L.C. System with auto sampler including R. I. detector to evaluate the quality of formulated products, impurity profile and active pharmaceutical ingredients. The system is equipped with the latest version of clarity and empower-2 software [CFR21 Part II compliant] and high quality columns like Zorbax, Inertsil, Lichrocart and Chiral etc.



### GAS LIQUID CHROMATOGRAPHY [G.L.C.] WITH HEADSPACE

MALPL employs various GC like varian 3400CxG.C with Head Space analyzer & autosampler to estimate the purity or content of the substances, which have properties of vaporization at higher temperature. Residual solvents of Class I & Class II are tested as per their PDE limits by Head Space arrangement. Number of samples with the same operating parameters can be estimated in a sequence.

### ATOMIC ABSORPTION SPECTROPHOTOMETER [A.A.S]

Atomic Absorption Spectrophotometer is used to estimate elemental substances present in the formulated products. Some of the elements present due to their low absorption character and toxic elements present in low concentration are estimated by the use of a hydrated generator.



### FOURIER TRANSFORM INFRARED SPECTROPHOTOMETER [F.T.I.R.]

This is used for the measurement of the absorption of electromagnetic radiation in infrared region. It consists of an optical system capable of providing monochromatic light in the region of 4000 to 625  $\text{cm}^{-1}$ . This is normally used for identification of drugs.



## BREAKING NEW GROUND IN PRECISION



**Manisha Analytical Laboratories Pvt. Ltd.** is amongst the few testing laboratories in India who conducts **Method Validation & Stability** Studies according to **ICH guidelines**.

**Analytical Method Development** is required for:

- Macro analysis (Active ingredients)
- Micro analysis (Residues)
- Impurity profiling
- Achieving acceptance of products by international agencies
- Mandatory requirement for accreditation as per ISO/IEC 17025 guidelines
- Mandatory requirement for registration of pharmaceutical products

**MALPL** follows the following

### **Parameters for Method Validation:**

- Specificity
- Linearity & Range
- Accuracy
- Precision
- Limit of Quantification / Detection
- Ruggedness
- Robustness

**MALPL's lab** is equipped with the latest instruments to support **Method Validation**.



### **WATERS ALLIANCE 2695 HPLC SYSTEM WITH EMPOWER SOFTWARE**

- Method Validation of Assay Procedure and API
- Method Validation of Assay Procedure and Dissolution for formulated products
- Method Validation of chromatographic purity and related substances





### DISSOLUTION TESTER (USP) TDT-14L WITH 14 JARS WITH AUTO SAMPLER

This apparatus can produce the dissolution profile of 12 capsules / tablets according to ICH guidelines. It can be used to compare the dissolution profile of an innovator brand with the market leader. It is relied upon by pharmaceutical companies to gain an edge in an extremely competitive market.

### AGILENT 7890A GAS CHROMATOGRAPH WITH AUTO SAMPLER & HEAD SPACE ANALYSER

This GC is used for Method Validation of residual solvents in API as well as in formulated products. It is also used for Assay Method Validation of API and formulated products.



### STABILITY CHAMBERS

MALPL offers comprehensive stability testing services according to ICH guidelines. Manisha Analytical Laboratory has installed 3 dedicated stability chambers for real time and accelerated conditions. A backup chamber has also been set up to allow uninterrupted testing even in case of an emergency.

- $25^{\circ}\text{C} \pm 2^{\circ}\text{C}$  &  $60\% \pm 5\% \text{RH}$
- $30^{\circ}\text{C} \pm 2^{\circ}\text{C}$  &  $65\% \pm 5\% \text{RH}$
- $40^{\circ}\text{C} \pm 2^{\circ}\text{C}$  &  $75\% \pm 5\% \text{RH}$

All storage chambers are completely automated. They are equipped with an emergency alert system, and are monitored 24x7. Moreover, being 21 CFR Part 11 compliant, they have generator backup to ensure uninterrupted service even in case of power failure.



## PRECISION IS IN OUR DNA

**Manisha Analytical Laboratories Pvt. Ltd.** believes in partnering its clients all the way. Hence, our microbiological department has state-of-the-art testing facilities for conducting Microbiological Tests. The facility has special Air Handling Units (AHU), which ensure that all tests are carried out in a strictly controlled environment.



**MALPL** conducts **MICROBIOLOGICAL TESTS** like:

- Microbiological Method Validation
- Microbiological Assay, Sterility
- Preservative Efficacy, Microbial Limits, Bioburden
- Surgical Dressings and Medical Devices
- RWC Test, SC Test
- Bacterial Endotoxin [ LAL Test]
- Environmental count [Air Sampling Of Agar Plates & Agar Strips]
- Water analysis

### BIOLOGICAL DEPARTMENT

Biological lab is situated at Goregaon [West].

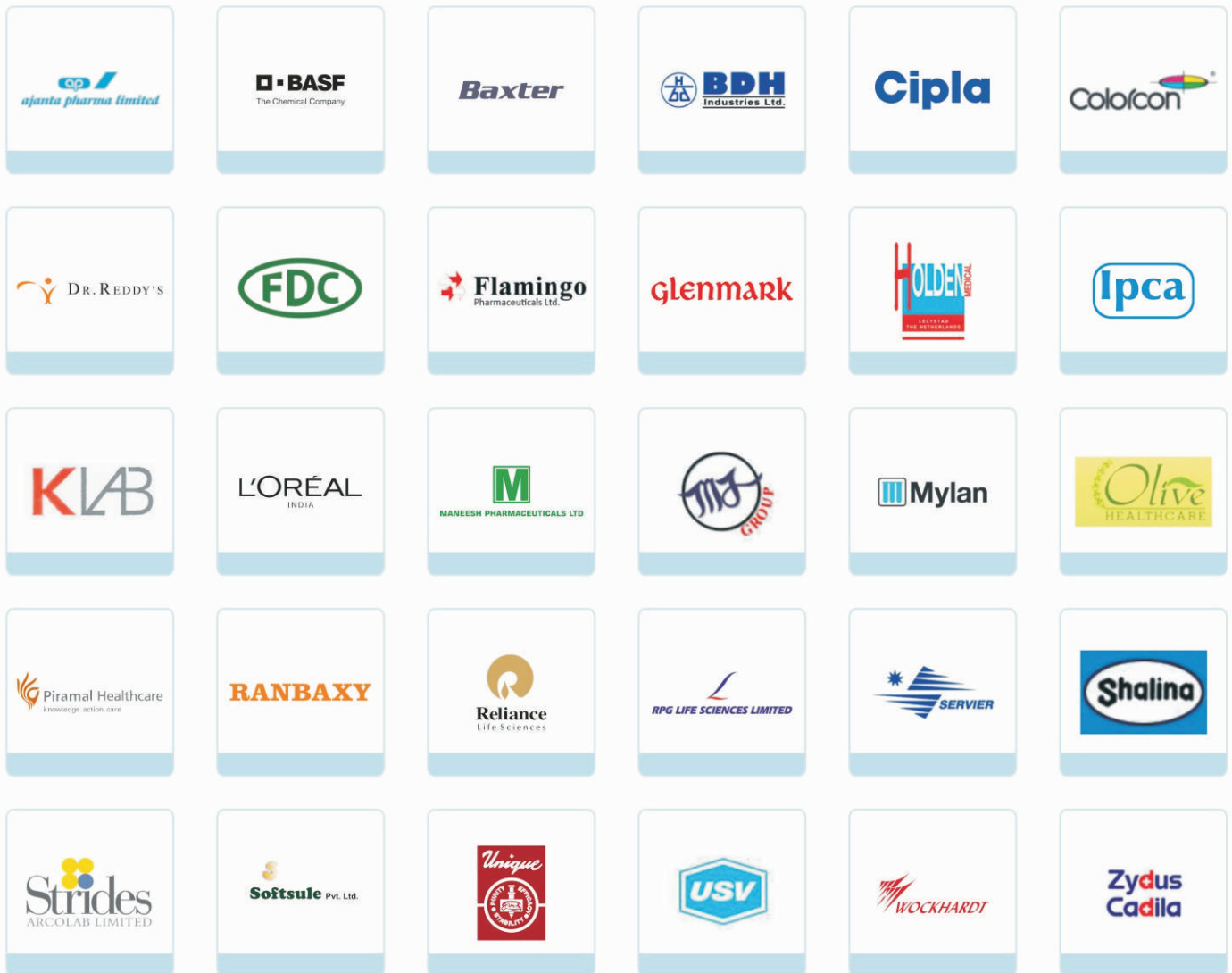
**MALPL** conducts biological tests like

- Pyrogen
- Toxicity
- Biological Tests [Systemic injection & intracutaneous injection]
- Eye irritation test
- Skin irritation test



## PARTNERSHIPS DRIVEN BY PRECISION

**Manisha Analytical Laboratories Pvt. Ltd.** is the preferred testing partner for a number of esteemed organizations from both the Government as well as the Private sector.



To all the esteemed customers not listed, we always remain indebted to your valuable support.

**Manisha Analytical Laboratories Pvt. Ltd.** has come this far primarily because of the continued patronage and support of our esteemed customers. Going ahead we expect to form new partnerships and garner even more support. For it is this trust and encouragement from our customers that help us cross new frontiers in quality, dedication and integrity.



"Achieving Excellence Through Analytical Service"



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### **Manisha Analytical Laboratories Pvt. Ltd.**

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