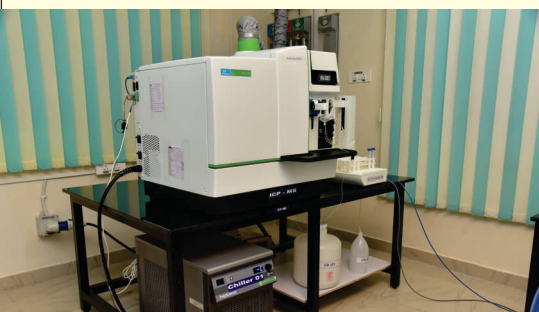




MART Specialities Lab. LLP



Office Address:

13-6-438/A/83
Srisathyanarayana Nagar
Mehdipatnam
Hyderabad - 500 028

Website: www.martsplab.com

Mail Id: martspecialities@gmail.com

Work Address:

Plot. No:31, First Floor
ALEAP Industrial Area
Gajularamaram
Quthbullapur (M)
Medchal-Malkajgiri (Dist)
500055, TS, India

Technical Contact:

Mrs. K. Parjanya
Director - Technical
Ph. No :9866178556
8500798350

Administrative Contact:

Mrs. R. Jacinta
Director - Administration
Ph. No : 9848125019
8500798350

Legacy of Commitment.....

Legacy of Commitment.....

Introduction



M/s Marayya's Laboratory for Analytical Research and Testing Pvt. Ltd (MART LABS) was incorporated in the year 2007 and entered into an agreement with Hyderabad Pharma Infrastructure and Technology Limited (HPITL) and Jeedimetla Industries Association (JIA) to Operate and Maintain the state-of-art laboratory for a period of 10 years from June, 2010 to June, 2020. Successfully completed 10 year lease in June 2020 with a customer base of 100+.

MART LABS was a USFDA inspected facility since December 2016. USFDA's current requirement as per 21 CFR part 11 necessitated upgradation of the existing lab and so in 2019 we floated MART Specialities Lab, LLP complying all the requirements and established the same in June 2020. Equipped with the latest technology instruments to provide specialised analytical services.

M/s Marayya's Laboratory for Analytical Research and Testing Pvt. Ltd with two Directors Dr. R, Marayya and R. Jacintha has promoted "**MART Specialities Lab, LLP**" with one more Director, K. Parjanya as the new legal entity. This Regulated Laboratory is located at Road. No: 3, Plot. No: 31, ALEAP Industrial Area, Pragathi Nagar, Gajularamaram, Medchal-Malkajgiri Dist, 500055.

In September 2020, the information pertaining to "**Mart Specialities Lab, LLP**" (site master file, site address, instruments list, incorporation, DCA/CDSCO approval, etc) were submitted to USFDA Regulatory Authority against their request. Further, we have proactively registered this new facility "**MART Specialities Lab, LLP**" with DUNS No & FEI No.

Quality Policy

"To ensure accurate, consistent, impartial and timely delivery of Quality Services to customers by implementing the policies and systems through competent technical personnel. The Management of MART Specialities Lab, LLP aims for continual improvement in Quality services provided to customers by establishing compliance with Management system as per ISO/IEC 17025:2017."

Core Objectives

- ✧ We provide Impartial and Ethical Quality services to customers.
- ✧ We ensure unparalleled quality services in the fields of testing.
- ✧ We adopt Quality Analytical testing as culture.
- ✧ We are guided by customer and not by competition.

Mission Statement

Assurance of Total Quality Service
at an Affordable Cost

Vision Statement

To Emerge as a Knowledge Based and
Quality-Culture Analytical Research and
Testing Laboratory with Global Recognition.

Laboratory Special Features

- ✧ MART Speciality Lab, LLP is designed with the State-of-the-art facilities.
- ✧ Installed and Qualified instruments are the latest Models in design.
- ✧ The software used for Electronic data handling are **21 CFR Part 11** compliant.
- ✧ Traceability and Assurance of documentation to ensure adherence to GLP principles.

Specialized Services Offered

- ✧ Spectral characterization of materials.
- ✧ Polymorphism studies.
- ✧ Thermal properties of materials.
- ✧ In-organic elemental impurities determination.
- ✧ Organic elemental impurities determination.
- ✧ **Method development, Optimization and Validation** studies.
- ✧ On-site hands on training on instruments.
- ✧ cGMP and GLP training.



DIFFERENTIAL SCANNING CALORIMETER (DSC)



MAKE: TA Instruments
MODEL: DSC 25



MICROBALANCE
MAKE: RADWAG
MODEL: MYA 5.4Y

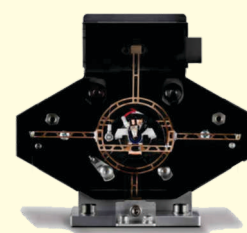
- * **Discovery DSC** is the **World's finest** line of Calorimeter from TA Instruments with Patented Fusion cell technology.
- * Measures thermal transitions like glass transition temperature, onset and peak temperatures during melting endotherms, heat flow and decomposition pattern.
- * Temperature range: **-180 to 600°C**.
- * Lowest baseline noise and highest sensitivity.
- * **TRIOS software** for instrument control, data analysis and reporting of thermal analysis results is **21 CFR Part 11 compliant**.
- * Applicable for evaluation of thermal properties of Pharmaceutical materials and polymorphism studies. Applicable to polymers, plastics and packaging material evaluation.

THERMOGRAVIMETRY ANALYSER (TGA)



MAKE: TA Instruments
MODEL: TGA 55

- * **Discovery TGA** is TA Instruments **proprietary Tru- Mass Balance**.
- * More sensitive and accurate thermo balance.
- * Ultra low drift balance design ensures accurate detection of even small weight changes.
- * Can be operated from room temperature to 1000°C.
- * **TRIOS Software** for instrument control, Data analysis and reporting of thermal analysis results is **21CFR part 11** compliant.
- * Applicable for pharmaceutical materials evaluation studies like determination of moisture and low volatiles, decomposition pattern studies, thermal stability of materials, compositional analysis and residual ash content.
- * Also applicable to Polymers, Composites, Plastics and Additives evaluation, Metal and Alloy Industries.



TRU MASS BALANCE SYSTEM

ORGANIC ELEMENTAL ANALYSER (CHNSO)



MAKE: Elementar
MODEL: Unicube

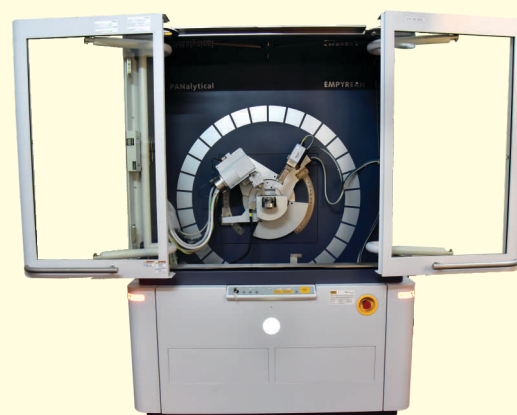


**Direct Temperature
Programmed Desorption
(Direct TPD)**

- ✧ **Unicube Model** is the 6th **Generation Microelemental Analyser** for simultaneous analysis of Carbon, Hydrogen, Nitrogen, Sulphur and Oxygen in solids and liquids.
- ✧ **Unicube Model** is Elementar's proprietary and improved Direct temperature Programmed Desorption (**Direct TPD**) technology for highest reliability and performance in gasses separation technology.
- ✧ **Unicube** has State of art highly sensitive Thermoconductivity detector and double furnace technology for Combustion and Reduction.
- ✧ **UNICUBE software** used for data handling is **21 CFR Part 11 compliant**.
- ✧ Applicable for analysis of samples in industries like
 - ☆ Pharmaceuticals, Food and Agriculture
 - ☆ Coal, Fats and oils
 - ☆ Forensic materials, Chemicals and polymers.

- ✧ **Intelligent 3rd Generation EMPYREAN Diffractometer.**
- ✧ The **Pixel 1D detector** is the only detector that can be used as **Point, Line and Area Detector**.
- ✧ Powerful non destructive technique for characterizing crystalline materials and provides information on structures and phases of materials.
- ✧ **Conventional** PXRD systems have LOD in the range of 1.0-2.0% whereas latest generation **PXRD** with **Pixel Detector** has brought down this value to about **0.1- 0.2%** level (**Available in our lab**).
- ✧ Pixel detector has unrivalled signal to noise ratio and unmatched dynamic range and linearity.
- ✧ Ability to measure all sample types from powders to thin films and from nanomaterials to solid objects on a single instrument.
- ✧ **Data Collector, Data Viewer and High Score Processor Software** used for data handling is **21 CFR Part 11 compliant**.
- ✧ Applicable to API, Drug products, Pre- formulation optimization studies.
- ✧ Polymorphs Detection and Quantitative determination.
- ✧ Amorphous and Crystallinity Quantitative determination.
- ✧ Structures of variable hydrates, solvates investigation.

X-RAY POWDER DIFFRACTOMETER (PXRD)



MAKE: MALVERN PANALYTICAL
MODEL: EMPYREAN with Pixel Detector

INDUCTIVELY COUPLED PLASMA - MASS SPECTROMETER (ICP-MS)



MAKE: Perkin - Elmer
MODEL: Nex-Ion 2000

- * Nexlon-2000 is the latest generation with Lumicoil technology.
- * Can be operated in three modes: **Standard, Collision and Reaction.**
- * The most versatile ICP-MS on the Market with High Performance.
- * Nexlon 2000 is the only ICP-MS that can run with pure ammonia and other reactive gasses in the reaction mode.
- * Capable of handling any sample matrix, including samples with **high inorganic TDS content.**
- * Can handle high concentration of **DMSO** for the analysis of samples readily soluble in organic medium.
- * Fast, safe, cost effective microwave sample preparation for closed- vessel digestion system.
- * **Syngistix Software** with enhanced security capabilities used for data handling is **21 CFR Part 11 and other regulations compliant.**
- * Applicable to Pharmaceuticals (API and Drug products), Minerals, Metals, Refractory materials, Semiconductor, Electronics, Plastics, Rubbers, Coatings, Polymers, Agriculture and food industries.

MICROWAVE DIGESTOR



MAKE: CEM
MODEL: Mars oNE

ATOMIC ABSORPTION SPECTROMETER (AAS)



MAKE: Thermo Scientific
MODEL: iCE - 3300

- * The high Precision, **Double beam optics** provide unrivalled performance, unparalleled detection limits and exceptional optical stability.
- * Universal **Finned Titanium Burner** to enable the use of both air/acetylene and nitrous oxide/acetylene flame types and maintains a stable, reproducible flame.
- * Deuterium background correction for high Accuracy.
- * Superior detection limits and a fully inert sample system.
- * Wide measurement range with ability to measure major elements in samples as well as key contaminants that pose risk to product quality.
- * **Solaar Security software** with all the tools used for data handling is **21 CFR part 11 compliant.**
- * Applicable in qualitative and quantitative analysis of Pharmaceuticals and clinical analysis of metals in biological fluids and tissues.

ULTRA PURE WATER SYSTEM



MAKE: TKA
MODEL: Omnia Tap
Omnia Pure

Resource Personnel

DR. R. MARAYYA, M.Sc, Ph.d (Analytical Chemistry) Business Head & CEO

PROFILE SYNOPSIS

- ✧ Dr. R. Marayya has 30 years industrial experience in the fields of pharmaceuticals, chemicals and allied fields and polymers.
- ✧ Specialized in Quality (QA& QC) operations, Quality Management Systems (QMS) and International Regulatory requirements (cGMP).
- ✧ Has varied and extensive exposure in analytical Instrumentation techniques (Spectroscopy, Chromatography, Thermal, etc), materials characterization techniques and Analytical Method development and Validation studies.



LANDMARK ACHIEVEMENTS

- ✧ 10 years as consultant to Pharmaceutical and allied industries. Has obtained 15+ USFDA regulatory approvals (Drug substance, Drug Product, Herbal and Semi-synthetic Product. DMF's for various products to US FDA, EDQM, TGA and other Regulatory authorities.
- ✧ Has conducted number of cGMP Training Programmes at Engineering Staff College of India (ESCI, Gachibowli) to different Pharmaceutical Industries.
- ✧ Played a key role in designing Post Graduate Diploma in Quality Control, Chemical Analysis and Quality Management (PGDCAQM) programme at University of Hyderabad (Central University, Hyderabad) through distance education mode in the year 2000-2001, which is an ongoing yearly course.
- ✧ Co-authored the book on "Quality Assurance and Quality Management in Pharmaceutical Industry."

RECENT PAST ACTIVITY

- ✧ Has incorporated Marayya's Laboratory for Analytical Research and Testing (Marayya's Laboratory/ MART) at Jeedimetla Industries Association (JIA) for operation and Maintenance of the state-of-art Analytical Testing Laboratory for 10 years. It was a journey for accomplishment of providing Quality Analytical Services at affordable price to 100+ customers successfully. This facility was USFDA inspected.

Mrs. K. Parjanya, M. Pharm (Industrial Pharmacy) Director - Technical

- ✧ Mrs. K. Parjanya has M. Pharmacy (Industrial Pharmacy) from JSS University, Mysore and Bachelors in Pharmacy from Rajiv Gandhi University, Bangalore.
- ✧ Has actively participated in various Poster and Paper presentations conducted all over India.
- ✧ She was awarded Gold Medal for being the Best Outgoing Student in the department of Industrial Pharmacy at JSS University for the year 2012.
- ✧ She has 08 years of experience in the field of Formulation Development and Pharmaceutical Instrumental Analysis.
- ✧ Has exposure in Analytical Instrumentation techniques like Spectroscopy and Thermal, Analytical Method development and Validation studies.
- ✧ Trained in Laboratory Quality Management System and Internal Audit as per ISO/ IEC 17025:2017.



Mrs. R. Jacinta, B.Sc, B. Ed Director- Administration

- ✧ Mrs. R. Jacinta has an experience of 30+ years in moulding students with her effective teaching.
- ✧ She has 10+ years of experience as an administrator at MART Labs, Jeedimetla.
- ✧ During her tenure as administrator at MART Labs, she was involved in inculcating effective communication among the employees and creating a conducive work environment.



Regulatory Information

DCA/CDSCO Approved
NABL Accredited
FEI NO: 3018694293
DUNS's No :87-741-2748

Administrative Information

Incorporation: AAP-4589
GST No : 36ABLFM6523E1Z8
PAN No : ABLFM6523E
TAN No : HYDM20523G
MSME No: TS02F0044462

Commercial Information

Bank Name: Punjab National Bank
Account No: 10931132000548
IFSC Code: PUNB0109310
Branch: Ameerpet