

SHAGUN MEDI TESTING PVT. LTD.

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ACCREDITATIONS AND CERTIFICATES



ISO CERTIFIED



FDA CERTIFIED



GLP CERTIFIED



NABL CERTIFIED



हरियाणा सरकार
AYUSH CERTIFIED

*Under Process

COMPANY PROFILE

Shagun Medi Testing Pvt. Ltd.

is a state of art analytical laboratory, approved by Govt. of Haryana, offering standard analytical testing techniques for the Drug & Pharmaceutical Products, Cosmetic & Personal Care Products, Ayush & Herbal Products, Nutraceutical and Food Products. We provide high superior outcomes and for us outstanding customer service is paramount.

Our connoisseurs goes beyond just relaying test results; we offer guidance to industry. We have proven industry experience and quality assurance expertise; our experts are dedicated to helping you gain a better understanding of the quality and effectiveness of your products and processes throughout every stage of development.



Welcome to Analytical Solutions Services

- Pharmaceutical Products Analysis
- Cosmetic Products Analysis
- Herbal Products & Extracts
- Analytical Method Development & Validation
- Analytical Support for Product Development
- Quality Assurance
 - Dossier for Overseas market
 - Food /Nutraceuticals Products Analysis



ABOUT US

Shagun Medi Testing Pvt. Ltd. is approved by FDA, Health and Family Welfare Department, ISO ,FSSAI*, and Ayush* Testing Laboratory for the analysis of Allopathic Drugs, Cosmetic products, Ayush and Food products. We provide high quality control testing for Pharmaceutical, Cosmetic, Ayush and Food products including method development and method validation. We have skilled proficiency and regulatory qualifications needed to accurately perform essential chemical and phyto pharmaceutical tests on raw materials, APIs, finished products of pharmaceutical and cosmetic products. We are supported by excellent dedicated, well qualified, competent and practiced team. We compromise all-inclusive testing amenities, in well equipped, state of the art laboratory, according to the pharmacopoeia (e.g. IP, EP, USP, BP, JP) and Customer Required Specifications.

*Under Process



INFRASTRUCTURE

Shagun Medi Testing Pvt. Ltd.

is located in Barwala, Haryana. Current facility is spread in approx. 3000sq feet area. Facility is housed as per GLP, GMP and WHO guidelines with complete analytical solution for Pharma, Cosmetic, Food products & Herbal Products for analysis by latest state of art novel instruments.

Latest Sophisticated Analytical Instruments we have:

- HPLC
- AAS
- GC
- Liquid Particle Counter
- FTIR
- UV Spectroscopy
- GC-Headspace
- Disintegration Test Apparatus
- Dissolution Test Apparatus
- Melting Point Apparatus
- Friability Test Apparatus
- Karl Fisher
- Weighing Balance
- pH, Conductivity Meter
- Microbiological Instruments

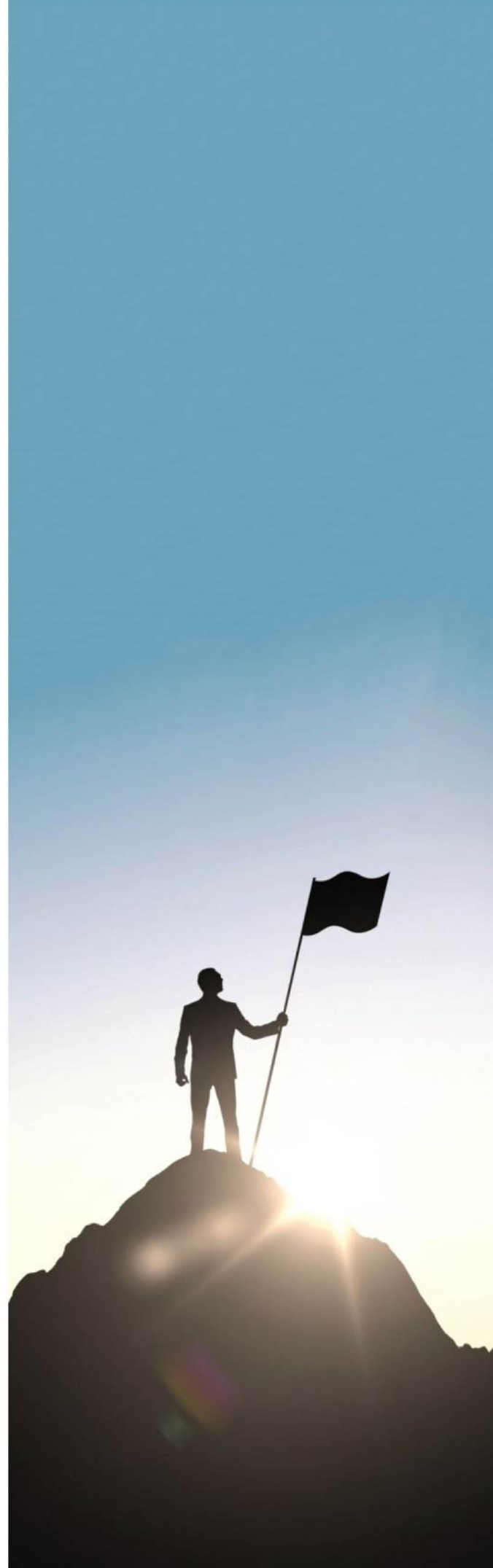


MISSION

To ensure accurate & reliable test results by having strict Quality Control and Technical Proficiency conquered through several years of experience in the Pharma industry.

Shagun Medi Testing Pvt. Ltd. is committed to:

- Good professional practices by attending its customers' needs for Chemical and/or Biological testing of submitted samples, using standard/validated methods; Conducting Pharmaceuticals/Cosmetic/Ayush, Food and an Environmental Impact Assessment studies as per existing constitutional necessities.
- Embolden Quality consciousness among staff and train concerned personnel to ensure putting into practice of well-known Policy & Procedures in their work.
- To maintain internal/external communiqué as per established procedures.
- Conserve methodical cogency of test upshots.
- Comply with ISO/IEC guidelines & applicable Statutory, Governing necessities to persistently expand the efficiency of the management co-ordination.



To be recognized internationally as a trustworthy testing firm by providing tailor-made solutions that cater to the industrial needs in Pharmaceuticals/ Cosmetic/ Ayush/ Food/ API / Analytical/ Chemical/ Microbiological and Environmental services through inventiveness, tractability, invention profundity and procedural proficiency, with total focus on customer contentment and quality workmanship.

- To progress innovative services and technologies customized as per client needs, enhance & ensure quality, to develop as a research institution that is into research and development in the areas of special significance to diverse industrial sectors, government agencies and several other organizations.
- We are dedicated to advance, revolutionize, evaluate and apply skills for products and processes to develop research partnership with various universities and Pharma industries.
- To encourage a physical activity centre by establishing tailor-made training sequences in the extents of console applications, Pharmaceuticals/ Cosmetic/ Ayush/ Food/ API / Analytical/ Chemical/ Microbiological and Environmental Management & Food Safety.

VISION



OUR CORE VALUE



Quality:

- ✓ Highly sophisticated and advanced technology
- ✓ Accurate & reliable
- ✓ High degree of ethics use
- ✓ Continual improvement of Quality Management System as per ISO/IEC 17025

Compliances:

- ✓ Fulfill the Requirement of GxP Policies
- ✓ Compliances to worldwide regulations
- ✓ ALOCA compliances

Team Strength:

- ✓ Continual training process
- ✓ Value for each other
- ✓ Rewards and appreciation
- ✓ Empowerment

Customer Segment:

- ✓ Honesty and time bound process
- ✓ Innovative solutions
- ✓ High degree of satisfaction
- ✓ Confidence



SHAGUN MEDI TESTING PVT. LTD.

**QUALITY
POLICY**



SMTPL Quality Control laboratory is committed to provide “Best in Class” Testing Services. This commitment is achieved by dedication to duty by the personnel of each department, which also leads to continuous improvement and customer satisfaction.

The above commitment is also supported by following actions:

Ensuring compliance to our clients.

The timeless and quality of response to all customer enquiries and complaint.

Laboratory management is committed to comply with ISO/IEC 17025:2017; all applicable regulatory & statutory requirements and will continually improve the effectiveness of its management system.

Laboratory gives utmost importance to ensure analytical integrity, impartiality and confidentiality.

Mr. Anshul Madaan
(Designated Partner)

Mr. Goldy Kashyap
(Technical Director)

OUR SERVICES

DRUGS & PHARMACEUTICALS

Any pharmaceutical product manufacturer requires a quality control which is one of the pre-requisite to regulatory compliances. Shagun Medi Testing is glad to inform that our lab is undertaking Analysis of product(s) covering Drug substance (API), Pharmaceuticals AID, Drug Formulations (Capsule, Cream, Ear Drops, Ointment, Gel, Oral Solutions, Oral Suspension, ORS, Injectables, Tablets, Vitamins etc.)

Data Integrity is the most essential part in our lab. The lab is well equipped to conduct all sorts of tests as per IP, BP, USP, and EP, NF or In-house tests methods. Our lab is occupied with latest art of sophisticated instruments up to benchmarks all are compliant to stringent requirement of 21 CFR parts 11 compliant, like:

- HPLC
- AAS
- GC
- Liquid Particle Counter
- FTIR
- UV Spectroscopy
- GC-Headspace
- Disintegration Test Apparatus
- Dissolution Test Apparatus
- Melting Point Apparatus
- Friability Test Apparatus
- Karl Fisher
- Weighing Balance
- pH, Conductivity Meter



With the Pro Active Support of all latest technology we provide the Complete Testing Solutions for all Parameters Like:

Assays and chemical tests

- UV/Vis
- IR
- Chromatographic Tests
- HPLC
- GC

- Identification of active ingredients and impurities
- Physical and physico-chemical determinations
- pH
- Viscosity
- Melting point
- Loss on drying
- Limit tests
- Elemental impurities
- Ash
- Residual solvents
- Volatile organic compounds (VOC)
- Organic volatile impurities (OVI)
- Pharmaceutical technical procedures
- Disintegration
- Dissolution
- Element Impurities
- Micro Biology
- Stability Testing etc.
- Uniformity of Contents
- Bacterial Endotoxins
- Sterility
- Microbial Contamination etc.



We also have the facility to cover Pharmaceuticals Impurities Profiling (Organic & Inorganic) at PPT to percent Level according to IP, BP, USP (232/233)/ICH, IHS, EP, JP & WHO etc.

In Pharmaceuticals Research and Development field we also provide support for Method Development and Validation and Stability testing of newly Synthesized Drug Formulations (Capsule, Cream, Ear Drops, Ointment, Gel, Oral Solutions, Oral Suspension, ORS, Injectables, Tablets, Vitamins) etc. as per ICH Guidelines.

COSMETIC & PERSONAL CARE PRODUCTS

Cosmetics are used almost universally on a regular basis. The safety in cosmetics and toiletries is of prime importance, as only safe products should be used by consumers. An EWG analysis of government and industry sources shows that at least 146 cosmetic ingredients may contain harmful impurities linked to cancer and other serious health hazards. Safety Assessment according to the EC/1223/2009 Cosmetics Regulation, Annex I, part A and part B

Our services for Cosmetic & Personal Products (In Raw material and Finished products):

Quality Parameters:

Shagun Medi Testing Pvt Ltd. has fully operated chemical section to ensure the quality of cosmetics like pH, total fatty matter, identification of herbs and plant extract viscosity, consistency, fineness in skin creams and face packs, acid value and peroxide value in hair oils, foam height, active ingredients in shampoo, foreign dye in heena powder, menthol content in shaving cream by GC-FID etc.

Other Critical and Essential Tests:

- Heavy metals
- Phthalates
- Preservative (Parabens, Sulphate)
- 1,4-Dioxane
- Bisphenol A
- Residual Formaldehyde
- GC- Profile
- Residual Solvents
- Aflatoxins
- Identification of Herbs

AYURVEDIC AND HERBAL PRODUCTS

(RAW AND FINISHED PRODUCTS)

Plant and their products are an essential source for human and other living organisms for the basic requirements related with nutrition, dietary needs, medicines, fuels etc. The demand of herbal drugs seems to be increased as the skepticism against the synthetic drugs and their growing side effects. However, with no harmful side effects plant preparation are often considered useful for the treatment of less serious diseases, for



the supportive treatment of chronic diseases, for treatment over long periods of time, hence search and use of plant based drugs, dietary supplements and nutraceuticals have increased in recent years. Botanists, chemists, pharmacologists are combing the earth for natural phytochemicals and leads that they can utilized for treatment of chronic disorders.

Services for Ayurvedic and Herbal Products

PRODUCTS	TESTING PARAMETERS
Raw drugs	As per API Foreign matter, Total ash, Acid insoluble ash, water soluble extractive, Alcohol soluble extractive, Thin layer chromatography
Tablets/ Pills	Description, Colour, Odour, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Total solid content, Fat content, Total sugar, Friability, Hardness, Uniformity of weight, Disintegration time
Sharbat/ Syrup	Description, Colour, Odour, Viscosity, pH, Total solid, Total sugar, Reducing & Non reducing sugar, Specific gravity
Asva, Arishta, (Fermented liquid)	Description, Colour, Odour, pH, Specific gravity, Boiling point, RI, Optical rotation, Total acidity, Test for methanol, Reducing & non Reducing sugar
Ayurvedic Dusting Powder	Description, Colour, Odour, Particle size (by Sieve method), Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Bulk density
Avaleha/semi solid	Description, Colour, Odour, Consistency, Total acidity, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Total solid content, Fat content, Total sugar, Reducing & non Reducing sugar
Chewing Candy	Description, Colour, Odour, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Total solid content, Fat content, Total sugar, Reducing & non Reducing sugar, Salt content, Friability, Hardness, Uniformity of weight, Disintegration time
Oils & Ghee	Description, Colour, Odour, pH, Specific gravity, Boiling point, Essential oil, RI, Optical rotation, Viscosity. Rancidity, Iodine value, Saponification value, Unsaponifiable matter, Acid value, Peroxide value, Free Fatty acid, Fatty matter, Mineral oil test
Churna (Fine & Coarse Powder)	Description, Colour, Odour, Particle size (by Sieve method), Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Bulk density, Alkaloids, Tannins, Phenols, Flavonoids
Lepa/ Wax/ Cream	Description, Colour, Odour, Viscosity, Rancidity, Total acidity, Uniformity of content, pH, Thermal, Stability, Fat content, LOD, Spreadibility
EYE Drops	Description, Colour, Odour, pH, Clarity test
Plant Extract	Description, Colour, Odour, Volatile oil content, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Bulk density, Residual solvent, Alkaloids, Tannins, Phenols, Flavonoids, Saponins

Bhasam / Pishti	Description, Colour, Odour, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying, Particle size (by Sieve method), Sulphated ash, Assay for element (2 major elements), Nishchandrica, Rekhapurntava, Varitara, Nirthoom, Niswadu,, Apurnar Bhav
Granules	Description, Colour, Odour, Bulk & Tap density, Compressibility, Total ash, Total sugar, Reducing & non Reducing sugar, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive
Raw plant material	Description, Colour, Odour, Volatile oil content, Foreign matter, Total ash, Acid insoluble ash, pH, Water soluble extractive, Alcohol soluble extractive, Loss on drying.

NUTRACEUTICALS AND FUNCTIONAL FOOD

Nutraceutical or 'bioceutical' is a pharmaceutical alternative which claims physiological benefits. "Nutraceuticals" are largely unregulated, as they exist in the same category as dietary supplements and food additives by the FDA, under the authority of the Drug and Cosmetic Act.

Functional foods are fortified or enriched during processing and then marketed as providing some benefit to consumers. Sometimes, additional complementary nutrients are added, such as vitamin D to milk.

Functional foods are "ordinary food that has components or ingredients added to give it a specific medical or physiological benefit, other than a purely nutritional effect." All functional foods must meet three established requirements: foods should be present in their naturally occurring form, rather than a capsule, tablet, or powder; consumed in the diet as often as daily; and should regulate a biological process in hopes of preventing or controlling disease.

Services for Nutraceuticals and Functional Food:

Nutritionals & Contaminants

- Vitamins
- Minerals
- Amino acids
- Fatty acids-omega-3 and omega-6 fatty acids
- Pesticides residues
- Heavy metals
- Mycotoxins
- Synthetic dyes
- Allergens
- Para Amino Benzoic Acid
- Microbiology
- Stability Studies
- Nutritional Values

Active components of Nutraceuticals

- Quercetin
- Flavonoids as flavones, flavanones and flavonols
- Curcuminoids
- Gingerols
- Lutein
- Lycopene
- β -carotene
- Catechins
- Tannins
- Ferulic
- Coenzyme Q10
- Lutein and Zeaxanthin
- Resveratrol

WATER TESTING

Shagun Medi Testing Pvt. Ltd. offers a comprehensive water testing service for the packaged drinking water manufacturers and food and beverages processing companies. With state-of-the-art facilities and the latest analytical methodologies, SMPTL offers a complete analysis which includes **Pesticides residue, Heavy metals, Microbiological detection, Physical tests, Sensory tests, Chemical tests, PAHs, PCBs, Other miscellaneous tests.** Our testing services are specifically made to meet the water testing requirements.

Pharmaceutical grade water: We also offers complete testing of Pharmaceutical grade waters like: Purified water, water for injection, etc as per IP,BP,USP,EP,JP and In house specifications;

Parameters offered:

- Colour, Hazen
- Odour
- Taste
- Turbidity
- Dissolved solids
- pH value
- Total hardness
- Iron
- Aluminium
- Copper
- Manganese
- Zinc
- Magnesium
- Barium
- Calcium
- Silver
- Selenium
- Molybdenum
- Boron
- Nitrate
- Sulphate
- Sulphide
- Fluoride
- Chlorides
- Ammonia
- Chlorine
- Mineral Oil
- Anionic detergents
- Total Chromium
- Total Arsenic
- Mercury
- Cadmium
- Lead
- Nickel
- Cyanide
- Polychlorinated biphenyls
- Trihalomethanes
- Bromoform
- Dibromochloro methane
- Bromodichloro methane
- Chloroform
- Polyaromatic Hydrocarbons

Radioactive Materials

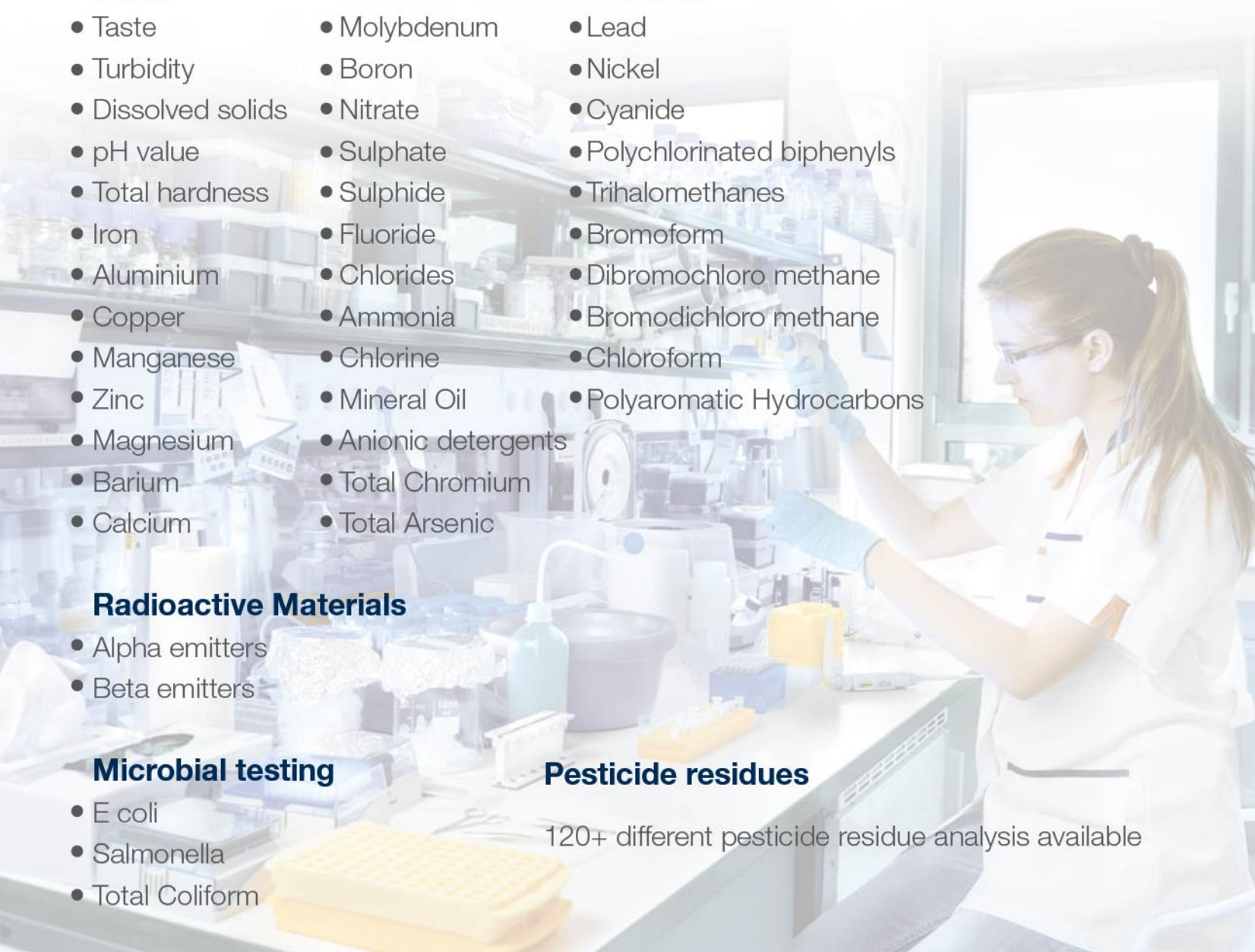
- Alpha emitters
- Beta emitters

Microbial testing

- E coli
- Salmonella
- Total Coliform

Pesticide residues

120+ different pesticide residue analysis available



BIOLOGICAL TESTING

Microbiological quality is critical in Pharma, Cosmetic, Food and Feed product safety assessment. Microbial testing is essential to identify borne pathogens and spoilage organisms. This testing can ensure continued safety of products along the supply chain. Monitoring of functional microbes which may be entered during production or in the final product is equally important.

Our microbial analysis will help clients to assess the safety and efficacy of ingredients, semi manufactured, final products and the entire processing steps. We have state of the art testing laboratory with most advanced technologies and experts developing up-to-date standards for microbial testing for diverse Pharma and Food samples.

Current microbiological testing Services:

Pathogens:

- Salmonella species
- Listeria monocytogenes and species
- Escherichia coli, O157:H7, O157, and STECs
- Staphylococcus aureus
- Campylobacter species
- Bacillus cereus
- Shigella species
- Clostridium perfringens
- Cronobacter sakazakii
- Pseudomonas aeruginosa

Indicators & Spoilage Organisms:

- Aerobic Plate Count
- Yeast & Mold
- Coliforms
- Enterobacteriaceae
- Lactic Acid Bacteria
- Alicyclobacillus
- Heterofermentative Lactic Acid Bacteria
- Spore-forming Mesophilic Aerobic Bacteria
- Spore-forming Mesophilic Anaerobic Bacteria
- Spore-forming Thermophilic Aerobic Bacteria
- Osmophilic Yeast & Mold
- Anaerobic Plate Count
- Psychotropic Plate Count



Our Research and Development

Analytical R&D

Analytical R&D is main core or backbone for any pharmaceutical and other research and development testing laboratory. The team of R&D is highly involved in process, development of new methods, new compound through innovation. The research & development has no barrier for of our thought, it is continuous process.

We establish the trust for quality of products through innovation and research. The lab has separate R&D division for development of testing procedures in area of foods and pharmaceutical products. We have skilled scientific players in area of food, chemical, pharmaceutical and biological disciplines.

We are provide the complete solutions like:

- Feasibility, Qualifications and Validation of methods to assess the quality of your manufacturing process and your Drugs Products like: Method development validation for Related Substances (Organic & Inorganic impurities), Dissolution (Sustained & prolonged release ,Comparative Dissolution profiling studies.), Assay in various Formulations (Capsule, Cream, Ear Drops, Ointment, Gel, Oral Solutions, Oral Suspension, ORS, Injectable, Tablets, Vitamins) etc.
- Transfer of methods previously validated • We also have the facility to cover Pharmaceuticals Impurities Profiling (Organic & Inorganic) at PPT to percent Level according to IP, BP, USP (232/233)/ICH, IHS, EP, JP &WHO etc.
- Provide complete Validation documentation file as required.



As per ICH guideline some analytical method validation parameters undertaken are

Sr. No.	Parameters
1.	System suitability
2.	Specificity
3.	Linearity
4.	Accuracy/Recovery
5.	Precision i) System precision ii) Method precision iii) Intermediate precision
6.	Robustness
7.	LOQ
8.	LOD

With this background we look forward to be of service to you and would be glad to be associated with your organization for providing best analytical services.

Please feel free to contact for more information. We assure you best of our services.

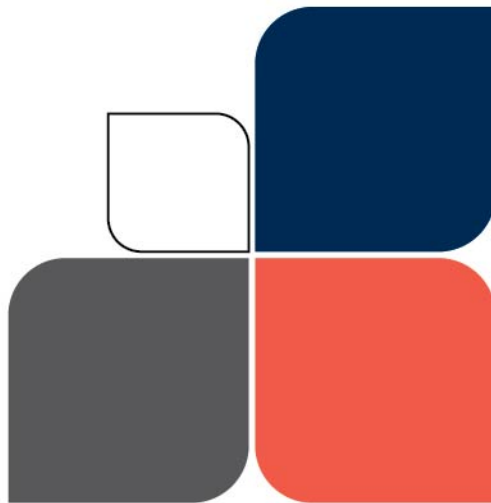


CONTACT US

Site Address: Plot No. L-36, Industrial Area, Barwala, Haryana 134118,
M: 7009077122 L. No.: 01733-297875
Email: info@shagunmeditest.com

REGD. Office: SCO-54, 2nd Floor, Sector -11, Panchkula, Haryana 134109
M: 7009077121
Email: support@shagunmeditest.com

Website: shagunmeditest.com



SHAGUN MEDI TESTING PVT. LTD.
(Govt. Approved Commercial Test House)