

BIOFACT RESEARCH PVT. LTD. *We Care For Quality*

Preferred Destination for R & D Services



Analytical Research Services



Medical Devices Testing Services



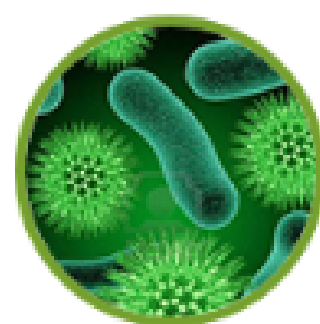
Radiological Testing Services



In-Vitro Toxicological Services



Food and Water Testing Services



Microbiological Screening Services



Formulation Research Services

Single Stop Solution Provider for research and Developmental Services



ABOUT US

Biofact research Pvt. Ltd., is a contract research organization, started operations in 2019 with a thirst to provide regulatory compliant research and developmental services to Pharma, Biotech, Medical Devices, Food and Water and Agrochemical Industries in line with the all applicable current regulatory standards. It is the first regulatory compliant CRO in the coastal region of Andhra Pradesh and offering comprehensive range of research and developmental services from product development to regulatory submission. State of the art infrastructural facilities, Sophisticated equipment, Skilled & Experienced Scientists, well designed, Spacious and Qualified laboratory areas have carved biofact as the preferred destination for product quality testing and regulatory submission.

We are the integral part of the product development cycle and provide quality testing services for the evaluation of Drugs, pharmaceuticals, biologics, medical devices, radioactive residues, food, water and agrochemical products.

It is ISO 17025: 2017, 21 CFR Part 210 & 211, CDSCO and PIC (S) compliant laboratory and offering services such as

- 1) Analytical Research Services
- 2) Medical Devices Testing Services
- 3) Food and Water Testing Services
- 4) Agrochemical Research Services
- 5) Radiological Testing Services
- 6) In-Vitro Toxicological Services
- 7) Microbiological Services
- 8) Mechanical Testing Services
- 9) Packaging Validation Services

Why Biofact

- First Regulatory compliant CRO in coastal region of Andhra Pradesh
- Customer centric CRO
- End to end service provider
- Quality Service with regulatory compliance
- Fast Turn Around Time (TAT)
- CDSCO, 21 CFR PART 210 & 211, ISO 17025 and PIC (S) compliant laboratory
- Team of Experienced, Competent and Qualified Scientists
- Sophisticated equipment from world's best manufacturers
- Robust Quality management system
- Well established regulatory framework
- Regulatory compliant State of the art infrastructure and facilities
- Customer Support till marketing of the product
- Cost Effective and Efficient research solution provider
- Dynamic Leadership
- Confidentiality and Impartiality
- Laboratory with Paperless data management
- Well defined procedures as per global standards.



OUR SERVICES

ANALYTICAL RESEARCH SERVICES



- Analytical method development & validations as per ICH
- Pharmacopoeial testing (IP, BP, USP, EP, JP)
- Impurity profiling as per ICH guidelines
- Drug characterization studies
- Stability indicating assays as per ICH
- Quantification of genotoxic impurities as per ICH M7
- Particle size characterization
- In-vitro binding studies
- Assay by Dissolution
- Thermal analytical studies
- Stability studies
- Wet analysis

MICROBIOLOGICAL STUDIES



- Microbiological tests and assays
- Microbiological Limit tests
- Sterility tests
- Bacterial Endotoxin test(BET)
- Preservative Efficacy test (PET)
- Biological reactivity as per USP 87
- Bioburden test
- Antibiotic & vitamin assays
- Validation of microbiological methods
- Antibiotic susceptibility & resistance studies
- Cleaning validation studies

MEDICAL DEVICE TESTING



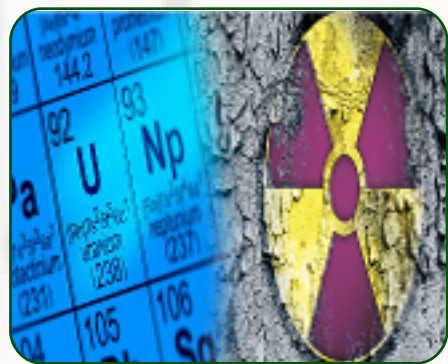
- Establishment of Extractables and Leachables studies for all the Biomaterials as per ISO 10993-Part 12
- Chemical characterization of Biomaterials as per ISO 10993-Part 18
- Estimation of ethylene oxide residues as per 10993-Part 7
- In-Vitro Bio-compatibility studies
- Dimensional and functional attributes testing
- Microbiological evaluation of all medical devices
- Packaging Validations
- Shelf life/ Ageing studies

FOOD & WATER TESTING



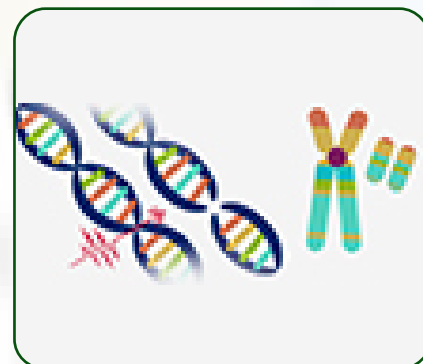
- Water testing as per IS 14543, IS 13428, IS 10500 USEPA and WHO standards
- Food safety & Quality assessments
- Food additives & contaminants testing
- Proximate & nutritional analysis
- Pesticides, Heavy metals and Drug residue analysis
- Veterinary drug and antibiotic residue analysis
- Radioactive nuclides analysis
- Mycotoxines testing

RADIOLOGICAL STUDIES




- Estimation of gross Alpha and Beta emitters in water
- Estimation of Ra236 and Ra238 in water
- Identification and Estimation of Radio nuclides in food & soil matrices

INVITRO TOXICOLOGICAL STUDIES




- AMES tests (OECD 471)
- Chromosomal Aberration test (OECD 473)
- Micro Nucleus test (OECD 487)


Our Product Testing




Drugs & Pharmaceuticals




Medical Devices




Radio Active Substances



Food and Water



Biologics



Agrochemicals



QUALITY POLICY

Biofact research Pvt. Ltd. is committed to achieving customer satisfaction by providing quality regulatory compliant research and developmental services to the indigenous and global health care market players in compliance with internationally recognized regulatory standards and guidelines through stringent quality management system, robust regulatory frame work and effective implementation of GXP practices.

Mission

To be an integral part of product research and developmental cycle, through which a Safe and effective product for human use is discovered and developed in compliance with internationally recognized regulatory standards and guidelines.

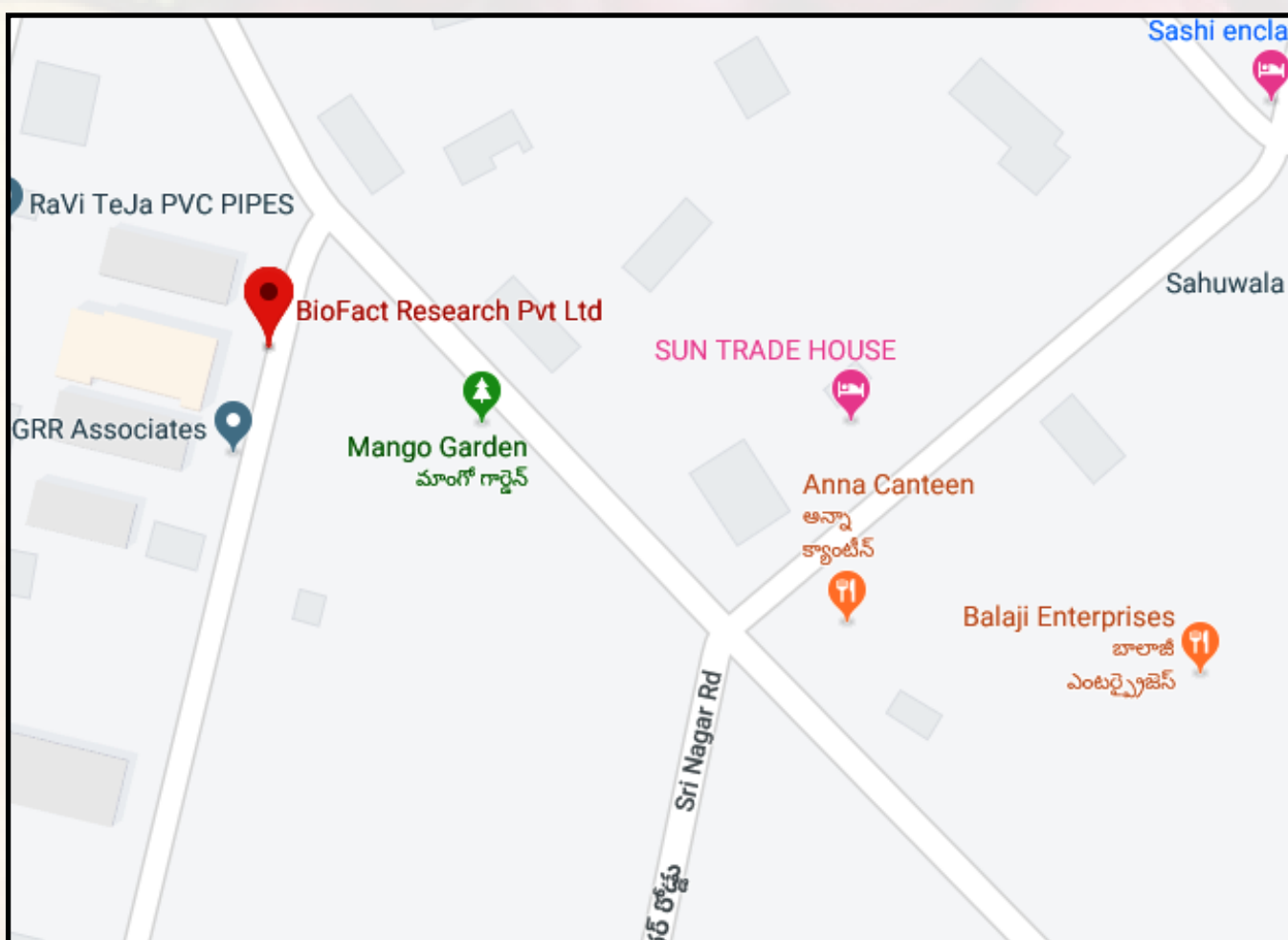
Vision

To be a first referral contract research organization to render One Stop Solution for research and developmental services in compliance with global regulatory requirements to the client across the globe.

OUR ACCREDITATIONS



Reach us at



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