

## Impact Analytical

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NUMBER OF EMPLOYEES  
30

DATE FOUNDED  
1996

# OUTSOURCING and Consulting Services



## Impact Analytical

### General Company Description

Impact Analytical is a full-service contract analytical testing laboratory dedicated to providing pharmaceutical companies with drug development and manufacturing support.

The laboratory provides a suite of comprehensive testing services to support pharmaceutical manufacturers from preclinical through phase III development of small and large molecule APIs and finished drug products. Impact Analytical has bundled these testing services under the brand Pharma Impact. Pharma Impact was created to provide pharmaceutical companies with a complete set of services to meet all analytical testing needs. All testing is performed by Impact's expert scientists that have an average of 20 years of experience and are supported by FDA-compliant, state-of-the-art processes and instrumentation. The laboratory is FDA registered, cGMP and GLP compliant, ISO 9001:2008 certified and DEA licensed. Impact has been audited by the FDA 3 out of the last 4 years—without a single 483.

### Laboratories:

- Gas Separations
- Liquid Separations
- Molecular Characterization
- Microscopy
- Elemental Analysis
- Thermal/Mechanical Properties

### Analytical Instrumentation & Capabilities:

- GC-MS, GC-FID, GC-TCD
- HPLC (CAD, RI, DAD, UV-Vis, RI Detection)
- UPLC
- SEC/GPC
- Titration (acid/base and Karl Fischer)
- 400 MHz NMR (C-13, H, P, Si, F)
- LC-MS (ion trap)
- Exact Mass LC-MS (Q-toF)
- Direct Probe MS (EI & CI)
- FT-IR (ATR, microscope)
- ICP-MS
- ICP-OES
- SEM
- DSC
- TEM
- TGA
- TMA

### Technical Services

#### Pharmaceutical Testing Services:

- Actives Quantitation
- Batch Release Testing
- Dissolution Testing
- Impurities Identification
- Extractable and Leachable Analysis
- Method Development & Validation
- Method Transfer
- Molecular Characterization
- Package Testing
- Pharmaceutical Product Deformulation
- Problem Solving
- Quality Control Testing
- R&D Support
- Raw Material Characterization
- Stability Studies
- Compendial Testing

### Major Services

Impact Analytical provides comprehensive contract testing solutions for all drug development, early stage, late stage and final product testing needs.

### Facility

Impact Analytical recently expanded its laboratory space and moved into a new location in Midland, Mich., in 2013. The leading-edge facility allows for faster turnaround times, carrying on the company's reputation for its high-quality product testing and innovative analysis solutions. The new building, which is located at 1940 Stark Road, represents a 55% increase in space. The expansion also allows operation of up to 84 instruments and house 35 scientists across laboratories consisting of elemental analysis, microscopy, molecular characterization, gas separations, liquid separations and thermal/mechanical properties.

### Markets Served

Impact Analytical serves small, mid-size, and global bio/pharmaceutical companies in US, Canadian, and international markets.



**IMPACT**  
ANALYTICAL