



## Analytical Sciences

Aptuit Verona offers unique integrated analytical capabilities and expertise. It delivers complete and high quality packages of analytical services for drug discovery and development of chemical entities customized for each phase, from early definitions through a fully validated GMP environment to analytical tech transfer. This translates in to benefits for our customers and is assured by a seamless transfer of knowledge and methods from one phase to the other.

### Spectroscopy and Spectrometry

- 1D and 2D NMR spectra acquisition
- Structural elucidation of reaction products, by-products, impurities, degradation chemistry, and metabolites
- Identity check by NMR and/or IR of starting materials, isolated intermediates, and API
- Full spectroscopic characterizations (NMR, MS, IR) supporting CMC documentations
- Reaction monitoring and kinetics by NMR and/or LC-MS
- Quantitative assays by NMR
- Heteronuclear NMR (19F, 31P, 15N, 11B, 29Si, 77Se, 119Sn, etc.)
- Critical Micelle Concentration (CMC) measurements by NMR
- Host-guest interaction studies by NMR
- Ligand-target interaction studies
- Exact mass measurement
- Complete impurities profile in batches by MSn and HRMS
- Routine QC by LC/UV/ELSD/MS

### Specialized Separation Capabilities

- Chiral parallel screening (HPLC, up to 8 columns)
- Automated method development workstations (6 port switching valve: column/12 port switching valve: column and solvent)
- Drylab® and Chromsword®: fully automated method development and validation software
- Semi prep-LC MDAP (achiral)
- Prep-LC (chiral and achiral) from mg to Kg
- Prep-SFC (chiral and achiral)
- Enantiomeric excess determination by % e.e.
- Impurities enrichment by LC/SPE
- High MW impurities ID by LC-SEC

### Method Development

- Method development (checking generic HPLC ok)
- HPLC method development RP (GMP)
- HPLC method development NP (GMP)
- GC method development (Standard)
- HPLC method development IC
- Trace level method development (limit/quant)
- Automated HPLC Assay and impurities combined method development
- Dissolution tests (manual and automated)
- Chiral SFC Method development
- Chiral HPLC Method development

### Method Validation

- Validation minimum pack (spec., LOD/LOQ, precision, stability during analysis)
- Validation up to Ph2 (spec., LOD/LOQ, precision, linearity (range), stability during analysis)
- Validation up to Ph2 (including accuracy, and intermediate precision (ruggedness))
- Validation Ph3 onwards (full ruggedness and robustness)
- Validation genotox (limit/quant)
- Validation IC for stoichiometric and limit tests
- Validation IC for trace level quant

### Stability

- Forced Degradation (deg ID up to m/z level, sufficient for method development)
- Forced Degradation (tentative struct ID by MSn and HRMS)
- Chemical stability up to tox (1 stressed point, one end of life duration tox study)
- Chemical stability (up to 3/6months)
- 3 year ICH stability
- Protocol design and study management
- Data evaluation, report and CMC packages



Aptuit Verona

## FACTSHEET



### Analytical Sciences

#### Characterization / Release

- Release SM
- In Process Control/Release IM
- API NON GMP 4-7day release
- API NON GMP DRF-MTD
- API 28 day tox release
- API GMP FTIH release
- API GMP post FTIH release
- Characterization of AWS
- Characterization of PRS
- Characterization of SM/IM
- DP GMP release (including pharmacopoeial testing)
- USP/EurPh testing
- Residual solvents, impurities (GC, NMR)
- Proof of structure package for regulatory file (NMR, IR, MS, HRMS or Elemental Analysis)

#### Others

- Cleaning verification CD
- Cleaning verification PD
- PD GMP in process control
- Excipients release
- Genotox testing of batch (FTE per genotox)
- Genotoxic risk assessment

#### Document Preparation

- Specification setting (table, justification prep)
- CMC document preparation (IMPD, IND like docs)

#### Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from drug discovery through to market, including consultancy services, API development and manufacture, preclinical technologies, clinical sciences, pharmaceutical development services, large and small scale manufacturing, IVRS and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

**For information about Aptuit's services, please call or email:**

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**Engineering a better drug development  
process through scientific excellence.**