SERVICE **PORTFOLIO**

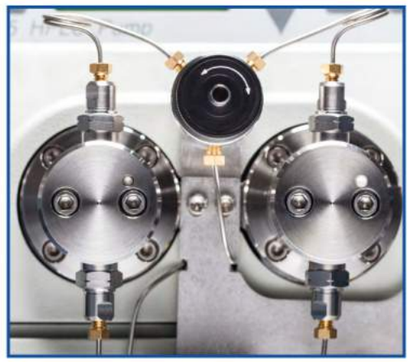
chromicent Pharmaceutical Services

Chromatographic method development & pharmaceutical analysis

Method Lifecycle Management (MLCM)

- Method development in a QbD framework (Stage 1)
- Robustness testing (Stage 1&2)
- Validation studies (Stage 2)
- Stress, stability and release testing (Stage 3)
- Troubleshooting of existing methods (in all Stages)
- Consulting and Training

certified GMP certified



Analytical capabitities

- Chromatographic systems controlled by Empower 3 (Waters)
  - HPLC (Waters Alliance)
  - UPLC (Waters Acquity)
  - UHPLC (Waters Acquity ARC), bio-inert
  - SFC (Waters Acquity UPC²)
  - IC and GC
- Comprehensive sample preparation equipment
- Pharmaceutical Technology equipment
  - Incl. Dissolution tester
  - sub-visible particle (SVP) analyzer
- Stability and Photo-stability chambers

Detection capabitities

- Photo diode array UV detection (PDA)
- Fluorescence detection (FLD)
- Refractive index detection (RID)
- Evaporative light scattering (ELSD)
- Single-Mass detection (QDa)
- Tandem-Mass detection (TQD) with ESI and APCI ion source
- Charged-Aerosol detection (CAD)
- Chemiluminescence nitrogen (CLND)
- Conductivity detection
- Electrochemical detection (ECD)

Impurity profiling

- Nitrosamine screening using our validated and published SFC-MS/MS method
- Nitrosamine detection using LC-MS/MS with APCI ion source
- Extractables and leachables studies
- Stress testing with mass balance consideration
- Photo stability testing
- ICH short- and long-term stability studies