

Analytical Services: comprehensive analytical solutions from drug substance (non & highly potent) to drug product.

Our value proposition consists of a broad range of state-of-the-art analytical services supporting clients from early phase Drug Substance development through to the marketing authorization of their Drug Product.

Minalytics relies on cutting edge technologies developed by our innovative and ambitious Minakem scientists over 20 years of serving the Pharmaceutical Industry



**CLOSE
PARTNERSHIP**



**FULL SERVICE
OFFERING**



**DEDICATED
PROJECT TEAM**



**ANALYTICAL
SUPPORT**



**SOLID FORM
SUPPORT**



**CUTTING EDGE
TECHNOLOGY**

We believe a **successful project partnership is based on open and transparent communication.**

Our skilled teams can provide analytical strategies, customize solutions, key technologies and high quality scientific advice in the management of your project.

Our key areas of expertise are analytical method development, validation and transfer from Drug Substance to Drug Product, ensuring an analytical continuum for our clients.

Key services

▶▶ API DEVELOPMENT ▶▶ LIFE CYCLE	▶ EARLY STAGE & PRECLINICAL	▶ EXPLORATORY DEVELOPMENT PHASE I & II	▶ CONFIRMATORY DEVELOPMENT PHASE III	▶ COMMERCIAL PHASE IV
Method development – Complete new method development or optimization of an existing method. – Development from preliminary to stability-indicating method & life cycle management with support of our Regulatory Affairs team.				
Method validation – Compliant with regulatory requirements & adapted to the development stage.				
Method transfer – From / to your laboratory & according to transfer strategy. – Sharing expertise.				
Impurities Management (PGI & NPGI) – Early stage: impurities profiling / DS characterization. – Advanced stage: studies according to ICH guidelines including forced degradations. – Troubleshooting.				
Elemental impurities Management (ICH Q3d)				
Nitrosamines Management				
Solid form Particle size & crystalline form – Development, validation, crystallisation studies, filtrability studies.				

One dedicated project team

- **Dedicated analytical project management** to ensure smooth and seamless progress on projects;
- **Open dialogue** with our scientific experts throughout the project lifetime;
- Writing of **technical and quality agreements**;
- **Gantt chart** and adherence to deadlines;
- **Regulatory Affairs support team** when needed;
- **Raw data access.**

Our commitment

- Open and **transparent communication**;
- **Fast, flexible, and responsive** to customer requests;
- **Continuous investments** & cutting edge technologies;
- **Analytical support** and expertise;
- Analytical process optimization is **driven by Operational Excellence.**

Key technologies on two sites

NON & HIGHLY POTENT DRUG SUBSTANCES / DRUG PRODUCT	MAIN TECHNOLOGIES
Analytical Development / Validation	Multibrand HPLC & UHPLC System with UV, PDA & MS detection / GC & HS-GC-MS, ILC / Physico-Chemical Equipment
Elemental Impurities Management	ICP-OES & ICP-MS
Non & potential genotoxic impurities management	Triple Quad HRMS
Nitrosamines Management	Triple Quad
Microbiological testing	Sterility, Endotoxins, TAMC, TYMC