

Capability Statement

Europe



RIGHT SOLUTIONS | RIGHT PARTNER



Core Values

Our Core Values are simple and we incorporate these in our daily operations, never forgetting the foundations of our success:

- Honesty and Integrity
- Exceeding Client Expectations
- Belief in our Ability
- Hard Work and Continuous Improvement
- Doing it Better
- Celebrating Success
- Safety as a Priority.



Introduction

ALS Pharmaceutical is one of the business divisions within ALS, focussing on delivering high quality pharmaceutical testing services and further enhancing our proud reputation within the pharmaceutical and healthcare industries.

We are committed to providing a responsive and flexible analytical service to meet our customers' needs, with the aim of exceeding their expectations and establishing productive, long-term relationships.

Our Pharmaceutical laboratory in Prague employs 50 professional and support staff. People and knowledge are key priorities for the group and as such, internal development programmes are routinely run to foster both technical and business skills.

ALS Pharmaceutical is part of the Life Sciences Division with an ever expanding global presence including operations in Australia, Asia, North and South America, Europe and the United Kingdom sharing world best practice and emerging analytical capabilities.

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Company Overview



Australian Laboratory Services (ALS) commenced operations in Brisbane as 'Australian Laboratory Services Pty Ltd' in 1974 as a privately owned company providing analytical services for the oil shale and mineral exploration industries.

Australian Laboratory Services (ALS) provides a broad range of sophisticated, state-of-the-art services to four main market segments, with a total of 13 unique service offerings:

Minerals – Geochemistry | Metallurgy | Mine Site | Inspection

Life Sciences – Environmental | Food | Pharmaceutical
Animal Health | Electronics.

Energy – Coal | Oil & Gas

Industrial – Asset Care | Tribology.

ALS has demonstrated over 30 years of strong business performance with global revenues exceeding \$1.5 billion. ALS continues to remain at the forefront of the testing services industry, building an enviable reputation as the provider of choice on a global scale.

Processing more than 20 million samples per year, our 13,000 staff operate from over 350 locations in 55 countries. We have laboratories strategically located around the world, operating in Australia, Asia, North America, South America, Europe, the Middle East and Africa; and are one of the largest analytical laboratory groups in the world.

Laboratory in Prague

Pharmaceutical laboratory carries out testing of quality, potency and/or quality compliance of raw materials, intermediates and final products for the pharmaceutical industry.

Our laboratory meets demanding requirements of national and international regulatory authorities. Established stable quality assurance system enables processing of both standard orders and non-standard individual projects.

Thanks to our highly qualified and experienced staff, modern analytical instruments and specially secured systems, we can process the orders quickly and effectively. Precision and accuracy of the results is always our top priority.



50+

COUNTRIES

13k+

STAFF

300+

LOCATIONS

40

YEARS IN OPERATION

Quality

Quality Management System

The ALS commitment to quality is a key factor amongst commercial and contract testing laboratories in the market, providing:

- Consistent quality standards
- GMP agreements
- Technical agreement proposal

ALS is committed to consistently providing quality data and service to satisfy the requirements of each client. Therefore ALS methodologies are performed and developed in accordance with Pharmacopoeial, regulatory and customer requirements.

ALS Pharmaceutical achieves premium service levels through continued investment in quality systems to guarantee on-going compliance.

Regulatory Compliance

ALS is regularly audited by:

- FDA
- SÚKL (State Institute of Drug Control)
- ÚSKVBL (Institute for State Control of Veterinary Biologicals and Medicines)
- ČIA (for purposes not in GMP mode analysis) to ensure compliance to ISO 17025

Our subcontracting laboratories, where we are able to perform the other required analyses, are approved by SÚKL.

Customer audits according to GMP - this provides our customers with confidence in the integrity of the ALS service offering. ALS welcomes customers to visit and/or audit us and in addition, we have our own internal, independent quality department which undertakes a programme of selfinspection.



Comprehensive Range of Services

ALS is a leading one stop shop for Pharmaceutical analysis in Europe.

PHARMACEUTICAL

TESTING SERVICES INCLUDE

- Chemical, Physical and Microbiological analysis, of human and veterinary products, intermediates and raw materials
- Pharmacopoeial Standards and methodologies according to:
 - ČL (Czech Pharmacopoeia)
 - USP
 - Ph. Eur.
- International Standard and inhouse methods as well as customer specific methods as required
- QC testing for batch release
- Method validation/transfer/verification
- Stability studies, including storage (ICH conditions)
- Routine or specialist projects and investigations
- Water testing – Chemical and Microbiological analyses, according to Pharmacopoeia

INSTRUMENTAL

- API Assay
- Excipient Assay
- Identification
- Related substances
- Dissolution profile
- Desintegration
- Tablets Hardness
- Tablets Diameter
- Tablets Width
- Tablets Thickness
- Tablets Length
- pH
- Conductivity
- Loss on drying in oven
- Loss on ignition
- Sulfate ash
- Water content
- IR identification
- UV/VIS Spectrophotometric parameters
- Optical rotation
- Specific optical rotation
- Refractive index
- Appearance and color of solutions
- Metals Assay
- Total organic carbon
- Content of residual solvents

NON-INSTRUMENTAL

- TLC Identification
- Sieve analysis
- Assay by titration
- Appearance
- Density
- Precipitation reaction of ions

MICROBIOLOGY

- TAMC
- TYMC
- Bacterial endotoxins - Gel method
- Bacterial endotoxins - Turbidimetric method
- Clostridium perfringens
- Escherichia coli
- Bile-tolerant gram negative bacteria
- Pseudomonas aeruginosa
- Salmonella spp.
- Staphylococcus aureus
- Total bacteria count
- Total fungi count
- Total viable count

Our growth has been built on long-term relationships. Our clients are accustomed to receiving high quality data, technical support and open communication. This approach includes project and client managers, skilled and qualified client services teams, access to technical experts and a management team committed to service delivery.

Our standard value-add services include:

- Results reported electronically in a secure PDF format
- Sample Receipt Notification (SRN)
- Expert technical advice and support on scientific issues
- Laboratory inspections and tours
- Technical newsletters
- Webtrieve™ (on-line access to the results)

Webtrieve™ is a secure internet based system that allows direct access to data. Features include:

- Compatible with desktop and mobile devices
- Real-time access to analytical results as they are authorised
- ALS analysis history in one place
- Remote downloading of analytical reports
- Tools for data management, including data exporting to Excel
- Rapid retrieval of reports, results, invoices etc.
- Multiple users and access control

Issue Date Page Work Order Client	: 50-AL05-2015 : 2 of 3 : 07/10/2012 : ALS Czech Republic, s.r.o.
Analytical Methods	Method Description
P-CAS01-1001	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Calcium and Magnesium in Aqua Purificata and Aqua ppm Spectro
P-CZ-1002	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Chloride in Aqua Purificata and Aqua ppm Spectro
P-COCL01E01	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Chloride in Aqua Purificata and Aqua ppm Spectro
P-HG-48847	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Chloride in Aqua Purificata and Aqua ppm Spectro
P-148E1-1001	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Heavy Metals in Aqua Purificata and Aqua ppm Spectro
P-ANM-1001	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Ammonia in Aqua Purificata and Aqua ppm Spectro
P-AOXS-1002	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Nitrate in Aqua Purificata and Aqua ppm Spectro
P-COXS-1002	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Oxidizable Substances in Aqua Purificata and Aqua ppm Spectro
P-RES-0901	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Residue after Vaporization in Aqua Purificata and Aqua ppm Spectro
P-SOXS-1002	Czech Pharmacopoeia / European Pharmacopoeia, Determination of Sulfates in Aqua Purificata and Aqua ppm Spectro

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