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A GLOBAL LEADER IN TESTING

Capabilities

- Environmental & occupational hygiene
- Equipment reliability
- Personal care & OTC
- Mining & commodities
- Food & beverage
- Pharmaceutical & healthcare


Environmental & occupational hygiene


Food & beverage


Pharmaceutical & healthcare

We are a partner & collaborator

ALS offers quality focused testing and proactively seeks to form long-term, mutually beneficial relationships. Our collaborative approach is driven by project and client managers, skilled and qualified client service teams, access to technical experts and a management team committed to exceptional service.

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MISSION

We leverage the power of data-driven insights to solve complex challenges for a safer, healthier world.

PURPOSE

Using science as our North Star, we are a trusted partner in leveraging technological expertise, sustainability and empathetic practices to help make the world a better place.

Personal care & OTC

Equipment reliability

Trade & inspection

CULTURE

We are deeply committed to providing positive employee experiences where team members explore solutions in a safe, inclusive and respectful environment. To ensure this, we employ top talent, enriched by ongoing training and professional development, and operate with the highest levels of integrity at all times.

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ALS is committed to sustainable activities and recognises the need to plan, manage and review those aspects of the business that may have an impact on our people, partners, the environment and the communities in which we do business.

Health, safety, environment & sustainability

Health, safety & the environment

Our responsibility is to provide a safe and healthy workplace for all employees, contractors and visitors as essential to our long-term success. We strive for continual improvement of its health, safety and environmental performance with the goal of eliminating work-related injury or illness.

Engaging with our communities

We strongly believe in being a positive influence in the community and we encourage all our employees across the globe to contribute to their local communities. Our response to community needs is continually demonstrated by fundraising and volunteering for a wide spectrum of charities and causes, including appeals for natural disasters, neighbourhood clean-up campaigns, children's charities, community health services, cancer research among others.

Reducing waste & managing risk

Our internal sustainability intranet site, where relevant information on environmental management programs are monitored and reported on by our employees to include: Energy, Waste, Water, and Gravimetric dust.

Our dedication to this effort also links our employees to waste registers, audit tools, suggestion and initiatives boxes, and key sustainability announcements.

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A GLOBAL LEADER IN TESTING

For more than 40 years, ALS has provided comprehensive testing solutions to clients in a wide range of industries all over the world. Our adoption of state-of-the-art technology and innovative methodologies – coupled with the strength of our international teams – ensure that we deliver the highest quality services using local expertise and personalized solutions.


Metallurgy & mineral processing


Coal


Geochemistry & mine site operations

PHARMACEUTICAL & HEALTHCARE

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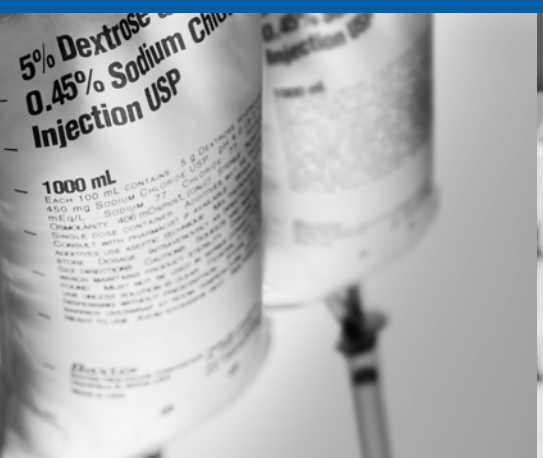
CAPABILITIES OVERVIEW



Laboratory network

Europe

Czech Republic

Prague
Na Harfě 336/9, 190 00 Praha 9
T +420 734 762 132

United Kingdom

Ely
2 Bartholomew's Walk
Cambridgeshire Business Park, Ely
T +44 1353 660 040

Denmark

Odense
Lille Tornbjerg Vej 24, 5220 Odense
T +45 65 93 29 20

Ireland

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Poligono Industrial El Montalvo II,
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T +46 829 7900

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Luleå
Aurorum 10
T +46 920 289 900

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3904 Del Amo Blvd. Suite 801
T +1 310 214 0043

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T +52 55 5650 0600

South America

Brazil

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T +55 19 3789-8610

APAC

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Carribean Business Park,
22 Dalmore Drive, Scoresby
T +61 3 8756 8111

Sydney
Unit 10, 2-8 South Street, Rydalmere
T +61 2 8832 7500

Singapore

Singapore
121 Genting Lane #04-01
ALS Building
T +65 6589 0118

India

Bangalore
No 65, Bommasandra Jigani Link Road
KIADB Industrial Area, Pin- 560105
Karnataka
T +91 636 486 4821

ALS offer quality focused testing and proactively seek to form long-term, mutually beneficial relationships. Our clients are accustomed to receiving high quality data, technical support and open communication. The collaborative approach is underpinned by project and client managers, skilled and qualified client service teams, access to technical experts and a management team committed to service delivery. Performing efficiently & ethically, against the backdrop of a fast growing global support network, leaves ALS very well placed to support the healthcare industries with trustworthy and reliable QC services.

ALS Limited. 09.22

Pharmaceutical services

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ALS offers established and leading testing services, incorporating the analysis of raw materials, intermediates, and finished products at locations strategically positioned to support the healthcare industries.

Our analytical services support the breadth of the pharmaceutical commercialization, manufacturing, and release processes.

We specialize in the validation and execution of quality control testing and have state of the art equipment, backed by a dedicated teams, to meet ever changing industry requirements.

With our laboratories all conforming to GMP or GLP requirements, ALS partners can have confidence in the integrity and quality of test results.

ALS laboratories are equipped to support physical, chemical and analytical testing needs across the entirety of pharmaceutical manufacturing operations.

Traditional wet chemistry goes hand in hand with modern, industry leading technologies. In addition, our analytical services underpin risk management and product development activity through Technical Projects & Contaminants Screening.

Chemistry testing

- **Finished product and raw material testing.** For QC batch release
- **Ph Eur (EP), BP, USP, JP Testing** (others available)
- **Water testing**
  - Pharmacopeial analysis of potable and purified water and WFI
  - Water from steam sterilisers and washer disinfectors (CFPP01-01Parts C & D, CFPP01-06, EN-285, HTM 2030 & 2031).

Microbiological testing

- **Bioburden & pathogen testing.** For Total Microbial Aerobic Count (TAMC) and Yeast and Mold Count (TYMC), fungi and specified pathogens in pharmaceuticals, cosmetics and medical devices
- **Endotoxin Testing.** Analysis performed on water, raw materials and finished products
- **Water Testing.** TVC and pathogens by membrane filtration employing various methods:
  - Pharmacopeia
  - CFPP
  - HTM
  - Client specific
- **Antimicrobial Preservative Efficacy Testing (PET)**
  - Pharmacopeial testing for pharmaceuticals and cosmetics
- **Disinfectant Efficacy**
  - BS EN methods
  - Testing can be performed for manufacturers and end users
- **Sterility testing**
  - Membrane filtration and direct inoculation per USP & AAMI
- **Particulate Matter USP & EP**
  - Light Obscuration (HIAC) method
  - Microscopic method

Technical projects

- **We offer a comprehensive range of services to support regulatory requirements including:**
  - Drug product ICH stability storage and testing
  - Test method validation (to ICH)
  - Test method development
  - Dissolution profile studies
  - Investigation Support

Batch release testing

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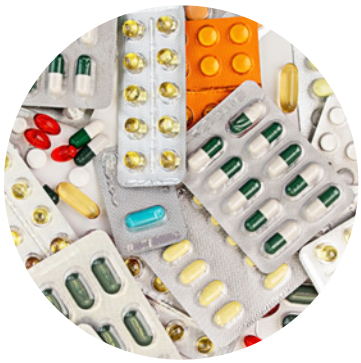
Pharmaceutical products and materials made under current Good Manufacturing Practice (cGMP) require batch or lot release against the approved product specification. Furthermore, importation testing is required for many EU, UK and Mexico destined generic products.

Our analytical laboratories possess a wide range of analytical instrumentation and expertise to provide responsive drug product and raw material release testing. Routinely handling a diverse range of sample matrices, including both small and large molecules, leaves ALS well positioned to meet the needs of our clients' ever expanding product portfolios and diverse product ranges.



Analytical Method Transfer (AMT) is performed as standard prior to conducting routine release testing.

We routinely handle:

- Tablets
- Capsules
- Powders and granules
- Syrups
- Creams, Ointments & Gels
- Oral and topical liquids
- Medical devices
- Injections
- High Potency/Cytotoxic
- Investigational Medicinal Products (IMP's)

ALS offer both chemical and microbiology testing services, including:

- Disintegration
- Dissolution
- Hardness
- Friability
- Dimensions
- HPLC – UV, RI, DAD & fluorescence detectors
- Ion Chromatography
- Sterility
- Particulate matter testing for injectables
- Residual Solvents USP <467>
- Gas Chromatography – Direct Injection and Headspace with FID, TCD & MS detectors
- Compendial analysis (BP, EP, JP & USP etc.)

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Physical & chemical analysis

At ALS, our pharmaceutical business provides a wide range of services to the pharmaceutical and healthcare industries. Committed to exceeding client expectations we are able to provide high quality solutions across a range of products, including human and veterinary products, intermediates and raw materials.

Testing is conducted according to international standards such as the British Pharmacopeia, United States Pharmacopeia, European Pharmacopeia and Japanese Pharmacopeia or alternatively to documented client specifications.

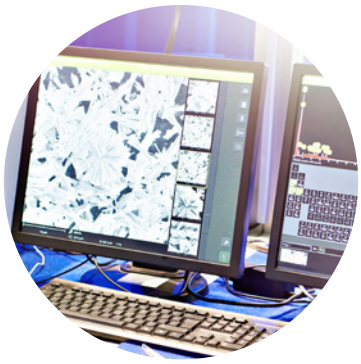
Scope of services

- **Pharmacopeial standards and methodologies**
  - BP - British Pharmacopeia
  - USP - United States Pharmacopeia
  - Ph. Eur. - European Pharmacopeia
  - JP – Japanese Pharmacopeia
  - CL - Czech Pharmacopeia
  - ICH Guidelines

Physical testing

- Hardness
- Disintegration
- Dimensions
- Appearance/Colour/Odour
- Viscosity
- Melting Point
- Friability
- Uniformity of Weight
- Specific Gravity
- Sub-visible particles

Chemical techniques & equipment



- ICP-MS, ICP-OES & ICP-SFMS
- HPLC detection by UV-Vis (Dual λ and PDA), RI, Flourecence
- Liquid and Headspace detection by FID, TCD and MS
- Ion Chromatography
- Atomic Absorption Spectrophotometer
- Dissolution Testing
- FTIR
- Karl Fischer Titrator
- Auto-titrator
- Total Organic Carbon Analyser
- UV/VIS spectrophotometer
- Refractive Index
- Conductivity

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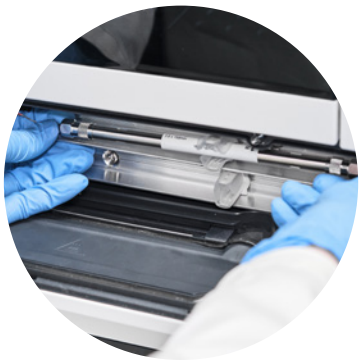
Method development & validation

Analytical method development, validation & transfer

ALS has extensive experience in delivering method development, validation, verification and transfer projects across a range of analytical methodologies. ALS are highly experienced in test method development and validation across various analytical techniques and product types in compliance with regulatory requirements.
ALS work collaboratively throughout the entire process including project planning, protocol preparation, and analytical testing to final project report and transfer.



- Background Research
- Developmental Process Design
- Risk Assessments
- Analytical Technique Selection
- Proof of concept work
- Determination of analytical conditions
- Stability indicating assessments
- Analytical Troubleshooting
- Method Optimization

Common projects include:

- Development in support of New Product Launches
- Adaption of compendia methods to alternative product dosage forms
- Method Screening across different column chemistry
- Transference from reverse phase HPLC to UPLC
- Application and implementation of newer analytical technologies
- Method consolidation

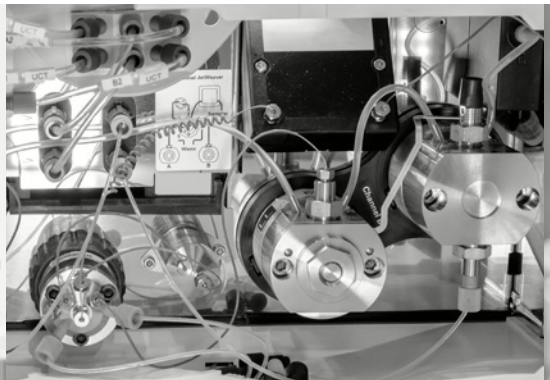
Analytical method validation & verification

Typical validation characteristics include:

- Accuracy
- Precision
- Repeatability
- Intermediate Precision
- Specificity
- Detection Limit
- Quantitation Limit
- Linearity
- Range
- Robustness
  - Filter Studies
  - Establishment of solution stability

Analytical Method Transfer

Analytical method transfer (AMT) is formal process for the introduction of new methods which allows the receiving laboratory to demonstrate that they can perform the analytical method effectively and reproducibly. Effective protocols should consider all critical quality attributes and method parameters with a view to maintain the method's validated state and support continued procedure performance verification.



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Physical & structural characterization

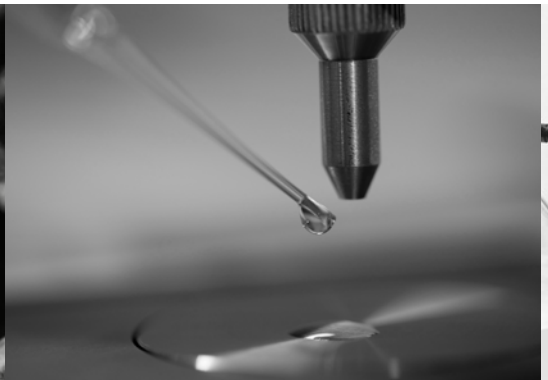
ALS offers a broad range of analytical techniques and expertise to characterize the physical and structural features of excipients, APIs, and finished products.

Understanding the physical properties of pharmaceutical raw materials is key to successful drug product development and performance. Physical properties such as size/shape, morphology, particle size distribution, flow, density, dissolution profile, bioavailability and melting point enable more efficient formulation and manufacturing process development at the drug product stage. These factors contribute to the evaluation of drug-excipient compatibility (which affects physicochemical stability) and physiological bioavailability.

Physical characterization techniques and services available at ALS include:

- Particle size distribution By Laser Diffraction (Mastersizer-3000) both in dry and wet mode
- X-Ray Powder Diffraction (XRPD)
- Differential Scanning Calorimetry (DSC)
- Thermogravimetry (TGA)
- Melting Point
- Infrared spectroscopy
- Water Activity
- Scanning electron microscope (SEM)
- NMR spectroscopy and Mass Spectrometery
- Bulk and tap density Testing
- FTIR and UV/VIS Spectroscopy

ALS has advanced NMR laboratories, where comprehensive structure elucidation expertise is coupled with state-of-the-art analytical techniques. NMR measurements are performed on one of five Bruker instruments, with up to 600 MHz equipped with CryoProbe technology. 2D NMR Services are also available.



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Extractables & Leachables Studies

ALS offers comprehensive analytical techniques and significant expertise to support extractables & leachables (E&L) studies wherever they may be required. Performing extractables & leachables (E&L) testing is an important part of verifying medical device safety.

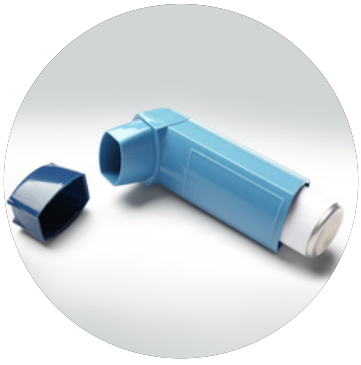
To design an effective E&L testing study ALS wholly evaluate materials, the expected use conditions and their associated risks.
Our collaborative approach combines analytical, technical and regulatory expertise to present well packaged E&L studies.

Capabilities includes:

- OINDPs (e.g. Nasal Sprays)
- Dermal and Topical Applications
- Label/Ink Migration
- Parenteral/Injectable
- Drug Delivery Systems
- Primary Container Closure Systems
- Secondary/Tertiary package materials
- Raw Material/Polymers
- Material Comparison
- Residual Analysis

Analytical services include:

- Organic analysis by GC, GC-MS/MS, HPLC, LC-MS/MS
- Elemental analysis by ICP-MS and OES.
- pH and Total Organic Carbon (TOC) provide non-specific indications of chemical migration
- Ion chromatography
- Particle size analysis
- Karl Fischer



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Elemental impurities testing

Elemental impurities in drug products may arise from several sources; they may be residual catalysts that were added intentionally in synthesis or they may be of unknown origin. As these impurities can be hazardous to patients, their levels in excipients, drug substances, drug products and dietary supplements must be controlled and minimized. ALS has some of the world's leading labs for Elemental analysis per the requirements outlined within ICH Q3D, USP <233> and Ph. Eur. method 2.4.20.

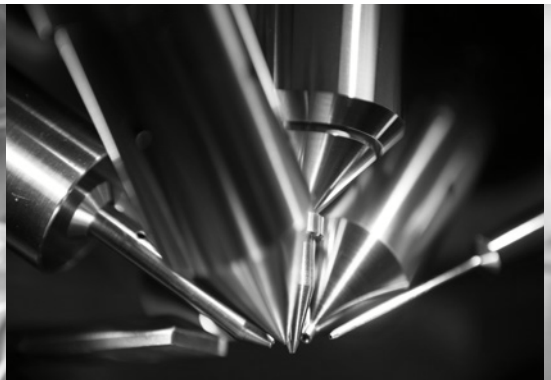
Determination of elemental impurities by ICP-MS

ALS offers GMP compliant elemental impurities analysis of pharmaceutical products, ingredients, APIs and other healthcare products in accordance with compendia requirements. Our facilities are equipped with some of the most sensitive techniques available coupled with decades of experience specifically in metals analysis. Typical limits of quantification reach far below typical PDE requirements; some reaching ppt (parts per trillion) levels with as little as 10mg in sample weight. Our facilities offer a full service range from initial scans to support pre- risk assessment understanding to full and thorough ICH method validation. Our extensive expertise allows for an open, collaborative approach towards managing each product and project.

- **Elemental impurities in purified water**
  ALS can quickly and effectively screen purified water, down to very low limits of quantification, to support risk assessments.

- **Contingency planning**
  ALS can help to mitigate risk by way of being a partner for independent analytical support and back-up. Contingency planning can be a necessity to help navigate through rare but critical times of need.

- **Clinical samples**
  Combined with isotope and elemental speciation capabilities, ALS offers a comprehensive portfolio of elemental analysis for clinical samples.



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Microbiological analysis

ALS provide a range of microbiological testing and support services to ensure raw materials, finished products, medical devices and production environments are appropriately monitored for microbiological contamination.

Through our dedicated GMP compliant laboratories, highly experienced staff and extensive range of microbiological tests, ALS provides clients with cost-effective quality assurance paralleled with easily accessible pharmaceutical microbiology expertise. Many ALS laboratories offer both analytical and microbiological testing under one roof offering simplified Quality Control solutions.

Microbiological quality testing:

- Microbial Examination of non-sterile products
- Total Aerobic Microbial Count (TAMC)
- Total Yeast, Mould & Fungi Count (TYMC)
- **Absence of Specific Pathogens**
  - *Staphylococcus aureus*
  - *Pseudomonas aeruginosa*
  - *Escherichia coli*
  - *Salmonella*
  - *Candida albicans*
  - Bile-tolerant Gram-negative bacteria (BTGN)
  - *Clostridia*
  - *Burkholderia cepacia* (BCC)

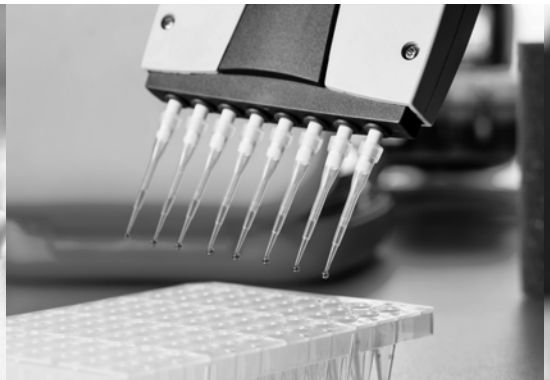
Other microbiological services

- **Preservative Efficacy Testing (PET)**
  - Pharmaceutical formulations – oral, topical, injectable
  - Cosmetic formulations
- **Disinfectant Efficacy Testing**
  - Suspension testing, BSEN 1276, 1650, 13704 (Phase 2,step 1) for bacterial, fungicidal and sporicidal assessments
  - Surface testing BSEN 13697 (Phase 2, step 2) for bacterial and fungicidal assessments. USP 1072, disinfectant and antiseptic testing
  - Tailored to client specific requirements - to conclusively demonstrate that their disinfectants are effective under the conditions in which they are used
  - Testing can be performed for manufacturers as well as end users
- **Bacterial Endotoxin Test (LAL)**
  - Gel Clot, Turbidimetric and Kinetic methods per USP and EP methods
- **Sterility testing**
  - Membrane filtration
  - Direct inoculation
- **Microbial identification by:**
  - DNA Sequencing
  - MALDI-TOF
  - MLST
- **Particulate Matter USP & EP**
  - Light Obscuration (HIAC) method
  - Microscopic method

Container Closure Integrity Testing (CCIT)

Destructive an Non-destructive techniques:

- Electrical Conductivity and Capacitance Test (HVLD)
- Laser-based Gas Headspace Analysis
- Blue Dye Ingres Leak Test
- Microbial Immersion Testing



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Environmental monitoring

ALS offers a complete range of supportive testing for both Sterile and non-Sterile environmental monitoring programmes, including:

Incubation, enumeration and reporting of:

- Settle Plates (Passive Air Monitoring)
- Contact Plates
- Active Air Plates and strips
- Glove Prints (Finger Dabs)
- Impacted Compressed Gas (supporting ISO 8573 requirements)

Inoculation of blank control plates for Growth Promotion / Fertility testing.

Water Testing (Performance qualification and routine monitoring)

- Purified Waters (Bulk and in Containers)
- Potable Feed
- Water used in washing process
- Steam

In addition to testing, ALS offers consultancy services and are proactive in supporting:

- Company-wide education of Environmental Monitoring programmes and their application
- The design and evaluation of Microbiological Monitoring Programmes
- Risk assessments
- Technique Training and Establishment (e.g. culture media selection, incubation condition selection, and sampling best practices)
- The validation of monitoring techniques
- Performance qualification and monitoring thereafter
- Acceptance Criteria Establishment and Limit Setting (Non-Sterile Environments)
- Investigations and root cause analysis

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Stability testing & storage

Being an essential component of pharmaceutical development, stability studies allow the evaluation of product stability under the influence of various environmental conditions. These include temperature, humidity and light, simulating different climatic zones from around the world. The data from such studies can be used to establish recommended storage conditions, retest periods and shelf life.

ALS offer ICH stability storage and testing programs for a wide range of API's, pharmaceuticals, biopharmaceuticals, medical devices, chemicals and cosmetics, whether required for initial product registration, Product Quality Review (PQR) or business continuity.

Our purpose-built reach-in stability chambers and walk-in stability rooms are fully validated to meet GMP regulations and can be utilised for both long-term and short-term shelf life studies. All rooms are monitored in real time and our monitoring systems are fully validated and compliant with 21 CFR Part 11 requirements.

Security

- All chambers are kept locked, with restricted access
- Audible and visual alarms for temperature and humidity (above and below set conditions)
- Data loggers have email and auto dial alert functionality
- UPS on data logger ensuring continuous monitoring and alarm call outs
- Back-up power

Photostability

ALS also offer photostability testing in accordance with ICH Q1B (option 2).

Conditions

Stability storage conditions available*:

- **-84° to -66°C.** Ultra Low Freezer
- **-20° to -10°C or -25° to -15°C.** Freezer conditions
- **5°C.** Long term conditions for cold stored products or retained/control samples
- **25°C/60%RH or AH.** Long term conditions for climatic zones I and II
- **30°C/65%RH.** Intermediate and long term conditions for climatic zones I, II, III and IVa
- **30°C/75%RH.** Long term conditions for climatic zone IVb
- **40°C/75%RH or AH.** Accelerated conditions for climatic zones I, II, III and IV
- **40°C/Not more than 25%RH.** Accelerated condition for semi-permeable containers
- **45° or 50°** with ambient humidity Accelerated conditions
- Photostability chamber
- Other conditions available on request

*Conditions may vary from location to location please enquire with your nearest facility for more details.

Definition of zones

Zone	Climate	Long Term Condition	Humidity
I	Temperate	21°C ± 2°C	40% RH ± 5% RH
II	Mediterranean / subtropical	25°C ± 2°C	60% RH ± 5% RH
III	Hot dry	30°C ± 2°C	35% RH ± 5% RH
IV	Hot humid / tropical	30°C ± 2°C	65% RH ± 5% RH
IVb	ASEAN testing conditions hot / high humidity	30°C ± 2°C	75% RH ± 5% RH
Refrigerated	-	5°C ± 3°C	N/A
Frozen	-	-15°C ± 5°C	N/A

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Purified water testing

Purified water is a vital ingredient used in the manufacturing of most pharmaceutical products. Therefore, it is essential that water purification systems are validated and routinely checked to ensure that the water produced is consistent and meets the specified quality requirements.

ALS provides a complete service for water testing in the pharmaceutical industry. We provide pharmacopeial analysis of highly purified water, purified water, water for injection (WFI), in addition to water from steam sterilisers and washer disinfectors.

Testing can be undertaken to various standards and guidelines including CFPP01-06, CFPP01-01 Parts C and D, HTM 2030 & 2031, EN285.

Physical & chemical

- Conductivity
- Total Organic Carbon (TOC)
- Heavy Metals
- Nitrates
- pH
- Acidity or Alkalinity
- Oxidisable substances
- Chloride, Sulfates & Ammonium
- Calcium & Magnesium
- Residue on evaporation
- Aluminium
- Iron, Silicates, Phosphates
- Ultra-trace elemental analysis

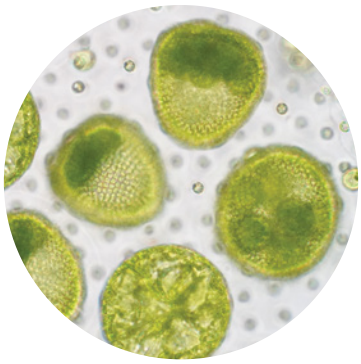
Microbiological

TAMC by Membrane Filtration using:

- R2A agar (Purified Water in Bulk)
- Casein soya bean digest agar (Purified Water in Containers)

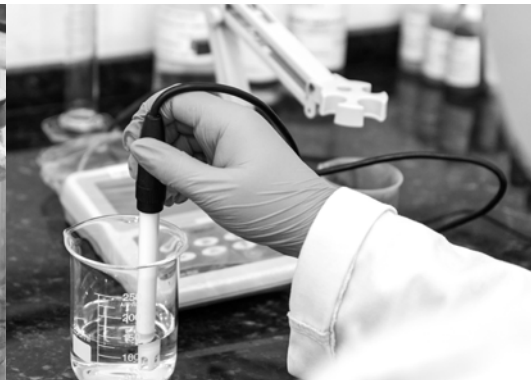
Selective media for additional specified pathogens and other objectionable organisms, including:

- *Escherichia coli*
- *Pseudomonas aeruginosa*
- Coliforms



Water for Injections

- Sterility
- Bacterial Endotoxin



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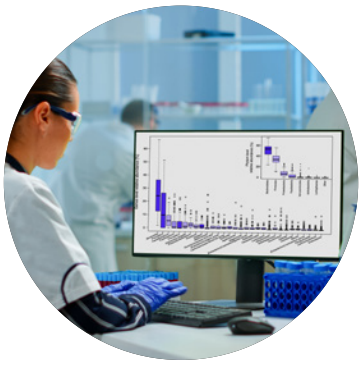
Service approach & value adds

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.



Standard offering

Our clients have access to a number of value-add services including:

- Results reported electronically in a secure PDF format
- Leading tailored electronic data delivery formats (EDD)
- Full Chain of Custody Protocols including receipt acknowledgement (SRN)
- Expert technical advice and support on scientific issues
- Laboratory inspections and tours
- Technical newsletters
- Webtrieve™

Technical bulletins

These publications are designed to communicate technical developments and act as an educational resource.

Regulatory, analysis, new technologies and key industry information are routinely featured.

Webtrieve™ service approach & value adds online data access & mobile apps

Real-time results to save you time and money

WebTrieve™ is a secure, internet-based application that provides real-time access to your laboratory data with the following convenient features:

- Internet access to view validated results
- Exclusive, complimentary service to our clients
- Export results to MS-Excel
- Security protection against unauthorized users
- Reports emailed directly to your address
- Multiple levels of access available
- Compare results to guidelines
- Data access 24 hrs/day, 7 days/wk, 365 days/yr
- Online request for quotes and bottle orders
- Online communication with ALS

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Quality management system

The integrity of our test results is of paramount importance, allowing our clients to make informed decisions. Clients work with us safe in the knowledge that their results are reliable, repeatable and meet regulatory requirements.

Regulatory compliance

ALS pharmaceutical laboratory achieves premium service levels through continued investment in quality systems and technology to guarantee ongoing compliance.
ALS pharmaceutical laboratories host more than 100 audits annually including:

- US-FDA
- National Regulatory Agencies (GMP, GLP)
- National Accreditation Bodies (ISO 9001)
- International pharmaceutical companies

ALS welcomes clients to visit and/or audit our laboratories. In addition to external audits, we have our internal, independent quality department, which undertakes a programme of self-inspection.

	GLP	GMP	ISO 17025
Australia, Melbourne		✓	✓
Australia, Sydney		✓	✓
Brazil, Campinas	✓		✓
Brazil, São Paulo	✓		✓
Brazil, São Roque	✓		✓
Czech Republic, Prague		✓	✓
India, Bangalore		✓	✓
Mexico, Mexico City	✓		✓
Sweden, Landskrona		✓	✓
Sweden, Luleå	✓	✓	✓
Sweden, Sollentuna		✓	✓
United Kingdom, Ely		✓	✓
USA, Torrance	✓	✓	✓

Proficiency schemes

To provide our clients with additional confidence in our tests results we regularly participate in proficiency schemes. **Schemes undertaken include:**

Scheme	Provider	Scope
EDQM	European Pharmacopoeia	Various analytical techniques and product types for pharmaceutical testing (as per Ph.Eur)
Pharmassure	LGC	Various chemical and microbiological techniques and products
LEAP	FPAS	Chemical Water Analysis
ILPQ	ACC	Endotoxin Analysis
EV - Inter-Lab Ring Trial	Evans Vanodine	Disinfectant Analysis

Certifications & accreditations

ALS global laboratory network holds and maintains a number of certifications and accreditations.