CAPABILITY STATEMENT

Pharmaceutical Services
EUROPE

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COMPANY PROFILE

ALS Pharmaceutical is one of the key business streams within the ALS Group, focussing on delivering high quality technical and service solutions to clients in the pharmaceutical industry.

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

Our pharmaceutical operations in Europe employ around 100 professional and support staff. People and knowledge are key priorities for the group.

ALS Pharmaceutical is part of the Life Sciences division with operations on all continents. Globally, ALS employs more than 13 000 staff with 1 200 staff employed in the Life Sciences division in Europe. Our network of pharmaceutical laboratories are all GMP compliant and inspected by the FDA on a regular basis.

As one of the world's largest and most diversified Testing, Inspection and Certification (TIC) companies, ALS has sites strategically located around the world to provide accurate and timely services. We have operations in more than 350 locations, 65 countries, and on 6 continents.

We are focused on delivering superior services through four main divisions: Life Sciences (Environmental, Food, Pharmaceutical, Consumer Products and Electronics); Minerals (Geochemistry, Metallurgy, Mine Site and Inspection); Energy (Coal and Oil & Gas); and Industrial (Asset Care and Tribology); and offering a broad range of technical services to our clients that is unrivalled.

ALS is the global benchmark for quality and integrity, and we have built our reputation on quality, client service, innovation, and technical excellence. Our commitment to systemisation and standardisation allows our people to focus on what is important.

As our company continues to grow, so do our systems, offering data and reporting solutions that not only meet but exceed client expectations.

A critical part of our overall strategy is to recruit and develop the best talent from across the industry and to ensure that every member of staff feels a valued part of the global ALS team. This positive working environment flows through to our clients, helping to underpin the great service that we strive to deliver with every ALS experience.

At ALS, we are committed to the well-being of our staff, the environment and the communities in which we operate, allowing us to establish long-lasting relationships with clients and make positive contributions to the regions in which we live and work.


150
YEARS IN OPERATION
13k+
STAFF
350+
LOCATIONS
65+
COUNTRIES

ALS PHARMACEUTICAL LABORATORIES

UNITED KINGDOM ELY

The ALS laboratory in Ely is one of the UK's leading providers of pharmaceutical testing services. A comprehensive range of services are provided from the site. The portfolio includes chemical and microbiological testing of API's, finished products for batch release, raw materials, intermediates, purified water, water for injection and waters for steam sterilisers and washer disinfectors (to HTM and CFPP guidelines). Pharmacopoeial or customer specific methods are employed.

The site is a dedicated pharmaceutical facility and offers a full range of chemical and microbiological testing testing including storage stability trials. Six storage stability rooms are available operating at the standard ICH conditions.

Our understanding of the pharmaceutical market and customers' requirement enables us to provide knowledgeable, proactive support and advice. Our staff pride themselves on their technical expertise and are always more than willing to discuss a customers' specific testing needs.

SWEDEN LULEÅ

The ALS laboratory in Luleå, Sweden, has been specially designed for trace and ultra-trace elemental analyses for a wide range of applications. By operating the most sensitive analytical technique available in a controlled environment, ALS Luleå can offer reporting levels (LOQs) that few laboratories can match.

Work flows are separated between sample types, from uncorking to instrumental analysis, to ensure the best possible analysis for your project. All incoming air in the clean room laboratory is filtered through HEPA filters and the ventilation system is designed to minimize the residence time of particles in indoor air and thus limit fall-out in the laboratory environment.

The laboratory provides more than 300 individual methods capable to determine over 70 elements in practically any sample matrix.

SWEDEN SOLLENTUNA

The ALS Laboratory in Stockholm is a leading microbiological laboratory with a broad portfolio of microbiological testing services to support the healthcare industry. We are an affectionate partner for both routine production units as well as for research and development departments. Since 1974, has Mikrolab been a partner to industry from raw material to finished product.

The laboratory is currently in a new "tailor-fit" lab facility in Sollentuna. The laboratory are split-up in a cleanroom „EU GMP Grade-A" for sterile work, and laboratory premises with LAF-hoods for routine microbiology.

ALS Stockholm is the only Swedish testing laboratory for microbiological analysis services both accredited according to EN ISO / IEC 17025 (Swedac) and certified as a quality control laboratory (GMP cert) and controlled by the FDA for compliance with the GMP requirements of Directive 2003/94/EC.

SWEDEN LANDSKRONA

The Landskrona laboratory performs a wide variety of analyses, ranging from analyses of raw materials, bulk products, semi-manufactured products and finished products. The analyses are performed in accordance with pharmacopeia methods; European Pharmacopeia, United States Pharmacopeia (USP/NF), British Pharmacopeia and other certified methods; or else according to the customer´s requirements. We also develop analytical methods and validation in accordance with ICH guidelines.

ALS Landskrona´s staff are skilled and have many years of experience in the trade. The department has steadily increased it´s range of instruments and has acquired a broad experience in instruments and methods. We can perform analyses on the following methodology: GC-FID, GC-MS, HPLC, IR, UV/VIS-spectrophotometri, fluorometri, ion chromatography and gel electrophores.

The quality system meets the requirements of the EU-GMP and is inspected by the Swedish Medical Agency (MPA) on a regular basis.

CZECH REPUBLIC PRAGUE

The Prague laboratory carries out chemical and microbiological testing of API's raw materials, intermediates and finished products for the pharmaceutical industry.

The laboratory meets demanding requirements of national and international regulatory authorities. An 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.

PHARMACEUTICAL
CAPABILITIES

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 Pharmacopoeia, US Pharmacopoeia, European Pharmacopoeia and Japanese Pharmacopoeia or alternatively to documented client specifications.

Pharmaceutical Chemistry testing services include:

- **Finished Product and Raw Material Testing**
  - For QC batch release
- **Ph Eur (EP), BP, USP, JP Testing (others available)**
  - To meet your requirements
- **Water Testing**
  - Pharmacopoeial analysis of potable and purified water and WFI
  - Water from steam sterilisers and washer disinfectors (CFPP01-01 Parts C & D, CFPP01-06, EN-285, HTM 2030 & 2031)

Pharmaceutical Microbiology testing services include:

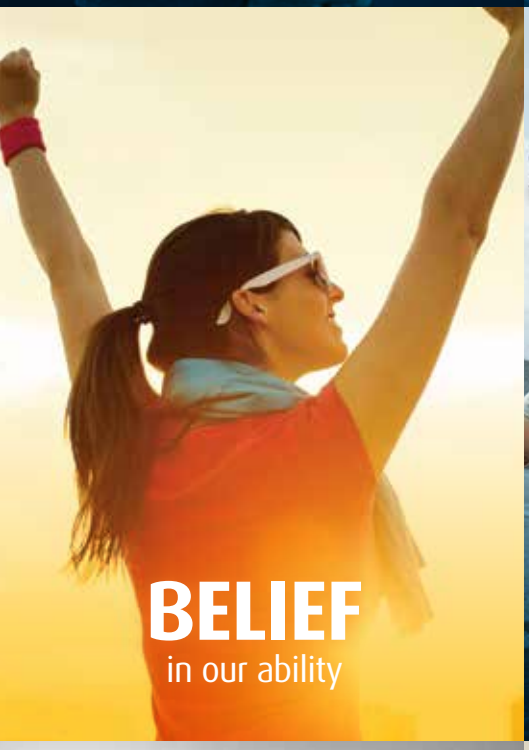
- **Bioburden & Pathogen Testing**
  - Testing for total viable count (TVC), fungi and specified pathogens in pharmaceuticals, cosmetics and medical devices
- **Endotoxin Testing**
  - Analysis performed on water, raw materials and finished products
- **Water Testing**
  - TVC and pathogens by membrane filtration employing various methods: pharmacopoeia, CFPP, HTM and client specific
- **Preservative Efficacy Testing (PET)**
  - Pharmacopoeial 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

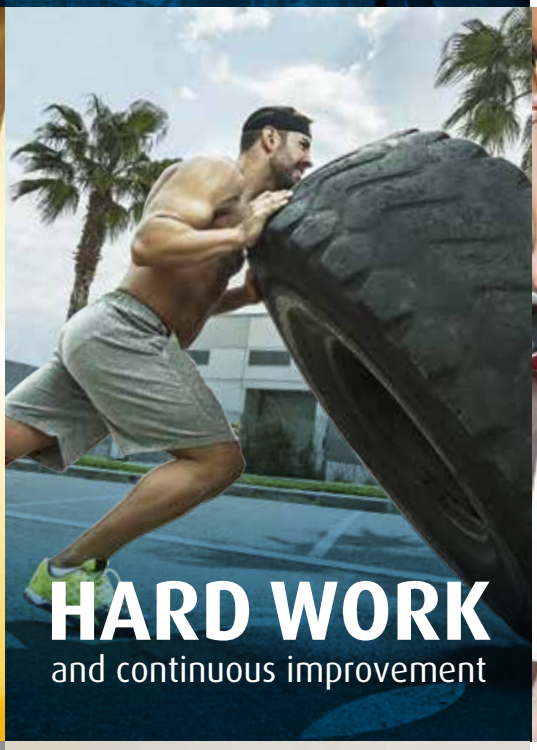
Technical Projects - services include:

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

CORE VALUES





Right Solutions
• Right Partner

BATCH RELEASE TESTING

Within the European Union (EU), Good Manufacturing Practice (GMP) for Medicinal Products requires batch release against the approved product specification, for medicinal products holding a marketing authorisation. Our QC batch release testing laboratories utilise a wide range of analytical technologies to provide responsive release testing using pharmacopoeial or client specific methods, confirming that products meet their specification. Routinely handling a diverse range of sample matrices 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.

Some examples of the sample matrices that we routinely handle:

- Tablets
- Capsules
- Powders and granules
- Syrups
- Creams, Ointments & Gels
- Oral and topical liquids
- Medical devices

We offer both chemical and microbiology testing services, including:

- Disintegration
- Dissolution
- Hardness
- Friability
- Dimensions
- HPLC - UV, RI, DAD and fluorescence detectors
- Gas Chromatography – FID and Headspace
- Ion Chromatography
- Compendial analysis (BP, EP, JP and USP etc.)
- Complete microbiological testing including total viable counts (TVC) and pathogens, microbial identification, preservative efficacy testing (PET), bacterial endotoxin (LAL) testing
- Sterility
- Elemental Impurities by USP <233> using ICP-MS
- Microbial Identification by DNA sequencing


GC SYSTEM 5
TRACE 1310

PHYSICAL
& CHEMICAL ANALYSIS

At ALS we have established an unrivalled testing service, incorporating the analysis of raw materials, intermediates and finished products.
With a comprehensive range of tests, qualified analytical equipment and experienced and skilled staff, clients can have confidence in the integrity and quality of test results. All laboratories are GMP compliant, FDA inspected and ISO 17025 accredited.

Scope of services

Pharmacopoeial Standards and Methodologies:

- BP - British Pharmacopoeia
- USP - United States Pharmacopoeia
- Ph. Eur. - European Pharmacopoeia
- JP – Japanese Pharmacopoeia
- CL - Czech Pharmacopoeia
- ICH Guidelines

International Regulatory Standards, customer specific methods as required for QC batch release testing and validated in-house methods.

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 (UV, diode-array, RI and Fluorescence detectors)
- GC (FID and headspace)
- Ion Chromatography
- Atomic Absorption Spectrophotometer
- Dissolution Testing
- FTIR
- Karl Fischer Titrator
- Auto-titrator
- Total Organic Carbon Analyser
- UV/VIS spectrophotometer
- Refractive Index

ELEMENTAL IMPURITIES

The ICH Q3D guideline presenting a policy for limiting metals in drug products and pharmaceutical ingredients has now reached step 5 - the implementation stage. ICH Q3D applies to new finished drug products entering the market and new products containing existing drug products.

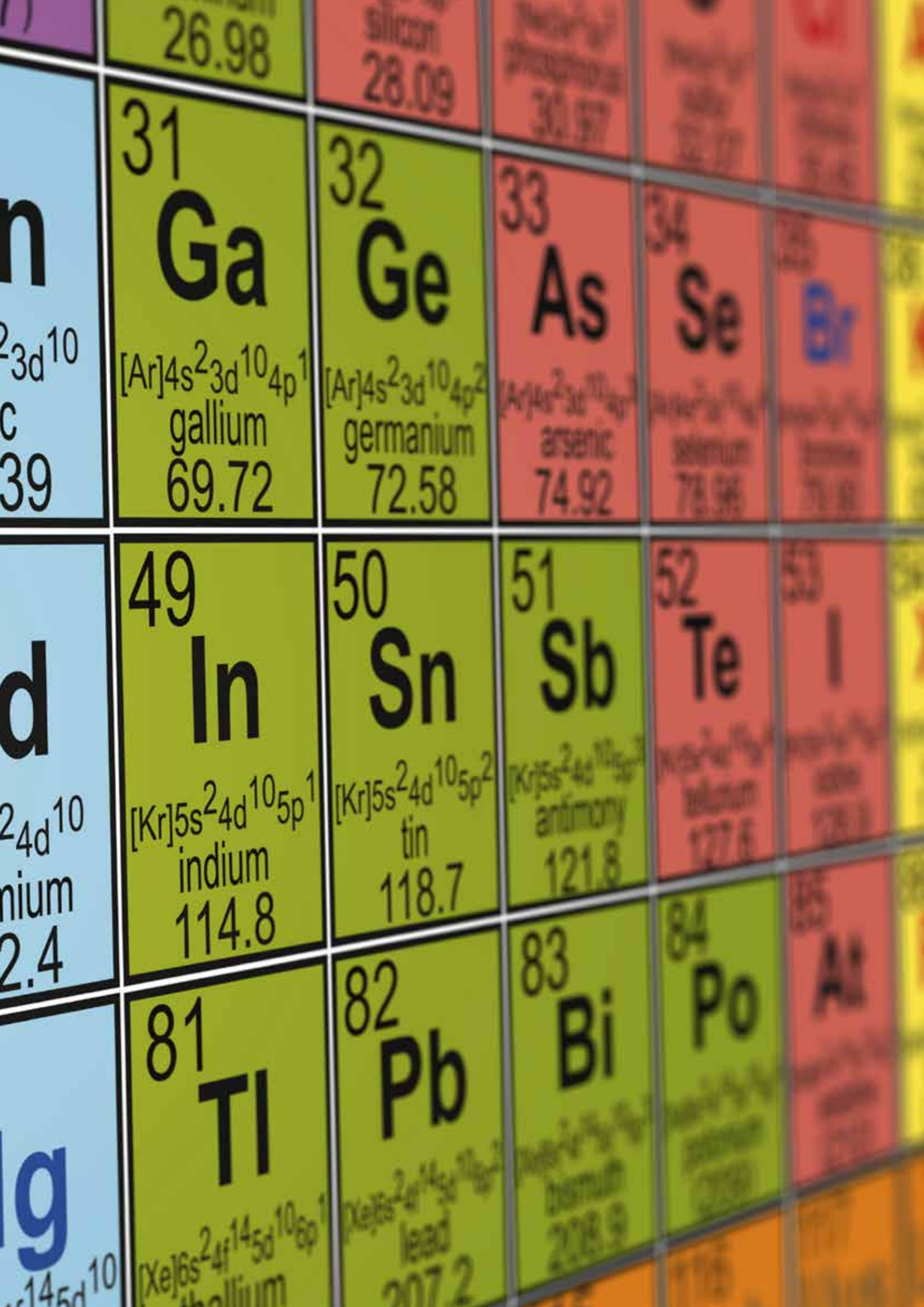
ICH Q3D has been adopted by CHMP and came into effect for new marketing authorization applications from June 2016. For existing medicinal products, the corresponding date is December 2017. USP has also aligned the effective date for their corresponding chapters, <232> and <233>, setting the date to 1 January 2018.

There are numerous potential sources of elemental impurities in the manufacturing process of drug products. While the most significant risk comes from intentionally added metal catalysts, other sources such as manufacturing equipment, solvents, water and reagents should also be considered. Particularly challenging is assessing the potential contribution of elemental impurities from excipients. Environmental factors will have a significant impact, meaning it is important to consider the source of the excipient. Figure 1 shows the elements included in ICH Q3D, and gives examples of potential sources for each element.

ALS offers tailor-made screening analyses for client-specific needs, from a single element to packages of all elements included in ICH Q3D, USP <232>, or even up to 70 elements in a single certificate of analysis. In the risk assessment process, non-validated analytical methods may be used. The results can thereafter be used to determine which elements to test for on a regular basis using a validated method.

ALS has successfully completed well over 100 method validations compliant with ICH Q2 (R1), USP <233> and Ph.Eur. 2.4.20 for clients in the pharmaceutical industry.

Our laboratory holds 11 ICP-SFMS (high resolution ICP-MS) instruments. Combined with decades of experience with ICP-techniques and method validations, this makes ALS Scandinavia a reliable partner with solid backup capacity.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antimony
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Tl
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84
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ALS
Right Solu

METHOD DEVELOPMENT
VALIDATION & TRANSFER

At ALS we have a proven track record of delivering method development and validation projects across a range of analytical methodologies.

Test Method Development and Validation

Highly experienced in test method development and validation across various analytical techniques and product types in compliance with regulatory requirements.

We can assist throughout the entire process including project planning, protocol preparation, analytical testing to final project report.

Methods can be developed and validated in accordance with ICH guidelines which include the following parameters:

- Specificity
- Linearity
- Accuracy
- Precision (Repeatability And Intermediate)
- Detection Limit (LOD)
- Quantitation Limit (LOQ)
- Robustnes
- Forced Degradation

Key test method areas in which we have expertise include:

- Dissolution profile studies
- Compendial methodologies bespoke to your product formulation
- Stability indicating test methods to comply with ICH

Analytical Method Transfer (AMT)

Analytical Method Transfer (AMT) is performed as standard prior to conducting routine release testing in accordance with regulatory requirements.

Analytical method transfer is critical to ensure continuity of data and with our experience in performing this comparative testing we can assist you throughout the entire process; from protocol preparation including guidance on testing requirements and acceptance criteria, analytical testing to final transfer report.


CV100

MICROBIOLOGICAL ANALYSIS

We provide a microbiological testing service to ensure raw materials, finished products, medical devices and production environments are safe from microbiological contamination.

Through our dedicated GMP compliant laboratory, highly experienced staff and extensive range of microbiological tests, ALS Pharmaceutical provides customers with cost-effective quality assurance.

Microbiological Quality Testing includes:

- Microbial Limit Testing
- Total Viable Count (TVC)
- Total Yeast, Mould & Fungi Count
- Microbial Identification

Absence of Specific Pathogens

- *Staphylococcus aureus*
- *Pseudomonas aeruginosa*
- *Escherichia coli*
- *Salmonella*
- *Candida albicans*
- Bile Tolerant Gram Negative Bacteria
- *Clostridia*

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
  - 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**
- **Sterility testing**
  - Membrane filtration and direct inoculation
- **Microbial identification by DNA sequencing**

Environmental

- Settle Plates – Total Bacteria, Yeast and Mould
- Air Plates – Total Bacteria, Yeast and Mould
- Contact plate analysis
- Swab and sponge analysis
- Gowning – contact plates
- Finger dabs

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 and/or Product Quality Review (PQR). Our purpose-built 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.

We operate emergency back-up facilities on site, allowing business continuity and complete peace of mind for our clients.

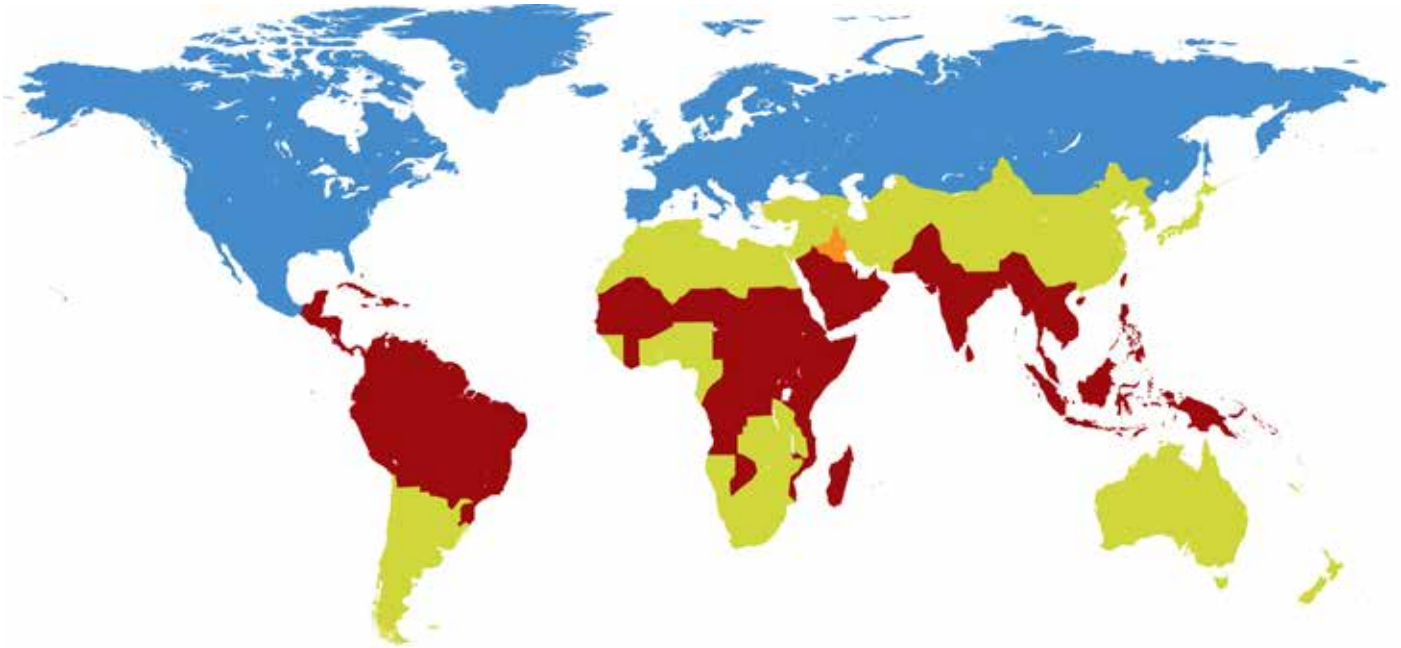
We can provide a solution tailored to your requirements - storage only or full storage plus testing. Samples can be stored and scheduled for testing or shipped to your chosen location at each time point or as required.

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

Definition of Zones

Zone I	Temperate climate
Zone II	Subtropical and Mediterranean climate
Zone III	Hot and dry climate
Zone IV	**Zone IVa** - Hot and humid climate **Zone IVb** - Hot and very humid climate



Conditions

Stability storage conditions available:

- **5 °C**
  Long term conditions for cold stored products or retained/ control samples
- **25˚C/60%RH**
  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**
  Accelerated conditions for climatic zones I, II, III and IV

Photostability

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

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 and Healthcare and industries. We provide pharmacopoeial 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

Analysis by membrane filtration for:

- Total Aerobic Count
- *Escherichia.coli*
- *Pseudomonas aeruginosa*
- Coliforms

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. Therefore ALS methodologies are performed and developed in accordance with Pharmacopoeial, regulatory and customer requirements.

Regulatory Compliance

ALS pharmaceutical laboratory achieves premium service levels through continued investment in quality systems and technology to guarantee on-going compliance.

ALS pharmaceutical laboratories in Europe host more than 100 audits annually including:

- FDA
- National Regulatory Agencies (GMP, GLP)
- National Accreditation Bodies (ISO 17025)
- 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.

Our laboratories in Europe have the following accreditation:

	Ely	Prague	Luleå	Sollentuna	Landskrona
GMP Compliance	✓	✓	✓	✓	✓
GLP Compliance			✓		
FDA	✓	✓	✓	✓	✓
ISO 17025	✓	✓	✓	✓	✓

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	FAPAS	Chemical Water Analysis
ILPQ	ACC	Endotoxin Analysis
EV - Inter-Lab Ring Trial	Evans Vanodine	Disinfectant Analysis

WHY CHOOSE ALS?

We realise that invariably there are two main reasons why you may look to change your choice of contract laboratory: either to improve the quality of the service and the integrity of the test results or to reduce costs. At ALS, we are confident of being able to meet your needs in both of these areas.

In addition, we also feel that there are a number of other important considerations when choosing a testing laboratory:

Quality first

Having provided pharmaceutical testing for over 15 years in accordance with internationality recognised standards, ALS continues to keep quality and transparency at the very core of everything we do. This is evidenced both through the quality systems and equipment we have on site as well as the quality and experience of our staff.

Trust and reliability

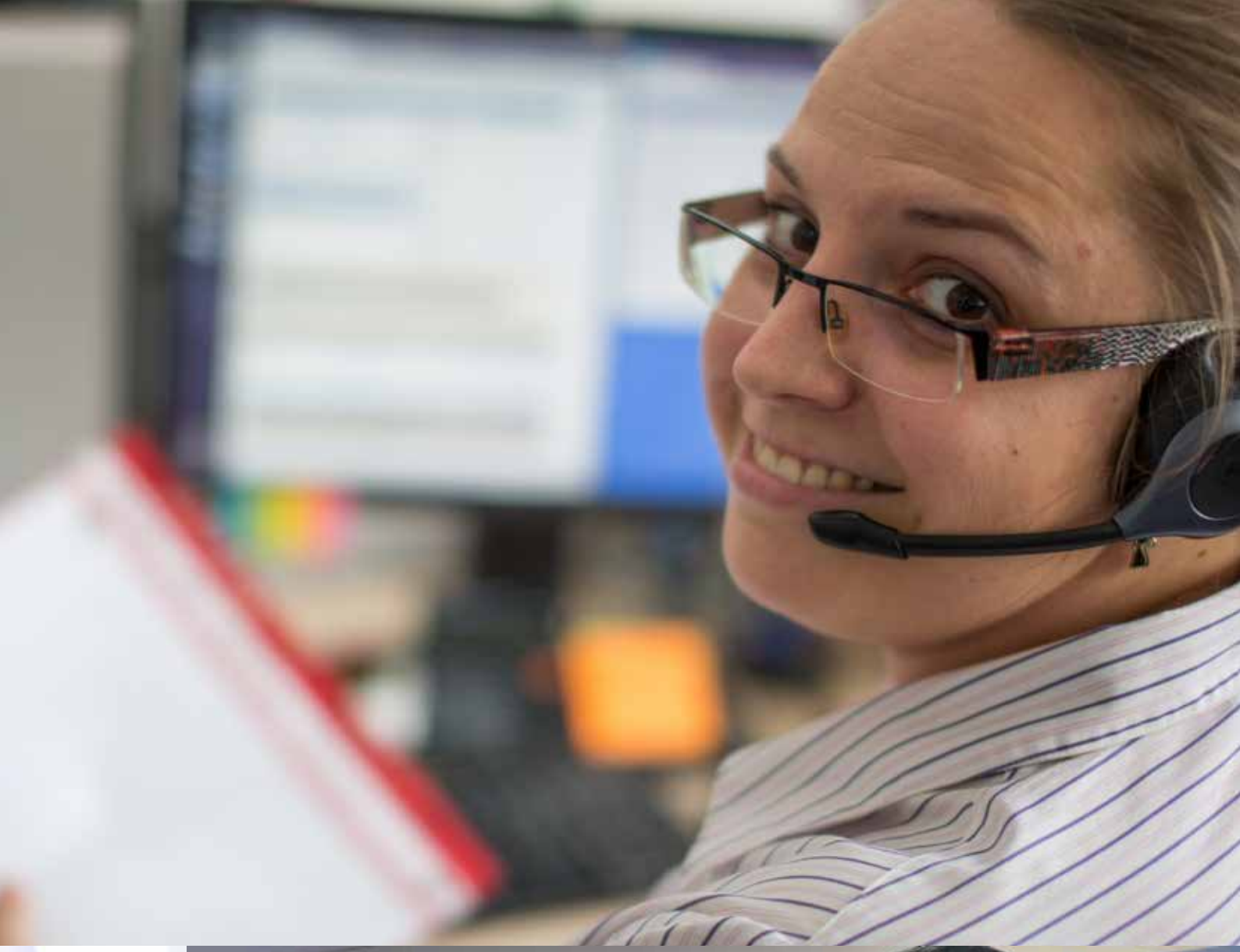
At ALS, we understand that it is not just the quality of testing which is of paramount importance but the opportunity to develop strong and long-standing relationships with our clients. We always strive to go the extra mile for our clients and in times of need, you can be assured that ALS will be right behind you.

Size, scale and diversity

ALS offers its clients access to a global network of accredited laboratories that provide a comprehensive range of tests and services. We cater for businesses of all shapes and sizes and through a process of continuous improvement and investment in our sites we work hard to tailor our solutions to meet the specific needs of each organisation.

Making change easier

At ALS, we appreciate that changing your testing provider is never an easy decision to make. With this in mind, we have a specific implementation process in place (developed over the past several years with other new clients) that ensures all aspects of our service are set up accurately from the outset and that we provide you with the very best of service levels from day one.



MY NOTES


Right Solutions
• Right Partner

ALS Pharmaceutical
2 Bartholomew's Walk
Cambridgeshire Business Park
Ely, Cambridgeshire
CB7 4ZE

E sales.uk@alsglobal.com
T +44 (0) 1353 660040
F +44 (0) 1353 660050
W **www.als-testing.co.uk**

ALS Czech Republic, s.r.o.
Na Harfe 336/9
190 00 Praha 9
Czech Republic

E czsupport.pharma@alsglobal.com
T +420 226 226 998
W **www.alsglobal.cz**

ALS Scandinavia AB
Aurorum 10
SE-977 75 Luleå
Sweden

E info.lu@alsglobal.com
T +46 920 289900
W **www.alsglobal.se**

ALS Sollentuna
Kung hans väg 3
192 68 Sollentuna
Sweden

E sollentuna.lab@alsglobal.com
T +46 829 7900
W **www.alsglobal.se**

ALS Landskrona
Rosenhällsvägen 29,
261 92 Härslövsweden
Sweden

E landskrona@alsglobal.com
T +46 418 707 00
W **www.alsglobal.se**

www.alsglobal.eu