Pharma Services

Your Contract Research Organisation (CRO)

Sample Management

Keeping your samples under controlled conditions at all times is the prerequisite for reliable results. Strict handling processes executed by trained lab professionals using state-of-the-art equipment ensure maximum repeatability and prevent external factors from influencing your test results.

Compliant Documentation

Everything we do is about compliance – from test execution to documentation. Whether your service includes simple test records or requires comprehensive studies for filing with regulatory authorities, you can expect our documentation to meet all applicable international standards.

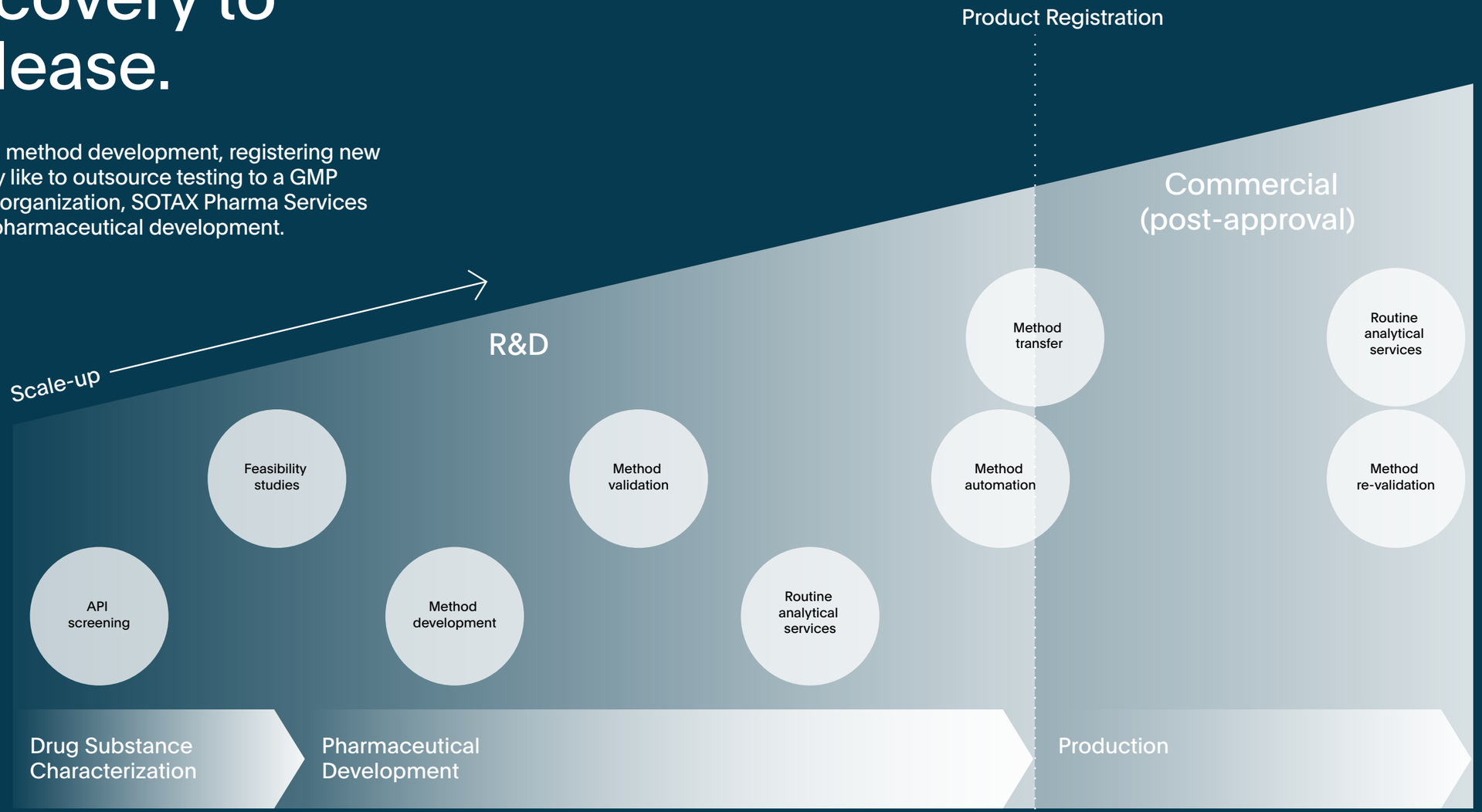
FDA | GMP | EMA

Testing & Analysis

We are experts at what we do. Our pharmaceutical professionals are experienced in mastering all analytical techniques and our laboratories are equipped with instrumentation from different manufacturers – allowing our team to perform a wide range of tests and analytical analysis.

From Discovery to Batch Release.

Whether you need support in method development, registering new formulations, or would simply like to outsource testing to a GMP compliant contract research organization, SOTAX Pharma Services assists you throughout your pharmaceutical development.



API

API Screening
- Intrinsic dissolution
- Apparent dissolution
- Processability

Formulation

API & Excipients
- Dissolution
- Analytics (UV, HPLC, UPLC)
- Particle size
- Reverse engineering / Deformulation
- Binary mixture stability
- Excipients comparison
- Powder properties

Final Dosage Form

Final Dosage Form
- Dissolution
- Content testing
- Physical testing
- Feasibility PAT/NIR

GMP Batch Testing
- All testing
- Analytical method validation
- Systematic stability testing

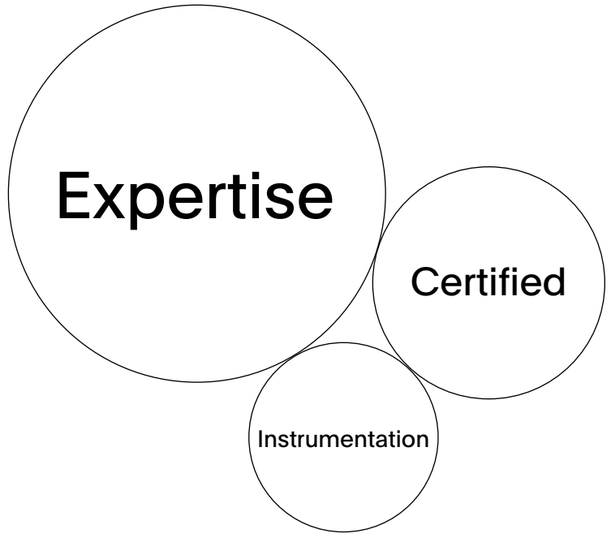
Manufacturing of Commercial Batches

Routine Testing
- Dissolution
- Content testing
- Physical testing

Post-approval Monitoring
- Periodic stability testing
- Scale-up & post-approval changes
- Lifecycle management
- Biowaivers

Experts for Experts.

Our global team of experts helps pharma companies worldwide in overcoming the various challenges associated with developing & testing pharmaceutical dosage forms.
Set in a US FDA-inspected facility with cGMP compliant processes, the scientific expertise of our staff paired with state-of-the art instrumentation ensures best in class service.



Three Labs.
One Philosophy.

Are you looking for a certified pharmaceutical establishment to perform release testing for the European Union (EU) or the United States (USA)? Do you need assistance with developing your analytical method – or would you like to avoid costly human studies by performing in-vitro characterization and in-vitro bio-equivalence studies? SOTAX operates dedicated Pharma Services laboratories on three continents with local experts covering different disciplines for your individual challenge.

Personnel
Job descriptions
Qualification

Lab operations
Reagents
References
Samples
Safety aspects

Quality management
Deviation
Change control
CAPA
OOS

Documentation
SOPs, project documents, and templates for analysis records

Facilities
Laboratory structured and organized in line with our operations

Equipment
Qualification
Maintenance
Software validation

Americas
Westborough, MA (USA)

Europe
Orléans (France)

Asia-Pacific
Ahmedabad (India)

Dissolution Experts.

In-vitro dissolution testing is in our DNA. Being the only Contract Research Organization (CRO) specialized in dissolution testing our team has a proven track record of finding the most suitable method for products ranging from APIs and tablets to implants, semi-solids, and many more.

- Tablets
- Capsules
- APIs, powders, granules
- Soft-gelatin capsules, suppositories
- Medical devices, stents, implants, coated lenses
- Microspheres, nano-suspensions
- Injectable suspensions
- Semi-solids, gels, creams
- Transdermal patches

Beyond Dissolution.

SOTAX specializes in in-vitro dissolution testing since 1973, but our range of Pharma Services extends far beyond “only” dissolution-related services. From API characterization to stability testing – our teams have access to state-of-the-art instrumentation and are experts in mastering different analytical techniques for different types of tests.

Analytical Techniques

- HPLC / UPLC with different detectors (ELDS, RI, UV, FLUO, MS, DAD)
- Spectrophotometry (UV-Vis)
- Gas Chromatography (GC)
- Ion Chromatography (IC)

Types of Tests

- Dissolution with different instrument designs, apparatus types, and methods (USP 1/2/3/4/5/6/7, Vertical Diffusion Cell, Immersion Cell, Microdialysis, and other in-vitro methods)
- Assay, Degradation Products and Content Uniformity (CU)
- Testing of physical properties
- Particle microscopic analysis
- In-Vitro Permeation Testing (IVPT)
- LC/MS testing for impurities / nitrosamines

R&D Services — For your formulation.

API Screening & Characterization
Analysis of how API characteristics impact on processability of the powder, dissolution of the drug, bioavailability, and stability.

Solubility Studies
Evaluation of the solubility of your API in one or more aqueous media mimicking the physiological conditions and allowing to fulfil sink conditions.

Method Development
From quickly evaluating the technical feasibility of a method to optimization and executing all required steps for filing a complete finalized method.

In-Vitro Release Testing (IVRT)
Dissolution testing with different apparatus types, methods, automation levels and test setups to determine the most robust method.

Microdialysis-based IVRT
IVRT studies based on a novel in-vitro technique for complex formulations such as liposomes, injectables, or ophthalmic suspensions.

IVPT of Oral Dosage Forms
In-vitro permeation testing to assess bioequivalence (BE). Predict IVIVC and rank order formulations to increase the success rate of your BE study.

IVPT of Topical Dosage Forms
In-vitro permeation testing to evaluate drug delivery into the various skin layers and to select formulations for topical and transdermal application.

Deformulation
Reverse engineering to determine the formulation composition of a reference drug for generic pharmaceutical companies.

Q3 Characterization
Achieve Q1 / Q2 similarity and perform Q3 characterization to obtain a biowaiver for your complex generic product approval.

IVIVC (In-Silico Simulation)
Develop IVIVC models, evaluate predict-ability, establish specifications for dissolution, and apply IVIVC as a surrogate for in-vivo bioequivalence studies.

Analytical Method Automation
Complete method transfers from manual to automated platforms with comparison studies and final transfer report.

Cleaning Validation
Analysis of cleaning swabs to develop a robust manual or automated method for regular cleaning validation by the customer.

Routine Testing Services (GMP)

Stability Studies
Storage of samples under controlled conditions in climatic chambers and performing stability testing according to defined test plans.

In-Vitro Bioequivalence (BE)
Studies and comparison tests following FDA guidances and USP <1090> to obtain a biowaiver for your generic products.

Clinical & Commercial Batch Release
Testing of your clinical and commercial batches with full qualitative and quantitative analysis for European Union (EU) and US markets.

Analytical Method Validation & Transfer
GMP compliant documentation for different methods with written method, approved protocol, and validation or transfer reports.

QC Analysis
Do you have to deal with missing capacities or are you looking for a reliable partner to perform some of your routine tests?

Dissolution / IVRT
Manual or automated dissolution tests performed and protocolled according to your validated method by our GMP-certified laboratory.

Physical Testing
Outsource your physical tests such as capsule disintegration time, uniformity of mass, tablet breaking force (hardness), friability, dimensional measurements, or powder characterization.

Assay, Degradation Products, and CU
Content testing according to your validated method. Professional sample management, test execution, and documentation.

LC-MS Testing for Impurities / Nitrosamines
Documented proof for the absence of carcinogenic impurities in your finished product with our LC-MS testing service.

Analytical Methods
Use our capacities and expertise for performing routine analysis with your analytical method (LC, UV-Vis, IC, GC with head space).

Support Services — Need help?

Consulting
De-risk your next development steps by having experts review analytical & clinical data from a failed bioequivalence study – or get guidance in defining actions based on the results of a GMP audit.

Investigations
From troubleshooting to out-of-specification (OOS) investigations, our team assists in identifying possible root causes and implementing solutions for specific problems throughout the lifecycle of your products.

Audits
Let us audit your manufacturing and testing contractors as an independent authority – or have certified subject matter experts perform technical audits of your analytical data to confirm compliance.

Training
Whether you would like to learn more about GMP, in-vitro dissolution method development, Good Dissolution Practices, or IVIVC, our professional training courses can be adapted to the specific needs of your team.

Q1/Q2 Regulatory Clearance
We are an experienced partner in guiding generic companies through the process of proving qualitative & quantitative sameness with regulatory authorities to obtain a biowaiver.

SOTAX Worldwide.

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