Pharma Services

Ortiv-Q3
A SOTAX Joint Venture

Experts for Experts.

Comprehending the requirements of multiple disciplines is fundamental to our Pharma Services. Our experts in dissolution testing and Q2/Q3 characterization have experience with a wide range of issues, including developing a robust method, analysing samples using different analytical techniques, governing norms and regulations, differently automated instrumentation, characterising APIs, routine testing, stability testing, and more. To fully utilise its potential, one must have a solid understanding of the different sectors that affect results, such as API characteristics, formulation composition, manufacturing process, and biopharmaceutical performance prediction.

Dissolution Experts.

Our DNA is in-vitro dissolution testing. Being the only Contract Research Organisation (CRO) with a disso-lution testing speciality, our team has a track record of successfully determining the best approach for a wide range of products, including implants, emulsions, suspensions, liposomes, nanoparticles, semisolids, tablets, APIs, and many more.

Beyond Dissolution.

In-vitro dissolution testing has been Ortiv-Q3's area of expertise since 2019, however the company offers much more than "just" dissolution-related services. It is a global provider of complete testing solutions for R&D, Quality Control (QC), and In-Process Control (IPC). The company also offers complex dosage form testing expertise. Our teams are proficient in many analytical techniques and have access to cutting-edge instrumentation for a wide range of test types, including stability testing and API characterization.

Quality System.

In accordance with US 21 CFR Parts 210, 211 and the guidelines of ICH Q10, the management of Ortiv-Q3 Research is dedicated to putting into place a Phar-maceutical Quality system that satisfies the relevant Good Manufacturing Practices criteria. Ortiv-Q3 Research is dedicated to the highest standards of professional conduct and customer service, utilising established protocols, techniques, and skilled and productive staff to deliver dependable, high-caliber outcomes on schedule.

Three Labs. One Philosophy.

Are you seeking for an accredited pharmaceutical facility to conduct release testing for the European Union (EU), the United States (USA) or Asia-Pacific (IN)? Do you need help creating your analytical method, or would you want to carry out in-vitro bio-equivalency and characterisation investigations in order to save money on expensive human research? SOTAX has specialised Pharma Services labs with local specialists covering several fields for your unique problem across three continents.

Americas
Westborough, MA (USA)

Europe
Orléans (France)

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Asia-Pacific
Ahmedabad (India)

Our Lab.

Ortiv-Q3 offers comprehensive contract research and testing services for a variety of dosage forms, from conventional to complex drug products. Their fully cGMP-compliant analytical setup boasts state-of-the-art instrumentation and a skilled technical team adept at developing and validating analytical methods, Q2/Q3 characterization, and both routine and specialized in-vitro release testing. The facility's experienced staff assist clients in data interpretation and regulatory filing, catering to both emerging and regulated markets.

R&D Services – For your formulation.

Analytical Services

API Screening & Characterization
An examination of the effects that the properties of the API have on the powder's processability, the drug's solubility, bioavailability, and stability.

Solubility Studies
An assessment of your API's solubility in one or more aqueous mediums that replicate physiological settings and meet sink requirements.

Method Development
From swiftly assessing a method's technical viability to optimising it and carrying out all necessary procedures to submit a fully developed method.

In-Vitro Release Testing (IVRT)
Dissolution testing to identify the best reliable approach using various apparatus kinds, techniques, automation levels, and test configurations.

Q3 Characterization
Attain Q1/Q2 similarity and carry out Q3 characterization to secure a biowaiver for the approval of your complex generic product.

IVIVC (In-Silico Simulation)
Create IVIVC models, assess predictability, set dissolution requirements, and use IVIVC as a stand-in for in vivo bioequivalency testing.

Microdialysis-based IVRT
IVRT investigations for intricate formulations like liposomes, injectables, or ocular solutions that rely on a revolutionary in-vitro methodology.

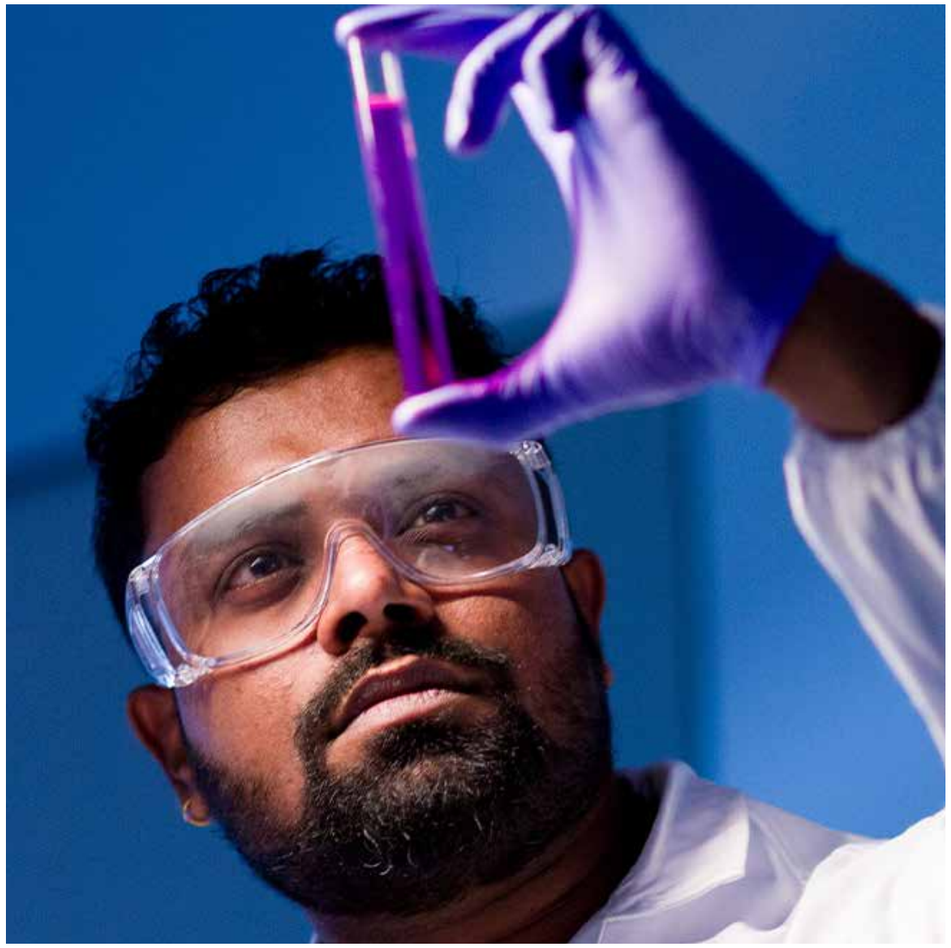
IVPT of Oral Dosage Forms
Bioequivalency (BE) is evaluated using in-vitro permeation testing. Predict IVIVC and rank-order formulas to improve your BE study's success rate.

IVPT of Topical Dosage Forms
To assess medication transport into the different layers of the skin and choose formulations for topical and transdermal use, in-vitro permeation testing is used.

Deformulation / Reverse Engineering
Reverse engineering is used by generic medication manufacturers to ascertain the formulation composition of a reference drug.

Analytical Method Automation
Complete method transfers, including comparison studies and a final transfer report, from manual to automated systems.

Cleaning Validation
Cleaning swab analysis to offer a dependable manual or automated procedure for the client's ongoing cleaning validation.



Formulation & Development Services

The newly extended formulation development lab at Ortiv-Q3 has focus on niche steriles and value-added generics. The leadership team of Ortiv-Q3 has proven capabilities across complex dosage forms. Our business strategy revolves around developing niche generic and specialty pharmaceutical products for global clients. It shall also aim at developing innovative drug delivery systems and licensing them at late stages to potential clients. Enhanced by strong existing analytical capabilities, the lab provides end-to-end support across product design, intellectual property, preclinical pharmacokinetics, regulatory affairs, and technology transfer. Ortiv-Q3 has established robust relationships with globally esteemed CMOs, facilitating smooth regulatory submissions and product commercialization.

- Development of Niche Generic steriles (US/EU)
- Development of Value-Added Generic Products
- NCEs performulation and lead optimization
- Development of New Formulation Concepts for Outlicensing
- Primary focus on injectables, ophthalmics, semi-solids, and liquid oral-based products
- Keen proficiency in liposomes, microspheres in situ gel forming depots and other nanotechnology

Routine Testing Services (GMP).

Clinical & Commercial Batch Release
Testing of your commercial and clinical batches for the US and EU markets, including comprehensive qualitative and quantitative analysis.

In-Vitro Bioequivalence (BE)
Research and comparative evaluations adhering to USP <1090> and FDA guidelines are necessary to secure a biowaiver for your generic items.

Stability Studies
Sample storage in climate chambers under regulated circumstances and stability testing carried out in accordance with predetermined test plans.

Analytical Method Validation & Transfer
GMP-compliant written procedures, approved protocols, validation or transfer reports, and other documentation for various methods.

QC Analysis
Are you trying to find a trustworthy partner to help you with some of your regular testing, or are you dealing with missing capacities?

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

ASSAY, DEGRADATION PRODUCTS, AND CU
Content testing according to your validated method. Professional sample management, test execution, and documentation.

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

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

LC-MS TESTING FOR IMPURITIES / NITROSAMINES
Documented proof for the absence of carcinogenic impurities in your finished product with our LC-MS testing service.

Support Services — Need help?

Consulting
To lower the risk involved with your next development steps, have experts assess the clinical and analytical data from a failed bioequivalency study, or ask for guidance on how to identify actions based on a GMP audit's results.

Training
Whether your staff needs to learn more about IVIVC, Good Dissolution Practices, GMP, or in-vitro dissolution technique development, our expert training courses can be tailored to meet their needs.

Investigations
Throughout the lifecycle of your products, our team helps you find potential root causes and put solutions in place for specific issues through troubleshooting and out-of-specification (OOS) investigations.

Q1/Q2 Regulatory Clearance
We have extensive expertise working with generic companies to help them demonstrate both qualitative and quantitative sameness to regulatory bodies in order to get a biowaiver.

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.

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