ANALYTICAL R&D

Tergus Pharma
Think Topicals, Think Tergus

Tergus has been providing analytical expertise and laboratory services for several years now. We provide analytical method development, validation and testing for your topical and specialty semi-solid dosage form. Our scientists have expertise in analyzing complex semi-solid matrices to support development, informal and ICH stability studies, and release of clinical trial materials.

Our Analytical Services Include

ANALYTICAL METHOD DEVELOPMENT

Phase- Specification Analytical method development, validation & testing for ANDA, NDA & OTCs

CLEANING VALIDATION

Cleaning methods for manufacturing equipment.

BATCH/LOT RELEASE TESTING

Batch/lot release testing for APIs and finished drug products including method transfers.

STABILITY

Stability testing (to support formulation development, preclinical, clinical and commercial activities)

GLOBAL REGULATORY COMPLIANCE

Compendial testing to meet various global regulatory needs, such as USP, EP, JP, MHRA, TGA, ANVISA, etc.

Analytical Instrumentation

Tergus has state-of-the-art equipment in place for the testing and analysis of semi-solid products. The lab capabilities continue to grow with customer and business needs.

HPLC / UPLC	Dissolution Apparatus	UV-VIS / FTIR / TLC	GC	LC-MS	Karl Fischer	Rheometers
Viscometers	pH Meters	Particle size analyzer	Photostability chambers	Texture Analyzer	High-resolution microscopes	Dropping Point Apparatus

Our team works closely with each client to not only meet their specific needs in the most efficient way possible, but they also strive to exceed those needs by anticipating obstacles and formulating solutions. The vast array of specialties encompassed in our services for topical products include method development and validation, as well as planning and execution of stability studies for both R&D and GMP purposes. We meticulously gather data throughout the analytical process to ensure reliable, specific, and robust results for analytical release, validation, and method development. We also have the capability to execute method transfers, refining the existing process to meet and/or exceed client and global regulatory needs.

Years of experience providing analytical and laboratory services

SKIN BIOLOGY

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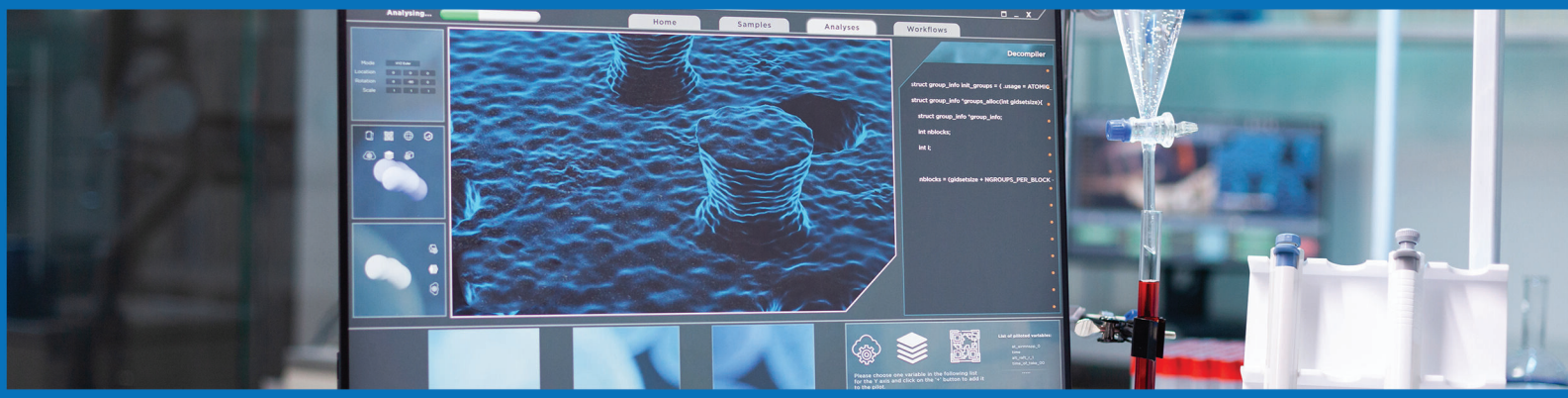

Tergus creates a solid foundation of discovery and true scientific understanding through well-designed and timely experimentation. What makes us unique is the ability to use our pool of talented people, state-of-the-art equipment, and quality processes to help eliminate ambiguity, reduce risk, and optimize the development process.

Skin biology studies play an important role in topical product development by identifying a lead formulation prototype based on its capacity to support the intended biological activity, as well as its skin permeation profile and other chemo physical properties. At Tergus, we use ex-vivo human skin models which are specifically designed for the molecular mechanism of the API and also to recapitulate various aspects of the targeted skin pathology. We have developed and validated multiple disease models (e.g. atopic dermatitis, psoriasis, alopecia areata, bacterial infection, etc.) in which some of the key pathological signaling pathways are activated, which mimics some of the molecular aspects of the pathology. This approach provides a relatively fast and cost-effective alternative to other approaches such as PoC animal studies.

Capabilities

EARLY SAFETY SCREENING

- Skin Irritation
- Skin Sensitization
- Phototoxicity
- Market Comparability Study

DRUG EFFICACY MODELS

- Retinoid Activity
- Anti-Oxidant
- UV Protection
- Skin Pigmentation /Lightening
- Ex Vivo Tissue Culture
- Reconstructed/3D Human Skin
- Market Comparability Study

CONSULTING SERVICES

- Strategy for Topical Formulation Development
- Claims Support
- Study Design
- Target/Asset Assessment

DRUG DELIVERY & EARLY DMPK

- skin Penetration (Distribution & Flux)
- Skin Binding
- Early DMPK
- PK/PD modeling

TOPICAL FORMULATION DEVELOPMENT

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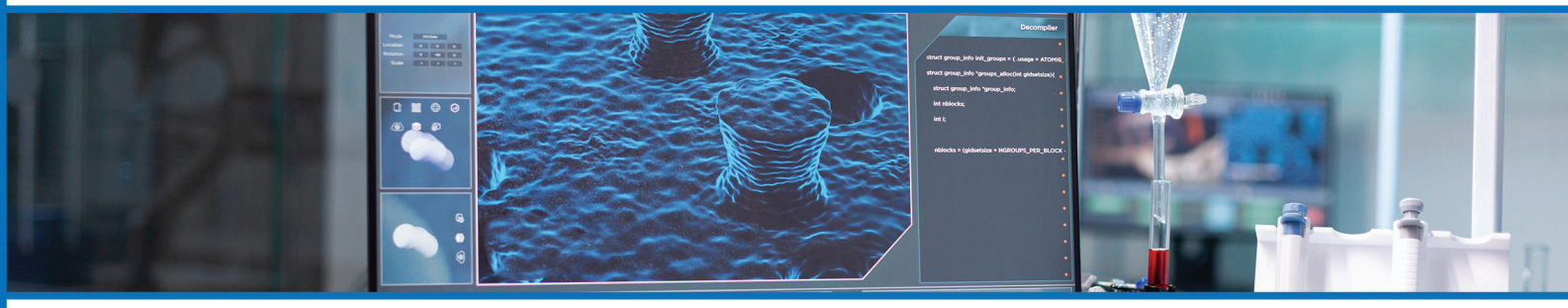

Tergus offers comprehensive solutions for your topical formulation development needs. We have expertise working with a range of Active Pharmaceutical Ingredient (APIs) including all BCE class compounds (especially poorly soluble and poorly permeable compounds), New Chemical Entities (NCEs), small and large molecules, pro-drugs, proteins, peptides, enzymes, Spherical Nucleic Acid (SNA), microbiomes, and high potency compounds. Tergus provides reproducible and scalable formulations by using quality-by-design and risk mitigation to produce a robust topical dosage form appropriate for proof-of-concept, GLP, clinical trials (Phase I, II, III), and subsequent commercial manufacturing. We can ensure the fastest path to market by customizing each development path to meet your phase-appropriate needs, allowing us to reach critical "Go/No Go" decisions earlier and achieve faster results.

- Development plan
- Patent strategy
- NDA/505(B)(2) /ANDA
- Pre-formulation
  - Multiple prototypes
  - QbD-DoE studies CMA/CPP evaluations
  - Stability studies
  - High throughput PoC screening(IVRT/IVPT)
- Final-formulation
- Scale up tech transfer
  - CMC support
  - GPL tox supplies
  - GMP clinical supplies

Our Topical Formulation Services Include

Tergus is a one-stop solution for your topical formulation development needs. Scientists at Tergus come from a variety of backgrounds including topical/transdermal skin delivery, pharmacology, topical formulation development, biology and pharmaceutical sciences.

- Complete NCE Generic and OTC product development
- Repurposing Phase I or II dosage form clinical setbacks via turnkey formulation solutions
- Manufacturing process optimization using QbD and CFR-compliant statistical software
- Evaluation of innovative platforms and technologies
- Expertise in developing non-infringing novel patentable formulations
- IP review and risk mitigation strategies
- Container closure selections
- Pre-clinical toxicology support
- 510(k) medical devices
- Addressing FDA deficiencies

Semi-Solid Dosage Forms

Topical Foam	Nail Lacquers	Topical Aerosols	Hydrogel	Hydro-alcoholic Gels	Oleaginous Gels	Lipoid Gels
Emulgels	Transdermal gels	Deep penetrating gels	Creams	Lotions	Suspensions	Ointments
Ophthalmic Preparations	Pastes	Liposomes	Microencap-sulation	Nano Emulsions	Topical Sprays	Topical solutions
Rectal Suppositories	Rectal Gels	Vaginal Creams	Vaginal Gels	Vaginal Pessaries		

IVPT/SKIN PERMEATION STUDIES

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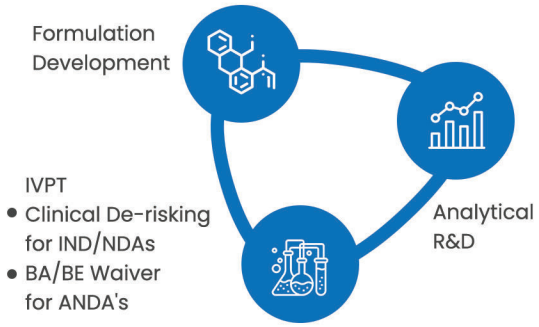


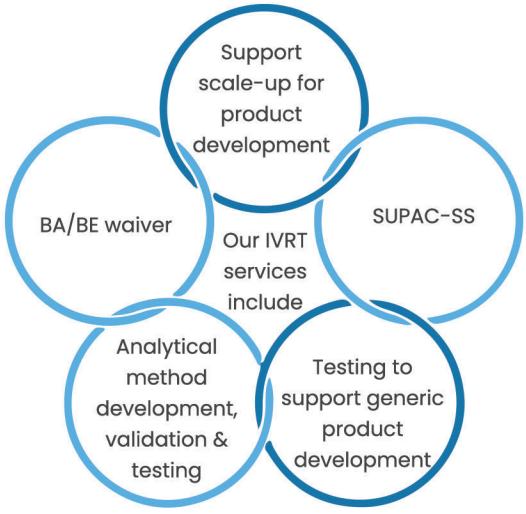
In Vitro Permeation Testing (IVPT), or skin permeation testing, is a critical tool for understanding drug delivery into the various layers of skin as part of the formulation selection process. Tergus is a recognized leader in skin penetration studies with in vitro and ex vivo model expertise.

Tergus has a large bank of 120+ vertical Franz diffusion cells to support IVPT studies. We can help you screen and select actives with optimal penetration properties, characterize the skin distribution of active ingredients and quantify which formulation delivers the drug to its target skin layer. We can also compare your optimized formulation to marketed products

IVRT (FRANZ DIFFUSION)

In vitro release testing (IVRT) is an FDA required test used to support post-approval manufacturing changes in compliance with SUPAC-SS requirements. IVRT is used in topical generic drug development as an accepted method of comparison to brand products. During topical drug product development, IVRT may be used to profile the performance characteristics of several prototypes formulations as a screening tool.

Tergus has a large bank of 120+ vertical Franz diffusion cells to support IVRT studies. We have developed specialized testing protocols to meet the needs of clients with challenging APIs. Our team has expertise in the design of discriminatory IVRT methods.



Our IVRT Services Include

- Analytical method development
- Validation and testing
- SUPAC-SS
- Generic product testing
- BA/BE waiver
- Support scale-up for product development

COMMERCIAL MANUFACTURING

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Tergus supports commercial manufacturing in our brand new 100,000 sq ft manufacturing facility:

- 30 L to 1500 L Scalable Batch Sizes
- Bulk to Finished Goods
- DSCSA Compliant
- Small Scale, HPAPI, Pediatric & Orphan Drug Production
- Tech Transfer Expertise
- Flexible Capacity

Flexibility and Customization

Tergus can provide specialized manufacturing services to meet your specific product and operational needs. And since markets and companies change and evolve, we can change with you by adjusting annual production volumes and managing supply chains. More than just a manufacturing site, Tergus is your strategic commercial manufacturing partner.

SEMISOLIDS

Leverage our industry-leading expertise and infrastructure for semi-solid manufacturing.

LIQUIDS

Tergus possesses low and high shear recirculating mixers in large and small volume tanks.

HIGH POTENT ACTIVES

Tergus has a dedicated suite designed specifically for highly potent manufacturing to help ensure safety and product integrity.

FILLING & PACKAGING

Tergus provides a wide variety of filling and packaging solutions to meet your specific product requirements.

STABILITY TESTING

Six walk-in stability chambers at ICH conditions with a dedicated stability coordinator.

CGMP TESTING SERVICE

Tergus offers comprehensive stability, microbiological, and QC testing for materials and method validation.