Fraunhofer
ITEM

FRAUNHOFER INSTITUTE FOR
TOXICOLOGY AND EXPERIMENTAL
MEDICINE ITEM

Scope of our services

Selected studies (as examples):

– Effects and toxicity of **plant extracts**
– Influence of **pharmaceuticals** on induction or inhibition of CYP450 monooxygenases
– In-vitro toxicity of inhalable **gases**
– In-vitro toxicity of **nanoparticles** (carbon black, carbon nanotubes)
– Cytotoxicity and genotoxicity of quartz-containing **ceramic dusts**
– Cytotoxicity and genotoxicity of novel antimicrobial **preservatives for cosmetics**
– In-vitro effects of **electromagnetic fields**
– Toxicokinetics and genotoxicity of a **mycotoxin**
– **Validation studies** in cooperation with regulatory authorities
– Cooperation partner in **EU projects** (e.g. SEAWIND, ARIMMORA, ACTICOSPACK, SILICOAT, PHOENIX)

The Fraunhofer ITEM offers contract research in the area of human health. The focus of research is on issues of preventive medicine, investigation of novel diagnostic methods and innovative therapeutic concepts, toxicological research, pre-clinical and clinical registration trials.

Contacts

Fraunhofer Institute for Toxicology and
Experimental Medicine ITEM
Executive Director: Prof. Dr. Dr. Uwe Heinrich
Nikolai-Fuchs-Strasse 1, 30625 Hannover, Germany
Phone +49 511 5350-0
Fax +49 511 5350-155
www.item.fraunhofer.de

Dr. Tanja Hansen
Phone +49 511 5350-226
tanja.hansen@item.fraunhofer.de

Dr. Jan Knebel
Phone +49 511 5350-273
jan.knebel@item.fraunhofer.de

IN VITRO AND MECHANISTIC TOXICOLOGY

TAILORED IN-VITRO METHODS

The Department of In Vitro and Mechanistic Toxicology offers a broad range of **in-vitro test methods** required for pre-clinical testing of pharmaceutically active ingredients. These tests are equally needed to assess the cytotoxic and genotoxic potentials of environmentally and occupationally relevant substances. The range of available methods also includes alternative test methods in line with the current European chemicals policy (REACH).

Selection of the appropriate **cellular test systems** and development of the study design is performed in consultation with the sponsor, governed by a variety of criteria such as relevance of the species, organ, and target site, endpoints to be analyzed, compliance with the relevant guidelines (e.g. OECD), and any additional requirements.

Environment
Health
Workplace
Nanotoxicology
Chemicals
Pharmaceuticals

Competences

– In-vitro exposure of cellular test systems, for example to gases, aerosols, and complex mixtures
– Determination of multiple parameters in cells
– In-vitro ADME assays (e.g. CYP450 monooxygenases, NAT profiling, biochemical parameters)
– Characterization of molecular mechanisms of action
– Regulatory assessments by means of standard genotoxicological tests in compliance with international regulations (OECD, EU, EPA, FDA, ICH)
– GLP certification for toxicological studies according to the German guideline ChemVwV-GLP No. 5.3/OECD (including genotoxicity studies and molecular toxicological studies)
– Cooperation in and coordination of national (BMBF, BfArM, BfR, BfS, UBA) and European (EU, EFSA, ECVAM) publicly funded projects

Methods

Biological test systems

– Primary cultures of human and animal origin, immortal and transgenic cell lines, co-culture systems, precision-cut liver and lung slices, microsomes

Exposure

– Liquid or soluble test substances
– Particulate substances in suspensions
– Airborne test substances (gases, aerosols, particles) in the patented culturing and exposure system P.R.I.T.®-ALI

Detection of biological effects

– General toxicity
  e.g. cytotoxicity, apoptosis, oxidative stress, proliferation, ATP status, interleukins, DNA damage, transcription factors
– Genotoxicity, mutagenicity
  e.g. comet assay, micronucleus assay, chromosomal aberration test, mouse lymphoma assay
– Molecular mechanisms
  e.g. expression of toxicologically relevant genes including analysis of specific pathways and transcriptome analyses, epigenetics, and DNA analyses