Quality Isn't What We Do. It's Who We Are.

### **QUALITASGLOBUS**

# PHARMACEUTICAL ANALYTICAL SERVICES





# PHARMACEUTICAL ANALYTICAL SERVICES

As the world becomes increasingly reliant on medication to treat everything from the common cold to chronic illnesses, the need for precise and accurate analytical services has never been greater. At QualitasGlobus, we pride ourselves on providing high-quality analytical services to our clients. Whether you need help with product development, quality control, or regulatory compliance, our team of experts is here to help. We offer a range of services, including method development and validation, stability testing, and impurity profiling. With our state-of-the-art facilities and experienced staff, we are confident that we can exceed your expectations.

Our Pharmaceutical Analytical Services include:

- 1. Pharmacokinetics study
- 2. Drug Metabolism and Pharmacokinetics study
- 3. ADME studies
- 4. Dose formulation analysis
- 5. Bioequivalence (BE) Studies Testing and Bioavailability Assay
- **6. Separation and Purification Service**
- 7. Analytical method development and validation
- 8. Impurity Testing Services
- 9. Stability Analysis
- 10. Out-of-specifications investigation



#### PHARMACOKINETICS STUDY

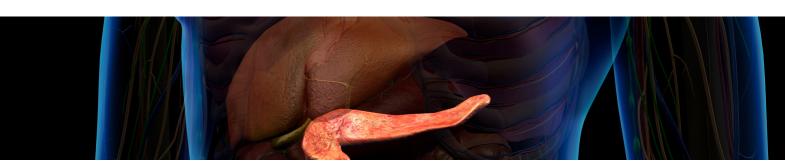
The pharmacokinetics (PK) of a drug is the study of how the body absorbs, distributes, metabolizes, and excretes the drug. PK studies are essential for understanding how a drug works in the body and how to optimize its therapeutic effect.

At QualitasGlobus, we have a dedicated team of PK experts who can help you with all aspects of your PK studies, from study design to data analysis. We also offer a comprehensive range of PK services, including method development and validation, bioanalytical services, and pharmacokinetic modeling.

# DRUG METABOLISM AND PHARMACOKINETICS STUDY

The study of drug metabolism and pharmacokinetics (DMPK) is essential for understanding how a drug is metabolized in the body and how this affects its therapeutic effect. DMPK studies are also important for determining the safety and efficacy of a new drug.

We offer a comprehensive range of DMPK services, including method development and validation, in vitro metabolism studies, in vivo PK studies, and drug-drug interaction studies. Our team of experts has extensive experience in conducting DMPK studies and can provide you with the guidance you need to ensure successful study completion.



#### **ADME STUDIES**

ADME studies are conducted to assess the Absorption, Distribution, Metabolism, and Excretion of a drug. These studies are essential for understanding how a drug is metabolized in the body and how this affects its therapeutic effect.

Our experts at QualitasGlobus offer a comprehensive range of ADME services, including method development and validation, in vitro metabolism studies, in vivo PK studies, and drug-drug interaction studies. We also offer a range of other services, such as tissue distribution studies and metabolite identification studies.

#### **DOSE FORMULATION ANALYSIS**

Dose formulation analysis is the study of how a drug is formulated and how this affects its therapeutic effect. This type of analysis is essential for optimizing the efficacy of a new drug.

Our team of experts at QualitasGlobus offers a range of dose formulation analysis services, including method development and validation, physicochemical characterization, and in vitro/in vivo correlation studies. We also offer a range of other services, such as drug-drug interaction studies and PK/PD modeling.



# BIOEQUIVALENCE (BE) STUDIES TESTING AND BIOAVAILABILITY ASSAY

Bioequivalence (BE) studies are conducted to assess the relative bioavailability of two or more formulations of a drug. These studies are essential for determining the therapeutic equivalence of generic drugs.

At QualitasGlobus, we offer a wide range of BE study services, including method development and validation, in vitro/in vivo correlation studies, and statistical analysis. We also offer a range of other services, such as pharmacokinetic modeling and PK/PD modeling.

#### SEPARATION AND PURIFICATION SERVICE

Separation and purification services are essential for the isolation and purification of drugs and their metabolites. These services are important for both research and clinical applications.

At QualitasGlobus, we offer a comprehensive range of separation and purification services, including HPLC, TLC, and other separation methods. We also offer a range of other services, such as method development and validation, and sample preparation.



### ANALYTICAL METHOD DEVELOPMENT AND VALIDATION

Analytical method development and validation are essential for the accurate and precise measurement of drugs and their metabolites. These services are important for both research and clinical applications.

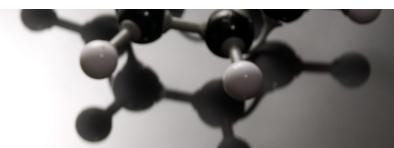
We offer a comprehensive range of analytical services, including method development and validation, chromatography, mass spectrometry, and other analytical methods. We also offer a range of other services, such as sample preparation and data analysis.

#### **IMPURITY TESTING SERVICES**

QualitasGlobus's impurity testing services can be used to detect degradation products formed during the storage or processing of drugs, as well as impurities present in raw materials or formulations. These services are essential for both research and quality control applications.

We offer a range of impurity testing services, including HPLC, TLC, and other analytical methods. Our services help you to ensure the quality of your drugs and help you to meet regulatory requirements.





#### STABILITY TESTING SERVICES

Stability testing is conducted to assess the shelf life of a drug. These studies are essential for understanding how a drug will degrade over time and how this affects its therapeutic effect.

QualitasGlobus offers stability testing services for small molecules, biopharmaceuticals, medical devices, cosmetics, food products, etc. We can test your products under various storage conditions, including accelerated stability testing (AST) and real-time stability testing (RST).

#### **OUT-OF-SPECIFICATIONS INVESTIGATION**

An out-of-specification (OOS) result is a result that does not meet the specification for a given parameter. These results can be caused by many factors, including errors in the manufacturing process, analysis, or storage conditions.

OOS investigations are conducted to determine the cause of an OOS result and to prevent future OOS results. QualitasGlobus offers OOS investigation services for small molecules, biopharmaceuticals, medical devices, cosmetics, food products, etc.

If your product fails an assay test or exhibits any out-ofspecification (OOS) results during manufacturing or QC testing, we can help you troubleshoot the problem. Our team has extensive experience in root cause analysis (RCA) and OOS investigation.



#### **GET A QUOTE TODAY!**

QualitasGlobus offers a wide range of analytical services for the pharmaceutical industry. Our services are designed to help our clients develop and manufacture safe, effective, and high-quality drugs.

Contact us today to learn more about our services or to request a quote!



# GUIDED BY PRINCIPLES, DRIVEN BY QUALITY

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