More than 25 years of experience in therapeutic drug analysis/management

MC.COMAC MEDICAL
EARLY PHASE CLINICAL DEVELOPMENT

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SERVICES OVERVIEW

- Bioanalytical Services
- Safety assessment
- Clinical Development
- Clinical Testing
- Pharmaceutical analytics
- Clinical trial supplies
- Research
- Consulting
- Statistics and Informatics

Contact

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LABORATORY SERVICES

Bioanalytics (LC-MS/MS)
Pharmaceutical Analytics
Clinical Trial Supplies

www.comac-medical.com

WHO ARE WE

Founded in 1997 Comac Medical is full-service Contract Research Organization (CRO), specializing in Phase I/IIa clinical trials. Having completed a number of successful research projects, we provide versatile services and outstanding results based on our many years of experience and motivation for progress.

BIOANALYTICAL SERVICES

Our skilled bioanalytical experts will help you overcome regulatory challenges and guide you through the process of reaching your goals. Using our strategic solutions we can solve time-consuming queries and lead you to success. Our services include:

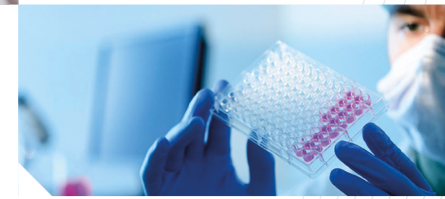
- Phase I/IIa and BA/BE clinical research development
- UPLC-MS/MS Waters Acquity Xevo TQS technology assays
- Method development, validation and transfer according to the latest regulatory trends (EMA and FDA)
- GLP/GCP compliance
- Drug Metabolism and Pharmacokinetics (DMPK) Studies
- Bioanalysis, including:
  - Small and large molecules
  - Biomarkers
  - Endogenous compounds
  - Concomitant medications
  - Ligand binding assays
  - Drug-Drug interactions
  - Matrix interferences
  - Bioequivalence
  - Bioavailability

CASE STUDY

Small molecule analysis with identification of metabolic interference during validation

Objectives:

To identify the cause of metabolic interference and to overcome its influence on the target molecule during validation and analysis processes.



Challenge:

To predict the behavior of the metabolite and its influence on the target molecule by series of experiments, considering the lack of studies performed and reported in the literature about the latter so far.

Solutions:

- To confirm the presence of metabolic interference according to known standards and regulations
- To develop a strategy for the performance of the necessary series of experiments
- To complete the research important for the evaluation of potential interfering agents
- To evaluate the percentage difference of metabolite to analyte transformation.

Outcome:

Results show that no significant interference is present that could possibly affect the validation and analysis outcome. Overall process met the timeline of 3 working days.