Company Profile

BIOMETRIK RISET INDONESIA

INDEPENDENT, RELIABLE, ACCURATE

OPENING SPEECH

Assalaamu'alaikum Warahmatullahi Wabarakatuh

In line with the development of science that supports the development of various sectors of the pharmaceutical industry, Biometrik Riset Indonesia is here to continue to synergize to serve the needs of Bioequivalence Test and Clinical Research. Bioequivalence studies are very beneficial for the pharmaceutical industry and the wider community, in general, to ensure the therapeutic equivalence of the copy drug to the innovator drug, therefore Biometrik Riset Indonesia is always committed to being a reliable and affordable laboratory with validity and high quality of the test results in accordance with national and international regulations.

With complete facilities, adequate resources, competitive prices, accurate results, and supported by sophisticated laboratory instruments, Biometrik Riset Indonesia is a trusted choice. Bioequivalence services at Biometrik Riset Indonesia are carried out in accordance with Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and ISO 17025 compliance. Our facilities have been audited by BPOM and the National Accreditation Committee (KAN).
Finally, we are ready to cooperate with the entire pharmaceutical industry and related sectors in the field of bioequivalence testing and clinical research, both private and government.

Wassalaamu'alaikum Warahmatullahi Wabarakatuh

apt. Dra. Effi Setiawati, M.M., M.Biomed.
Operation Director

CONTENTS

CONTACT AND FIND US

ADDRESS
Ruko Brickhouse Jl. Raya Bogor Km 31, No.52 Unit G, H, dan I, Kelurahan Cisalak, Kecamatan Sukmajaya, Depok, Jawa Barat, 16416

PHONE NUMBER
(+62) 2187731563

EMAIL AND WEBSITE
marketing@biometrikriset.com
www.biometrikriset.com

WORKING DAYS / HOURS
Mon - Fri 07.30 - 16.30 / Sat & Sun - Closed

WHAT BUSINESS ARE WE IN

WE ARE A CONTRACT RESEARCH ORGANIZATION ON BA/BE STUDIES

OUR VISION

To become independent **World Class Contract Research Organization**, emphasizing on Clinical Trial & Bioequivalence studies. Also recognized by local & international customer

OUR MISSION

To conduct reliable, rapid and high quality research services on bioequivalence studies with conformance to current national and/or international standards and guidelines

OUR VALUES

- Independency
- Professionalism
- Confidentiality
- Efficient
- Commitment to the quality and ethical conduct

OUR SERVICES

- **BIOAVAILABILITY / BIOEQUIVALENCE STUDIES**
- **CLINICAL RESEARCH**
- **BIO-ANALYTICAL STUDIES**
- **CHEMICAL ANALYSIS**

QUALITY & ETHICS STANDARDS

The International Conference on Harmonization (ICH) Harmonized Tripartite

Guideline for Clinical Practice (E6), November 2016.

World Medical Association Declaration Of Helsinki

Ethical Principles for Medical Research Involving Human Subjects, 2018.

Guideline on Bioanalytical Method Validation

European Medicines Agency, 2011.

Guidance for organizations performing in vivo bioequivalence studies

WHO Technical Report Series No. 996, 2016

ISO/IEC 17025

2017 - General requirements for the competence of testing and calibration laboratories

ASEAN Guideline

For Bioequivalence Study, 2015

Pedoman Uji Bioekivalensi

Badan Pengawas Obat dan Makanan 2015.

Guideline for Good Clinical Practice in Indonesia

Badan Pengawas Obat dan Makanan, 2001

OUR TEAM

BIOEQUIVALENCE STUDY TEAM

Clinical Site
- Principal Investigator
- Responsible Physician
- Pharmacist
- Phlebotomist
- Nurse
- Protocol Development & Data Management Team

Analytical Site
- Bioanalytical Manager
- Analyst
- Maintenance Technician

QUALITY ASSURANCE

To ensure the compliance of the study based on good clinical practices (GCP) and good laboratory practice (GLP)

CLINICAL ROOM AND FACILITIES

Briefing Room

Informed Consent Room

Doctor Room

Electrocardiogram Room

Dosing and Sampling Room

Subject Room

LABORATORY ROOM AND FACILITIES

PREPARATION ROOM

INSTRUMENT ROOM

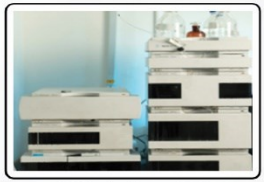
LABORATORY INSTRUMENTS & EQUIPMENT

LCMS-MS TQS Micro I Class

LCMS-MS Quattro Micro

LCMS-MS TQS Micro H Class

LCMS-MS TQS Micro H Class

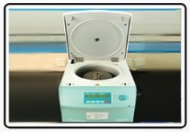


HPLC Agilent 1200

Flammable Cabinet

Freezer -80 °C

Analytical Balance



Centrifuge

Fume Hood

Reagent Storage

CLINICAL ACTIVITIES

Registration

Briefing, and Signing of Informed Consent

Screening (BMI, Vital Sign Monitor, EKG, Blood and Urine Sampling

Dosing

Blood Sampling

Biological Sample Handover to The Laboratory

LABORATORY ACTIVITIES

Study of Literature

Sample Preparation 1

Sample Preparation 2

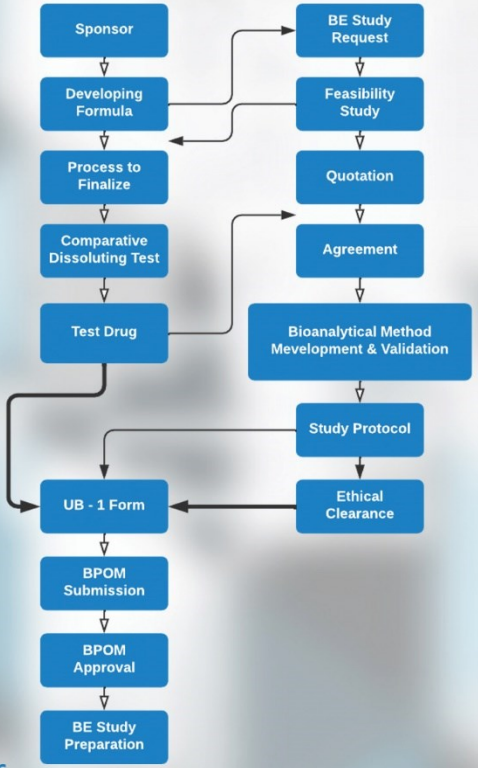
Sample Extraction

Sample Injection

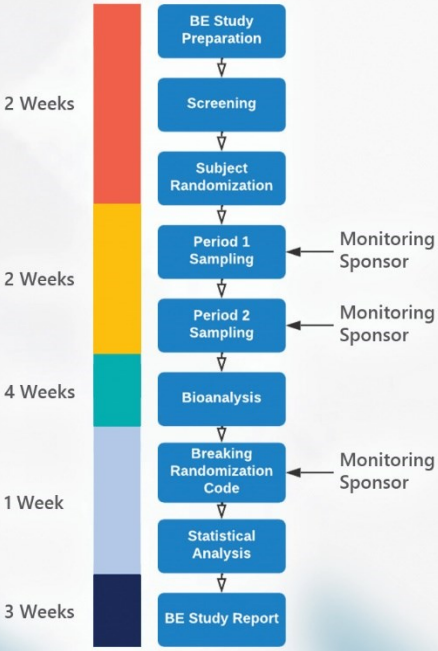
Data Processing

STUDY FLOWCHART

PRE STUDY



STUDY



Total: 12 Weeks / 3 Months

THANK YOU