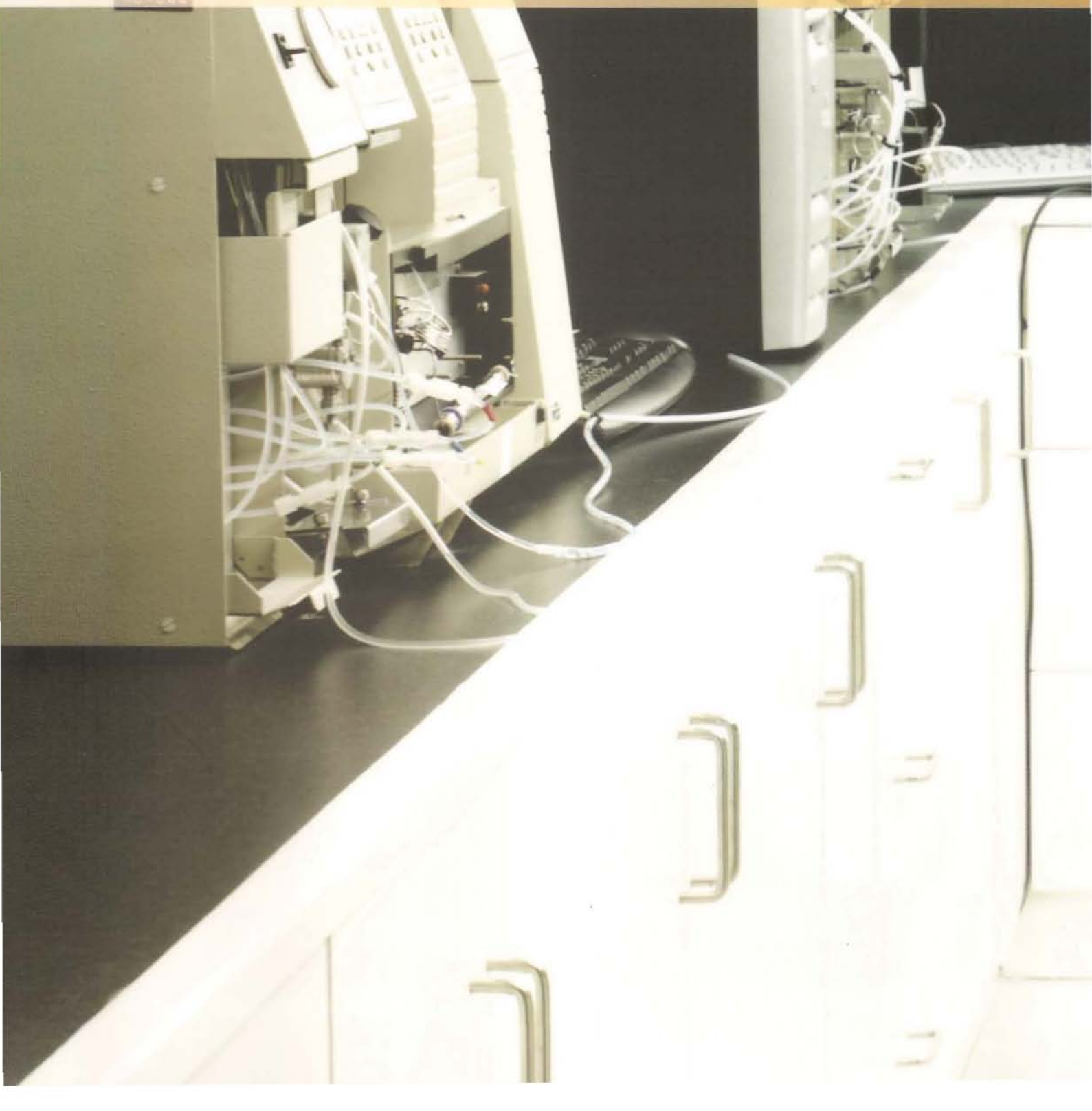
MEDICA INNOVA

*"Your trusted partner for **success**"*

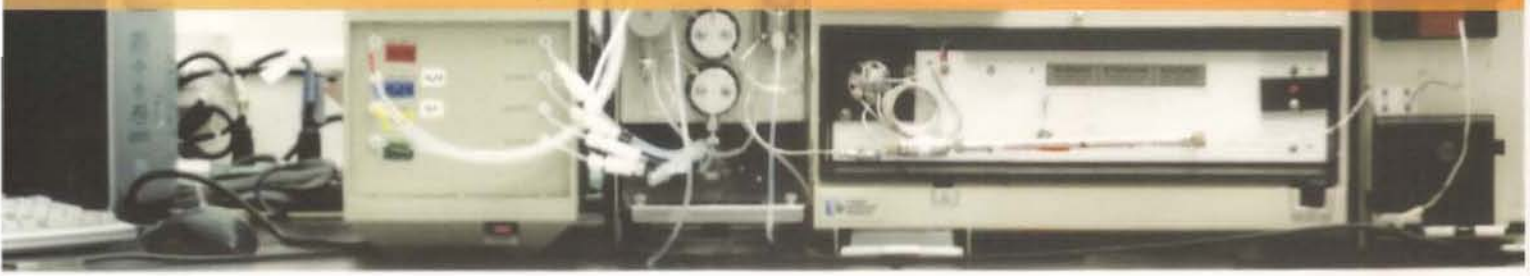
THE FIRST OECD GLP Recognition Private Company in Thailand

MEDICA INNOVA is the first independent Thai own "Contract Research Organization" providing services to Thai and International pharmaceutical industries in pharmaceutical product development, pharmaceutical product testing, and clinical research especially in bioavailability/ bioequivalence studies. Located in the heart of Bangkok business area, Thailand, our 3-stories laboratory has integrated pharmaceutical product development,



analytical and bioanalytical department. Our facilities are managed to meet the regulatory requirement.

Medica Innova commits to provide accurate, reliable, timely and cost-effective services to customers supporting by our professionals and technical experts along with our state-of-the-art pharmaceutical production equipments, analytical and bioanalytical laboratories



Vision:

To be Trusted and Recognized by Our Clients as an Innovator in the Development of Novel Drugs and to Accelerate our Clients' Molecules to Market Efficiently.

Missions:

- To provide clients with the highest-quality drug development services and expertise in clinical research
- To choose the right formulation for the right molecule
- To assist the pharmaceutical industry in developing drugs and to aid the community in gaining access to generic products that have comparable safety, efficacy and quality to the innovator products
- To provide an efficient alternative research site allowing you to bring your new drug product to market first
- To provide the greatest precision and accuracy in both analytical and bioanalytical services
- To employ the newest technologies and most up-to-date guidelines
- To build and maintain a proven track record for development process
- To provide comprehensive design, conduct, and interpretation in accordance with regulations and client needs
- To provide cost effectiveness and precise timelines in clinical services

Values:

Validity

Medica Innova adheres to proven work processes to validate all data produced.

Flexibility

Medica Innova values team-based professionalism while remaining flexible in responding to customers.

Quality

Medica Innova is committed to the word "Quality". We dedicate ourselves to continuously meeting the highest Quality standards in all aspects of our products and processes in order to satisfy the customers, patients, and regulators.

Trustworthy

Medica Innova maintains honesty in all aspects of our business. We take responsibility for all decisions we make and all actions we take.

Teamwork

Medica Innova emphasizes "WE", not "I". We work together to pursue excellence. We share knowledge and information freely, and we continuously treat others with respect and dignity

Services:

Pharmaceutical Product Development and Testing
Overview

The Pharmaceutical Product Development Department mainly emphasizes the satisfaction of client needs with the high quality of the marketed pharmaceutical products. We focus on not only the research and development of various non-sterile pharmaceutical products, but also the analytical methods by our expertise team. Moreover, we provide other services which are interpreted by qualified experts in specific fields.

For formulation development, the preformulation study and the prototype of formulation are provided according to the objective of client.

We offer a wide range of analytical services for all phases of drug development. The laboratory state of the art techniques, instruments and testing methods are utilized to provide the information of client needs for trouble-shooting, research and quality control.

We realize the importance of cost effective and on-time delivery project, while maintaining the highest quality.

Our Pharmaceutical Product Development and Testing services including:

I Preformulation:
- Solid-state characterization of drug substance
- Solubility profile/ pH- solubility profile
- Accelerated stability study of pharmaceutical substance and a wide variety of dosage form
- Drug/ Excipient/ Packaging component compatibility study including formulation compatibility study

II Formulation Development for Various Stages of Non-Sterile Pharmaceutical Products:
- Formulation for first time in man phase
- Formulation for industrial scale including process optimization

III Formulation Technology:
- Mixing and granulation
  - High shear mixer granulator
  - High efficiency drier
  - High efficiency mixer
- Tableting
  - Immediate release dosage form
  - Modified release dosage form
- Coating techniques
  - Delayed release dosage form
  - Taste and odor masking
  - Protective coating
- Capsule
- Semi-solid dosage form technology
- Transdermal technology

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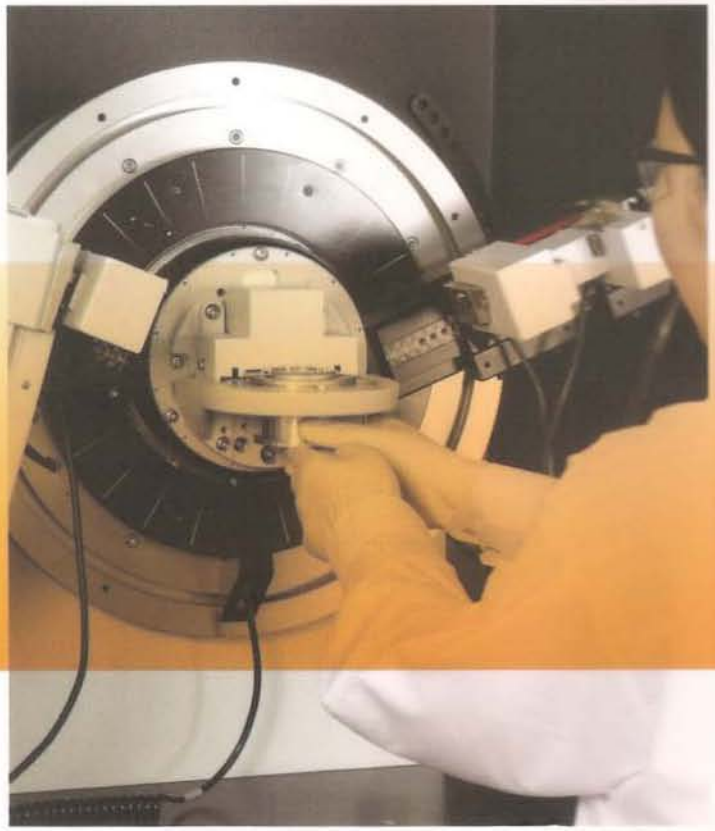


IV Analytical Services

- Sample testing
- Development and validation of analytical methods
- Drug-release profiling
- Stability studies
- Preparation of documentation to support regulatory filing

Sample Testing

Many types of samples: including

- Raw Materials : active ingredients and other excipients
- Finished products : tablets, capsules, liquids and semi-solids
- In-process products : bulk mixtures of solids or liquids prior to filling into capsules, bottles or before compressing into tablets

Development and Validation of Analytical Methods

We carefully develop and validate analytical methods which are performed according to many qualified tests complied with international requirements and regulatory laws. Parameters are considered including Linearity, Precision, Accuracy, Selectivity, LOD, LOQ, Ruggedness and Robustness

Drug-Release Profiling

With USP apparatus, we provide release profile data of drug in various dosage forms.

Stability Studies

Stability is seriously monitored according to guideline which samples are stored at controlled well-defined specific or customized conditions. The stability studies are monitored in accelerated, long-term and stressed (force degradation) conditions.

Medica Innova maintains **honesty** in all aspects of our business. We take **responsibility** for all decisions we make and all actions we take.

Clinical Research
Overview

We, clinical research development team in Medica Innova, have broad knowledge and experiences in clinical research from clinical trial design (Phase I-III), interpretation and execution to the preparation and submission of data to regulatory in Asian countries. We effectively manage studies from nonclinical to Phase I, IIa/IIb, III to assure fast decisions about the safety and efficacy of drugs.

We work in compliance with ICH-Good Clinical Practice (ICH-GCP) to ensure the clinical data and reported results are credible and accurate, and subject's right, integrity and confidentiality are protected.

Collectivity, our familiarity to regulatory and ethical environments in Thailand and countries across ASEAN benefits in shorten the start-up time for your clinical studies. We comprise of in-depth experienced staff bringing their expertise to handle your projects from site selection to study commencing, form clinical monitoring to study closing. Reliability and flexibility is the culture of working with our clients. We provide qualified study monitors to clinical trials at any stages of drug development process through post marketing studies.

In bioanalysis, we value your projects with Comprehensive, Innovative and OECD-GLP certified Bio-analytical Assays. All development and validation work is performed according to the most recent FDA guidelines. We develop the assay methods in the sensitivities range of pg/ml. Our 1,800 square meters laboratory equipped with state-of-the-art analytical instrumentation.

Clinical Pharmacology Services

1. Provide scientific input for clinical protocols and clinical development plans to achieve regulatory and scientific objectives

2. Provide expertise and clinical input to clinical trails from (Phase I-III):
    - Bioavailability and Bioequivalence Studies
    - Dose Escalation, First-in-Human and Food Effect Studies
    - Drug-Drug Interaction Studies
    - Special Population Studies; Hepatic and Renal Impairment Studies
    - Efficacy/Proof of Concept Studies (Phase I-III)

3. Provide advanced interpretations of clinical pharmacology and safety data (Phase I-III) for quick decision making with in-house pharmacokineticists/ pharmacometricians and be able to incorporate any data analyses into study reports required for regulatory

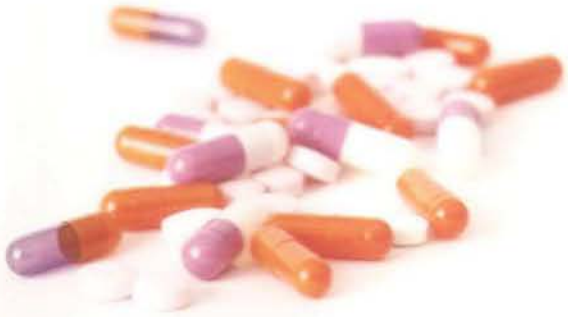
4. Expertise in clinical pharmacology data analysis including:

- Bioequivalence Analysis (Noncompartmental analysis, Statistical Analysis, Sample Size and Power Calculation)
- PK and PK/PD Analysis
- PopPK and PopPK/PD Analysis
- Clinical Trials Simulations
- Data Exploratory

5. Provide all scientific input to regulatory agencies on behalf of clients for successful drug approval

6. Ensure quality of all scientific documents:

- Regulatory Submissions
- Clinical Study Reports
- Clinical Study Protocols
- Manuscripts for Publication
- Abstracts, Posters, and Presentations



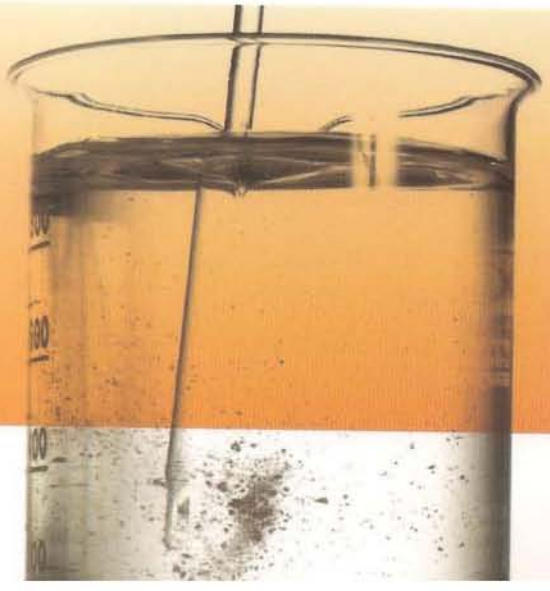
Bioanalytical Services

- Development & Validation of New Assays
- Method transfer
- Receive and analyse bio-samples for drug concentrations worldwide
- Long term storage for bio-samples
- Storage drug products at specific temperature and humidity
- Continuous computer monitoring for all storage locations
- Format data to meet customer reporting needs

Clinical Monitoring Services

- Pre-study & initiation visits
- Monitoring visits
- Close out visits
- Management tasks

Medica Innova adheres to proven work processes to **validate** all data produceds.



- Pharmaceutical Product / Drug Delivery System Development
- Clinical Study Design and Data Analysis
- Bioequivalence / Bioavailability
- Clinical Monitoring
- Clinical Project Management

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