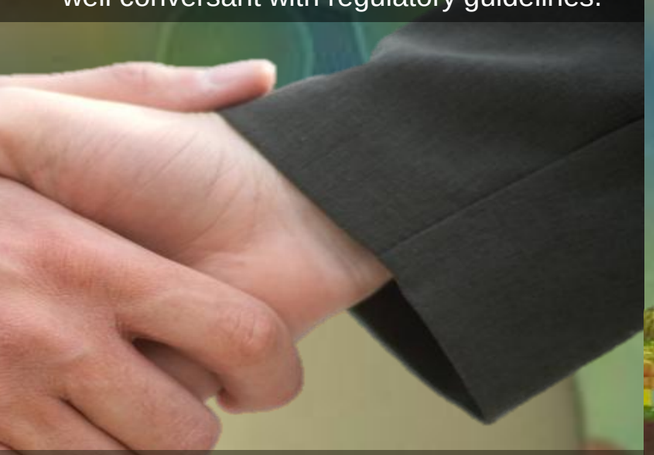
BIOAVAILABILITY & BIOEQUIVALENCE:

- Bioavailability is the fraction of unchanged drug reaching systemic circulation after administration by any route. When a drug is administered intravenously then its bioavailability is 100% but it may be less when it is given orally or by other routes.
- Two pharmaceutical products are bioequivalent when their bioavailability in the same molar dose is similar in efficacy and safety.

STUDY TEAM:

- IPER team is experienced and well-trained in ICH GCP and GLP guidelines. The team includes physicians, phlebotomists, scientists, Statisticians and programmers well conversant with regulatory guidelines.



SERVICES:

- Regulatory consulting
- Protocol design
- Ethics committee submission
- Volunteer recruitment
- Clinical study management
- Method development and validation
- Bio analytical testing
- PK analysis
- Statistical analysis
- Report writing
- Sample storage
- Archiving

VISION & MISSION:

With the forward looking vision and mission of the Vice Chancellor Prof. Dr. Masood Hameed Khan of DUHS, the Institute of Pharmaceutical & Environmental Research (IPER) is conducting BA/BE studies of drugs under the director Prof. Dr. Syed Khaqan Hasan Ph.D) with vast background of national and international experience

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Institute of Pharmaceutical & Environmental Research (IPER)

A reliable, multidimensional, independent research organization of Pakistan at

DOW UNIVERSITY OF HEALTH SCIENCES

Bioavailability & Bioequivalence Study Center

NEED:

Dow University of Health Sciences (DUHS) has fulfilled the need for facilities to study BA/BE of drugs due to the following requirements in Pakistan.

- Pakistan exports drugs worth US $ 200 million per year and these exports may increase further by carrying out BA/BE studies within the country saving also in the expenditure in foreign exchange for these studies abroad by Pakistani pharmaceutical companies.
- Drugs worth US $ 85 billion would become off patented during this year becoming Generic and creating huge market for BA/BE studies and Pakistan could get a good share of this business.
- World Health Organization (WHO) requires BA/BE studies for procurement of medical products
- Health Regulatory Authorities also need these facilities for registration and checking quality of drugs within Pakistan

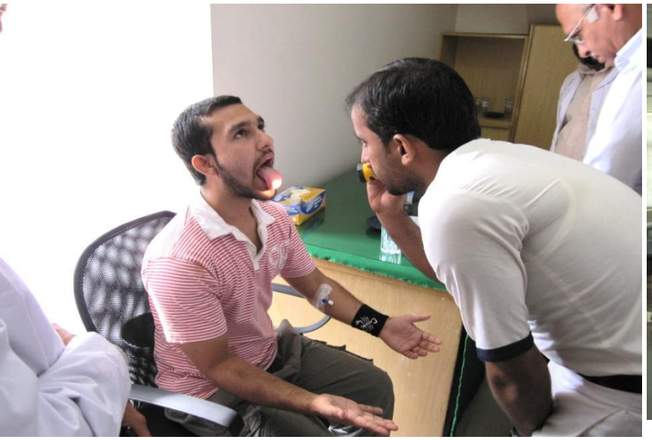
OBJECTIVE:

- To provide services for Bioavailability/Bioequivalence (BA/BE) of all pharmaceutical products, oral, injectable, single, double and triple dose
- Particularly cost effective drug development, drug testing, BA/BE studies (IRB/EC approved, ICH/GCP compliant quality controlled and quality assured studies)

Bioavailability & Bioequivalence Study Center

PROCEDURE

Both laboratory (in vitro) and in body (in vivo) studies are done to determine bioequivalence between two brands of a drug. In vitro studies are conducted according to standard procedures (B.P., U.S.P. etc.) while in vivo studies are done by administration of both (test and reference) formulations, each as a single dose, to normal healthy volunteers in an open labeled cross over procedure with randomization for treatment sequence and allowance for adequate washes between the two doses under strict regulations and monitoring.



VOLUNTEER RECRUITMENT

We have a database of volunteers including both genders,.
Recruitment is continuous for the volunteer pool in CESR (Clinical Eligible Subject Recruitment), a data base.

TERTIARY CARE HOSPITAL

A 500 bed hospital is located at close proximity of VHCF.

BIOANALYTICAL LABORATORY

The blood samples are collected from the volunteers at various intervals for a specific period after each dose and the plasma is separated from the samples in a refrigerated centrifuge. The samples are stored in minus 20 degree refrigerator for short periods before drug analysis and in minus 80 degree refrigerator for longer periods.
The resulting PK data and associated statistical analysis are examined according to a set of predetermined criteria to check bioequivalence. As the drug in blood samples is present in very small quantity, therefore, very sensitive techniques like High Performance Liquid Chromatography (HPLC) are used. A whole range of needed equipment for BA/BE and drug analysis is available in this laboratory.

VOLUNTEER HEALTH CARE FACILITY

This facility could house 26 volunteers in 13 double bed , spacious rooms with attached toilets under the supervision of medical doctors as Clinical Research Coordinators and other delegated study staff.

UNIQUE ONE WINDOW SERVICES

The BA/BE facilities are unique in Pakistan as these are located in a medical university which can provide one window services of international standards at DUHS.

FACILITIES

Following facilities at DUHS have been created according to international guidelines and regulations (ICH, Helsinki Declaration, WHO, GCP, GLP).

- Volunteer Recruitment Department
- Screening Area
- Diagnostic Laboratory
- Clinic Area (Volunteer Health Care Facility)
- Bio-analytical Laboratory
- Hospital

SCREENING AREA

At least three fold number of subjects need to be screened for each subject size of the study.
Screening Area consists of waiting area for 50 volunteers, room for three screening coordinators and a room for research nurses to conduct screening procedures.

DIAGNOSTIC LABORATORY

These facilities at DUHS are available at Dow Diagnostic Reference and Research Laboratory (DDRRL) and Radiology Department.

The state-of-the-art equipment for diagnostic tests are available in its chemical pathology, histopathology, hematology, microbiology and molecular pathology sections.

Institute of Pharmaceutical and Environmental Research, Dow University of Health Sciences