

About us:

Pharmaceutical services center (PSC) - Faculty of pharmacy- Tanta university was established in 6/4/1996 by a decision of Supreme Council of University (SCU) and accredited by Ministry of Health and Population in August 1998 for performing bioavailability/bioequivalence studies (PSC was re-accredited by Ministry of Health and Population in April 2008). PSC center had the certificate of ISO 9001-2000 by the American ASR company in January 2002 and re-certificated with ISO 9001-2008. PSC is seeking for international accreditation in performing in-vitro dissolution studied via ISO 17025:2005.

PSC has expanded the scope of work and was accredited by Ministry of Health and Population in performing accelerated stability studies in April 2012.

Mission:

- Presents pharmaceutical services in the field of pharmacy, national and international drug registration.
- Performs medical researchers to solve realistic problems facing productive activities in different social fields related to pharmacy and medical care.
- Shares in training of pharmacist and other workers in the field of pharmacy in dealing with new scientific ways to increase their productive potencies in different fields.

Vision:

To be one of the best centers in the field of pharmaceutical researches and pharmaceutical industries nationally and internationally.

Code of ethics:

The ethical committee of Tanta University Hospital formed from medical and non- medical members. The ethical committee follows Guidelines regarding participation, drug administration and sample collection which meet the requirements of the declaration of Helsinki. Ethical committee approves the study protocol and the written consent form by volunteers.

Organizational Chart:

Ethical Committee Members:

1.Prof. Mamdoh Gabr.

Professor of internal medicine, faculty of medicine, university of Tanta.

2.Prof. Basma Morad .

Professor of dermatology, faculty of medicine, university of Tanta.

3.Prof. Moussa Alnagar.

Professor of internal medicine, faculty of medicine, university of Tanta.

4.Prof. Nageh Elmahdy.

Head of pharmacology and toxicology department, faculty of pharmacy, university of Tanta.

5.Dr. Mostafa Bahgat.

Manager of Bahgat pharmacies, Tanta

6.Mr. Zakareya Abd Elkawy Ghonim

Manager of legal affairs, faculty of pharmacy, university of Tanta.

Services Performed By PSC:

1. Bioequivalence Studies

PSC center Perform Bioavailability and bioequivalence studies for Egyptian, Arabic and foreign pharmaceutical companies as a requirement of drug registration or drug exporting by measuring of drug concentration in biological fluids and calculation of drug pharmacokinetics in healthy volunteers.

2. Comparative Dissolution Studies

PSC center Performs comparative dissolution studies as a requirement of Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System.

3. Accelerated and long term Stability Studies

PSC center Performs Long term and accelerated (intermediate) stability studies to confirm the shelf life of a finished pharmaceutical products.

4. Expert Reports

PSC center perform clinical, non clinical, pharmacological and toxicological reports of pharmaceutical products.

5. Consultation

PSC center participate in solving formulation problems related to pharmaceutical formulations concerning safety and efficacy aspects.

Performing quality control tests for pharmaceutical, cosmetics and veterinary preparation

6. Training

PSC center participate in training sub-graduate students from Egypt and other countries. PSC allows sub-graduate students to be familiar with quality control instruments, concept of bioequivalence studies,etc.

PSC Labs:

Clinical Unit:

The clinic area is about 500m², in order to be sure of comfortable accommodation of about 24 volunteers. It consists of medical examination room, for complete physical examination of volunteers and measuring of vital signs before and during the study. Plasma samples collection area is well equipped with centrifuge, deep freezers in addition to -80°C deep freezer for better preservation of blood samples (prevent degradation of active ingredients by action of natural enzyme in biological samples). Sample collection room is fully equipped with the required first aid drugs and equipments (oxygen cylinder-Retinoscope).

The clinic is furnished with 24 beds. An emergency room was prepared in order to be ready for any unexpected adverse drug interactions or accidents.

In addition to separate area for medical supervisor in case of studies which extended over 24 hours. The clinic is also well furnished with accommodation services, air conditions and entertainments in order to be sure of complete comfort of volunteers.



Clinic reception



Rooms for volunteers





Deepfreeze -80°C



Pharmacy



Laboratory Store



Instrumentation labs:

HPLC unit:

Contains UPLC instruments equipped with UV-visible spectrophotometer and fluorescence detector used for drug analysis in biological fluids and dosage forms.



Ultra Performance Liquid Chromatography (UPLC)

A sensitive and versatile analytical technique, used for separation, identification as well as quantification of compounds. The UPLC provides better peak separation with little solvent consumption and time saving in comparison to traditional HPLC.

It is used for analysis of drugs in plasma, urine and aqueous media

Quality Control Unit:

The quality control unit is well equipped with the instruments required for quality control tests of pharmaceutical dosage forms. All equipments are maintained according to annual maintenance plan. Every equipment has its own Standard Operation Procedures



1-Dissolution Apparatus



Fully programmed dissolution apparatus
Contains eight 1 liter cups and equipped
with auto sampler to save time and improve
performance

2-UV-Visible Spectrophotometer 3-Hardness apparatus



It is used for analysis of samples by measuring the absorbance in both UV and visible regions



It is used to evaluate the hardness of tablet as a quality control requirement

4-Moisture balance

It is used for evaluation of moisture content in solid dosage forms

5-Cooling Centrifuge

Cooling centrifuge is an effective tool for drug extraction from complicated matrix such as plasma

6-pH Meter

It is used for determination of pH of aqueous solutions such as mobile phases of HPLC/UPLC and pH of aqueous dosage forms

7-Viscometer

It is used for determination of the viscosity and Rheology of semi solid and liquid dosage forms to check for the compliance with the regulatory authorities.

8-Digital Balance

A sensitive four digit digital balance

9-Friability Tester

It is used for determination of tablet friability

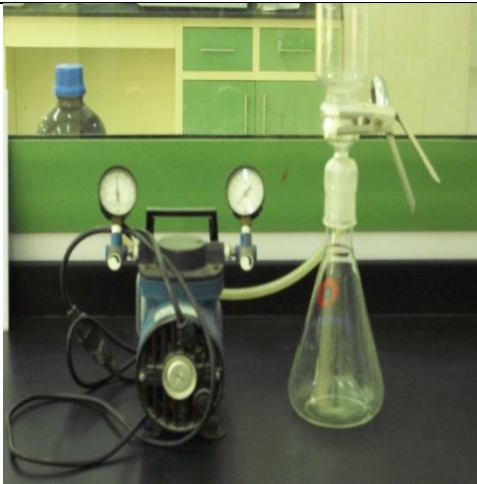

10-Sample concentrator



It is used to evaporate samples under nitrogen

11-Water bath

It is used for sample evaporation

12-Milipore filtration pump**13-Sonicator**

	
<p>It is used for filtration of aqueous media and HPLC mobile phases</p>	<p>It is used for degassing mobile phase</p>

<p>14-Water distillatory</p>	<p>15-Water de-ionizer</p>
	
<p>Two phases water distillatory used for preparing pure water suitable for analytical purpose</p>	<p>Used to prepare de-ionized water used for preparing pure water suitable for analytical purpose</p>

PSC was accredited in performing accelerated and long term stability studies in April 2012



Stability cabinet

It is used to achieve the required humidity and temperature levels in conducting stability studies on pharmaceutical products according to the latest ICH guidelines

Activities of PSC Center

Research Activities:

- Performance of bioequivalence studies of many pharmaceutical products for national and international pharmaceutical companies according to international guidelines.
- Proposal of scientific ways required to drug analysis of many products of pharmaceutical companies.
- Writing of expert reports for more than 200 product of pharmaceutical companies for clinical, non clinical, pharmacological and toxicological studies

Training Activities:

PSC participate in training more than 50 sub-graduate students from Egypt and other countries under the umbrella of cultural exchange programs presented by Tanta university.