The Essential Role of Measurement in Research and Development and safety of Pharmaceutical and Cosmetic Products

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The Government Pharmaceutical Organization (GPO), a state enterprise under the Ministry of Public Health by the Government Pharmaceutical Act, AD 1966 signed by Her Royal Highness Princess Srinagarindra, The Princess Mother.

GPO VISION

“To be a leader in pharmaceutical products and medical supply business sustainably beneficial and essential to the Thai and ASEAN community”

GPO Mandate

1. To produce and procure essential drugs and medical supplies with an aim to achieve world-class standard.
2. To stabilize drug price to ensure people's accessibility
3. To reserve drugs and medical supplies for national security.

GPO Rama VI Manufacturing Plant

Production capacity: 5 billion tablets/capsules

Rangsit 1 Manufacturing Plant

Rangsit Manufacturing Plant

Rangsit 1 Manufacturing Plant
Production capacity: 3.4 billion tablets/capsules

Rangsit 2 Manufacturing Plant
Production capacity: 6.0 billion tablets/capsules

Essentials of generic drugs

Cost reduction

30 - 60% less than original drug products

Impact on reduction of original drug's price and economics of health care industry

Increase accessibility extensively and improve quality of life

*Source: The generic imperative. Geriatr Nurs. 2008;29:223-226

Steps of generic drug research and development

Steps of generic drug research and development

1. Design of the product
2. Formulation development
3. Specification Setting as per Pharmacopeia
4. Bioequivalence study
5. Drug Registration
6. Productions of Commercial batches

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Quality must come first

The Essential Role of Measurement

- Measurement is a fundamental element of all standards.
- GPO has realized the importance of measurement standards and applied standardized measurements to all critical steps starting from research and development to routine production.

Quality Control of Raw Material

Particle size Analyzer

Identification by
Fourier Transform
Infrared Spectrometer
(FTIR)

In Process Control

Tablet Friability Analyser

Disintegration Tester

Quality Control of Finished Product

Dissolution tester

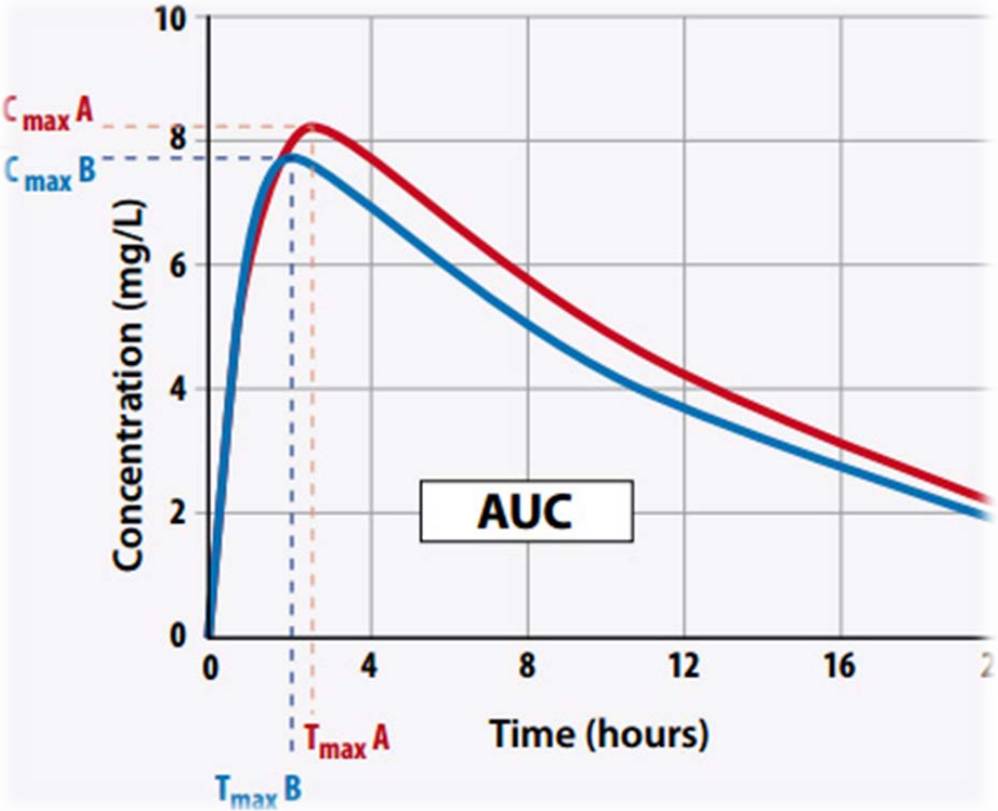
High Performance Liquid Chromatography (HPLC)

Bioequivalence Study

- To demonstrate equivalence in biopharmaceutics quality between generic and reference product.
- To evaluate bioavailabilities (rate and extent) after administration.
- To ensure comparable *in vivo* performance, i.e. similarity in terms of safety and efficacy.

Bioequivalence studies

- The plasma concentration time curve is generally used to assess the rate and extent of absorption.



Good Manufacturing Practice (GMP)

- GPO has received the certification for Good Manufacturing Practice (GMP) from the Food and Drug Administration.

Standardized measurements

- Standardized measurements including specific procedures and well calibrated measuring equipment with acceptable accuracy and precision are applied in all essential steps of research and development processes to obtain appropriate specification of a designed quality and safety product.

An example of essential of measurement on product quality

Package Seal Leaking

An example of essential of measurement on product quality

An inconsistency of temperature at different positions of the stripped pack roller was the cause of package seal leaking.

Equipment/Instrument to be calibrated

Calibration of > 10,000 equipment/instrument covered all activities is required.

Continuous Improvement on Quality

GPO has been accredited complying with ISO/IEC 17025: 2005 by Thai Laboratory Accreditation Scheme, Thai Industrial Standard Institute, Ministry of Industry as following scopes;

1. Thermo-hygrometer
2. Micropipette
3. Burette
4. Cylinder
5. Volumetric pipette
6. Volumetric flask
7. Graduated pipette
8. Electronic balance
9. Autoclave
10. Liquid bath
11. Temperature controlled enclosure

Continuous Improvement on Quality

GPO has been accredited as laboratories complying with ISO/IEC 17025: 2005 by Bureau of Laboratory Quality Standards, Ministry of Public Health as following scopes;

1. Dicloxacillin sodium working standard
2. Norfloxacin working standard
3. Atenolol Tablets
4. Curcuminoids content in curcuminiods capsules
5. Capsaicinoids content in dried capsicum fruit

Continuous Improvement on Quality

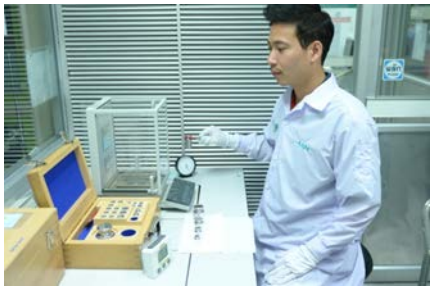
- Bioequivalence studies have been performed by GPO Bioequivalence Center which has been accomplished regulatory inspections of Good Laboratory Practice (GLP) compliance test facility by Department of Medical Sciences, ministry of Public Health

Collaboration with National Institute of Metrology

- GPO has a collaboration with National Institute of Metrology on study and verification on calibration of hardness tester for tablets and packaging.

Next Collaboration with National Institute of Metrology

- The Preparation on standard procedures of Operation Qualification/Performance Verification (OQ/PV) of High Pressure Liquid Chromatography (HPLC)



Reliable measurements play an important role in building customer's confidence.

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Thank you for your attention