**PART I: INFORMED CONSENT FORM (ENGLISH VERSION)**

**Title of Study:** [Insert study title]
**Protocol No.:** [Insert Protocol Number]
**Sponsor:** [Insert Sponsor]
**Principal Investigator:** [Insert Name, Contact Details]
**Site:** University of Santo Tomas Hospital

**Introduction**

You are being invited to participate in a research study called a **Bioavailability and Bioequivalence (BA/BE) Study**. Before you decide, it is important that you understand why the research is being done and what your participation will involve. Please read this form carefully and ask questions if anything is unclear.

**Purpose of the Study**

The purpose of this study is to compare how your body absorbs, distributes, and eliminates [study drug] compared with [reference drug]. This will help determine whether the two drugs are bioequivalent.

**Procedures**

If you agree to take part, you will be asked to:

* Attend [number] clinic visits over [duration].
* Receive a single oral dose of either the test drug or the reference drug under fasting/fed conditions.
* Provide multiple blood samples over [time period] to measure drug levels in your blood.
* Abstain from alcohol, caffeine, and certain medications before and during the study as instructed.
* Remain at the study site during the sampling period and comply with dietary and activity restrictions.

**Risks and Discomforts**

* Possible side effects of the drug may include: [list known side effects, e.g., nausea, headache, dizziness].
* Blood sampling may cause temporary pain, bruising, or infection at the puncture site.
* Fasting may cause hunger, weakness, or dizziness.
* There may be unknown or unexpected risks.

**Benefits**

* There may be no direct medical benefit to you.
* The information from this study may help ensure the safety and quality of medicines used by others in the future.

**Confidentiality**

Your records will be kept confidential. You will be identified by a code number, not by name. Only the study team, the Research Ethics Committee (REC), the sponsor, and regulatory authorities may access your records for verification purposes.

**Compensation**

* You will receive compensation of [amount] for your time, inconvenience, and travel expenses.
* Medical care will be provided if you suffer from any study-related injury, at no cost to you.

**Voluntary Participation and Right to Withdraw**

Your participation is voluntary. You are free to withdraw at any time at any point during the study without questions or reason and without affecting your medical care/treatment.

**Contact Information**

If you have questions about this research study, you may contact:

**Name of Principal Investigator:**

**Study Site:**

**Email:**

**Contact No.:**

The UST Hospital - Research Ethics Committee has approved the study and may be reached thru the following contact for information regarding rights of study participants including grievances and complaints:

**Name of REC Head:** Dr. JOSEPHINE M. LUMITAO

**Address:** REC Office 6/F St. John Macias O.P. Bldg. (formerly Clinical Division Bldg.) University of Santo Tomas Hospital, España Blvd., 1015 Manila

**Email:** usthrec@gmail.com

**Tel:** +63 2 8731-3001 local 2610

**PART II: CERTIFICATE OF CONSENT**

**Protocol Title:**

**Principal Investigator:**

**Contact Details:**

**Participant Statement:**I voluntary consent to take part in this study. This study has been explained to me in a language that I understand. The purpose and procedures of this study have been fully discussed and understood by me. I have been given enough time to ask any questions that I have about the study, and all my questions have been answered.

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Name of Participant/ Signature Date

Legal Representative

**Witness Statement:**

I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.

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Name of Witness Signature Date

**Investigator Statement:**

I, the undersigned, certify that I explained the study to the participant. To the best of knowledge, the participant signing this informed consent form clearly understands the nature, risks and benefits of his/ her participation in the study.

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Name of Investigator/ Signature Date

Person obtaining the consent