Study Synopsis

Title	The bioequivalence study of gabapentin 300 mg capsule
Sponsor	The Government Pharmaceutical Organization
Clinical laboratory	Department of Pharmacology, Faculty of Medicine, Chulalongkorn University
Analytical laboratory	Chula Pharmacokinetic Research Center, Faculty of Medicine, Chulalongkorn University
EC approval	Ethic committee of the faculty of medicine, Chulalongkorn University
Principal investigator	Associate Professor Supeecha Wittayalertpanya, M.Sc. Department of Pharmacology, Faculty of Medicine, Chulalongkorn University
Co-investigator	Associate Professor Sumana Chumpootaweep, MD., MPH. Department of Pharmacology, Faculty of Medicine, Chulalongkorn University
Analytical investigator	Ms.Nantaporn Prompila, M.Sc. Chula Pharmacokinetic Research Center, Faculty of Medicine, Chulalongkorn University
Pharmacokinetic and/or statistical investigator	Mr.Wasan Punyasang, M.Sc. Clinical Epidemiology Unit, Faculty of Medicine, Chulalongkorn University
Objectives	To compare the bioavailability of new generic product of Gabapentin 300 mg capsule (Gabapentin GPO®, Government Pharmaceutical Organization) with the innovator product (Neurontin®, Pfizer Limited).
Study design	A randomized, two treatment, two-period, two sequence, single dose crossover design with one week-drug free interval between the periods in 26 healthy male subject
Test product	Gabapentin 300 mg capsule, Lot. S510449 Mfd. 19/12/08, Exp. 19/12/10 Manufactured by GPO, Thailand
Reference product	Neurontin® 300 mg capsule, Lot. 0003048 Mfd. 01/04/08, Exp. 01/03/11 Manufactured by Pfizer Inc., NY, USA

Study subjects	Twenty six healthy Thai male volunteers with aging between 18-45 years
Demographic data (n = 26)	Age: 25.08 ± 6.31 year Height: 1.72 ± 0.05 m. Weight: 64.82 ± 6.74 kg BMI: 22.07 ± 1.80 kg/m^2
Admission and confinement	Prior to all dosing events, subjects were fasted overnight at least 8 hours prior to study drug administration. On study day, a standardized light lunch was provided 4 hours post-dose.
Drug administration	One capsule (300 mg) gabapentin will be orally administered to all subjects with water (200 mL) in the fasted state during 2 separate periods.
Study period	Period I: 31 January 2009 – 1 February 2009 Period II: 14-15 February 2009
Washout period	7 days from the first drug administration
Safety assessment	All adverse events, physical examination, laboratory tests and vital signs were recorded and evaluated.
Blood sampling schedule	In each period, a total of 16 blood samples (7 mL each) were collected up to 32 hours post-dose. The total volume of blood draw was 224 mL for each subject.
Blood sampling handling	The blood samples were centrifuged at 3,200 g for 10 minutes.
Clinical sample storage	The resulting plasma was transferred into polypropylene tubes and stored at -70ºC until anaylsis.
Bioanalytical methodology	Gabapentin plasma concentration was assayed using a validated HPLC-UV method. The lower limit of quantification of gabapentin plasma concentration was 25 ng/mL.
Pharmacokinetic Parameters	Primary pharmacokinetic parameters (C_{max}, AUC_{0-t}, AUC_{0-inf}) and secondary pharmacokinetic parameters (T_{max}, k_{el}, $t_{1/2}$) will be determined from the plasma concentration data of analytes

Confidence Intervals	90% CI for geometric mean of test/reference ratio C_{max}: 85.35-99.10 AUC_{0-t}: 87.28-105.67 AUC_{0-inf} : 87.44-105.49
Conclusions	The peak and total systemic exposure of Gabapentin 300 mg were similar between the 2 formulations. The 90% confidence intervals for the test/reference ratio were 85.35-99.10% for C_{max}, 87.28-105.67 for AUC_{0-t} and 87.44-105.49 for AUC_{0-inf}. Since 90% confidence intervals for the parameters C_{max}, AUC_{0-t} and AUC_{0-inf} were within the bioequivalence range of 80-125%, it can be concluded that the gabapentin 300 mg capsule (Test formulation) is bioequivalent to Neurontin® 300 mg capsule (Reference formulation) under fasting condition.