2.STUDY SYNOPSIS

GENERIC NAME Clindamycin	SPONSOR'S NAME : GOVERNMENT PHARMACEUTICAL ORGANIZATION (GPO)
TEST PRODUCT Clindamycin GPO	
REFERENCE PRODUCT Dalacin C™	
STUDY TITLE :	Bioequivalence study of Clindamycin HCl 300 mg capsule in healthy Thai volunteers.
INVESTIGATORS :	Duangchit Panomvana Na Ayudhya, *et al*.
DISSOLUTION INVESTIGAOTRS:	Wiwat Supasena
PROTOCOL NUMBER	BEGPO 01/2007
STUDY NUMBER	-
ETHICS AND APPROVAL DATE	Joint Research Ethics Committees, Thailand Approval Date : 22 September 2008
OBJECTIVES :	To investigate the single dose the bioequivalence of Clindamycin GPO (Test product) and Dalacin C™ n (Reference product) 300 mg per capsule in healthy adult Thai males after fasting conditions.
DOSAGE REGIMEN	Test Product : Single dose, 300 mg of Clindamycin GPO capsule Lot..No. S510114 Mfd. 12/05/08, Exp. 12/05/10 Reference Product : Single dose, 300 mg of Dalacin C™ capsule Lot..No. P04603 Mfg. 22/03/07, Exp. 29/02/12
CLINICAL STUDY SITE	Banphaeo Hospital (Prommitr Branch) 12 Soi Prommitr, Sukhumvit 39 Rd., Wattana, Bangkok 10110, Thailand
STUDY SUBJECTS	No. of subjects planned: 24(+2) No. of subjects dosed in period I: 26 No. of subjects dosed in period II: 25 No. of subjects withdrawn: - No. of subjects dropped out: - No. of subjects completed: 25 No. of subjects analyzed: 25 No. of subjects included in pharmacokinetic and statistical analysis:25

GENERIC NAME Clindamycin	SPONSOR'S NAME : GOVERNMENT PHARMACEUTICAL ORGANIZATION (GPO)
TEST PRODUCT Clindamycin GPO	
REFERENCE PRODUCT Dalacin C™	
DEMOGRAPHIC DATA (N=25)	Age = 24.56±4.42 year ; BMI = 21.14±1.86 kg/m^2 ; Weight = 61.35±5.76 kg ; Height = 170.40±5.55 cm
ADMISSION AND CONFINEMENT	Subjects were admitted the night before study drug administration, supervised for at least 10 overnight fasting and confined until collecting the 24-hr sample.
DRUG ADMINISTRATION	Each subject randomly received a single dose of the assigned formulation, administered with 250 ml of water.
STUDY PERIOD	Screening : 26,29-30/9/2008, 02,10/10/2008 Enrollment : 10/10/2008, 17/10/2008 Period 1 : 10/10/2008 – 12/10/2008 Period 2 : 18/10/2008 – 20/10/2008
WASHOUT PERIOD	7 days from the first period : 11/10/2008 – 18/10/2008
BLOOD SAMPLING SCHEDULE	Fifteen blood samples were drawn at 0.00 (pre-dose sample) and 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2.0, 3.0, 4.0, 5.0, 7.0, 9.0, 12.0 and 24.0 hours (post-dose). The total volume of blood drawn were 164 ml.
BLOOD SAMPLING HANDLING	The blood sample for clindamycin were place in EDTA tubes, and the separating plasma samples were stored at -20° C until analyzed.
CLINICAL SAMPLE STORAGE	Railway Hospital (Burachatchaiyakorn) lab., Makkasan Railway Estate, Rachathewi, Bangkok 10400
ANALYTICAL SITE	Bioequivalence Study Center Research and Development Institute, The Government Pharmaceutical Organization 75/1 Rama VI Rd., Ratchatewi Bangkok 10400,Thailand
BIOANALYTICAL METHODOLOGY	LC/MS/MS , LLOQ 5 ng/ml
TOLERANCE/SUBJECTS WITHDRAWAL/ADR	Both treatments were well tolerated. No clinically significant or serious ADR were observed.
SURROGATE PARAMETERS	Drug plasma concentrations to indicate clinical activity.

GENERIC NAME Clindamycin TEST PRODUCT Clindamycin GPO REFERENCE PRODUCT Dalacin C™	SPONSOR'S NAME : GOVERNMENT PHARMACEUTICAL ORGANIZATION (GPO)
PRIMARY PHARMACOKINETIC PARAMETERS	-Test product Pharmacokinetic parameters — Geometric mean — Arithmetic mean $AUC_{0\rightarrow tlast}$ (ng.hr/ml) — 10713.44 — 11585.35±4745.85 $AUC_{0\rightarrow\infty}$ (ng.hr/ml) — 10801.94 — 11685.64±4795.41 C_{max} (ng/ml) — 3248.99 — 3353.22±843.26 -Reference product Pharmacokinetic Parameters — Geometric mean — Arithmetic mean $AUC_{0\rightarrow tlast}$ (ng.hr/ml) — 10210.37 — 11394.99±5546.45 $AUC_{0\rightarrow\infty}$ (ng.hr/ml) — 10298.95 — 11500.52±5613.57 C_{max} (ng/ml) — 3281.91 — 3403.74±939.98
ANALYTE	Clindamycin
SECONDARY PHARMACOKINETIC PARAMETERS	-Test product — Arithmetic mean t_{max} (hr) — 0.75±0.32 $K_e(hr)^{-1}$ — 0.32±0.07 $t_{1/2}$ (hr) — 2.31±0.56 $AUC_{0\rightarrow tlast}/AUC_{0\rightarrow\infty}$ — 0.99% -Reference product — Arithmetic mean t_{max} (hr) — 0.69±0.28 $K_e(hr)^{-1}$ — 0.32±0.08 $t_{1/2}$ (hr) — 2.28±0.57 $AUC_{0\rightarrow tlast}/AUC_{0\rightarrow\infty}$ — 0.99%

GENERIC NAME Clindamycin	SPONSOR'S NAME : GOVERNMENT PHARMACEUTICAL ORGANIZATION (GPO)
TEST PRODUCT Clindamycin GPO	
REFERENCE PRODUCT Dalacin C™	
CONFIDENCE INTERVALS	90% Confidence Intervals for the ln-transformed Test/Reference ratios: Pharmacokinetic Parameters — Ratio (%) — 90% Confidence Interval $AUC_{0\rightarrow tlast}$ (ng.hr/ml) — 101.67 — 96.92-112.34 $AUC_{0\rightarrow\infty}$ (ng.hr/ml) — 101.61 — 96.84-112.32 C_{max} (ng/ml) — 98.52 — 93.29-105.13
CONCLUSION	In this study, the 90% confidence intervals for the ln transformed ratios (Test/Reference) for the $AUC_{0\rightarrow tlast}$, $AUC_{0\rightarrow\infty}$ and C_{max} were within the 80-125%. Both the test and reference products were considered to be safe and well tolerated. Therefore, the bioequivalence of Clindamycin GPO and Dalacin C™ 300 mg clindamycin per capsule, can be concluded.
DATE OF REPORT	18 December 2009