ASEAN GUIDELINES FOR THE CONDUCT OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES-QUESTIONS AND ANSWERS (Q &A)
(Version 5)

This has been agreed and adoped at the 19th. ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), July 2012

Question 1

Q1: A registered innovator product is an immediate release formulation. A generic drug company will produce a Modified Release (MR) formulation. How to design a BE study for a modified release formulation for once daily administration, can the immediate release comparator administered for 3 times daily?

A1: This situation is outside the scope of this guideline and should be referred to a specific modified release oral dosage forms guidelines such as' Note for Guidance on Modified Release Oral and Transdermal Dosage Forms, Section II (CPMP/EWP/280/96)'

Question 2

Q2: In case of 2 stage design study , how many subjects are recommended to start with in the first stage? If the first stage can reach BE, but the intra subject CV is high and the number of subjects is not enough to obtain the required statistical power, are additional subjects still needed?

A2 : Since this situation has been addressed in the new ASEAN Guidelines on BABE, kindly refer to paragraph 3.1.3 (Number of Subjects) and 3.1.8 (Evaluation, Two-Stage Design)
