ASEAN GUIDELINES FOR THE CONDUCT OF BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES - QUESTIONS AND ANSWERS (Q & A)
(Version 3)

This has been agreed and adopted at the 17 th ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group (PPWG), July 2010

Question 1

Q : For a drug which is subject to major genetic polymorphism, where phenotyping and/or genotyping should be considered, should the BE study be repeated if it was originally conducted overseas in a different population group?

A : The BE study need not be repeated. Since BE study is conducted using cross-over design where each subject becomes his/her own control, there will be no effect on BE study result whatsoever whether the subjects are poor or extensive metabolisers.

Question 2

Q : In what circumstances can we use pharmacodynamic parameters to prove therapeutic equivalence?

A : In case bioequivalence cannot be demonstrated using drug concentrations, pharmacodynamic or clinical endpoints may be needed.
Since there is no detailed explanation in the guideline specific to this matter, this should be referred to therapeutic area specific guidelines.

Question 3

Q : For a modified release preparation, should the study be conducted both in fasting and fed condition?

A: This situation is outside the scope of this guideline and should be referred to specific modified release oral dosage forms guidelines such as 'Modified Release Oral and Transdermal Dosage Forms : Section I and II (CPMP/QWP/604/96,CPMP/EWP/280/96)

Question 4

Q : **If the production site of the comparator product used in BE test is different from that in the importing country, then dissolution test between both comparator product is required.**
Can the dissolution test use different batch of comparator product from that used in the BE study?

A : Yes, the dissolution test using different batch from the batch used in BE study can be allowed .