Comparative Dissolution Profile (CDP) between Generic Product and Comparator Product with Gastro-Resistance Formulation

As agreed upon in 'Mesyuarat Jawatankuasa Kajian Bioekuivalens Kebangsaan 1/2016', 16 June 2016:

There are two (2) options in comparing the dissolution profiles of generic product and comparator product with gastro-resistance formulation:-

(i) According to European Medicines Agency (EMA) Questions & Answers: Positions on Specific Questions Addressed to the Pharmacokinetic Working Party (PKWP), 26 June 2015, the in-vitro dissolution test should be conducted following the conditions as below:

a. 2 hours in pH1.2 media followed by 45 minutes in pH6.8 media
b. 2 hours in pH4.5 media followed by 45 minutes in pH 6.8 media

(ii) According to ASEAN Guideline for the Conduct of Bioequivalence Studies, March 2015, the in-vitro dissolution test should be conducted in three different buffers (pH 1.2, 4.5 and 6.8).