## 3 Ways and 4 Ways Bioequivalent Studies

As agreed upon in 'Mesyuarat Jawatankuasa Kerja Bioekuivalens Kebangsaan 1/2009 – 19 Ogos 2009':

'3 ways' and '4 ways' study design can be allowed as follows:

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|---|---|
| Scenario A<br><br>Study which involved the same sponsor<br>i) Reference Tablet 500mg vs<br>- Test A 250mg Tablet & Test A 500mg Tablet<br>ii) Reference Tablet 500mg vs<br>- Test A 250mg Tablet & Test A 250mg/5ml Suspension<br>ii) Test A 250mg Tablet vs<br>- Reference Tablet 250mg from Austria & Reference Tablet 250mg from UK | Scenario A is allowed since it is a standard design . However, it is only restricted up to '4 ways' only. |
| Scenario B<br><br>Study which involved more than 1 sponsor with the same comparator<br>i) Reference Tablet 250mg vs<br>- Test 250mg Tablet from manufacturer A & Test 250mg Tablet from manufacturer B | Scenario B is allowed with the following conditions:<br>i) Applicant need to declare that the study is using '3 ways' or '4 ways' design.<br>ii) Report of BE study must include information for all products involved (3 ways – 3 products, 4 ways – 4 products) |