INDONESIA

in APAC 2021

To encourage scientific and risk based approach to Bioequivalence (BE) Studies for post approval change (PAC) in "your Country/ Region" in the present status,

Question 1: ***Have you ever applied "BCS-based Biowaiver approach" * for the PAC (ex. formulation change or manufacturing site change) of branded (new) drugs?***

**** "BCS-based Biowaiver approach " means in vivo bioequivalence studies is not required by this approach.***

Please click "YES" or "NO",

YES

YES

- We haven't Full Implemented the BCS-Based Biowaiver yet. It is based on case-by-case review. The applicant needs to submits a Biowaiver proposal and NRA will assess the proposal, it is concluded that it meets the criteria of Biowaiver, then the biowaiver for BCS 1 can still be considered.

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If Yes,

please provide examples that BCS-based biowaiver approach were applied.	
1	Dose proportional pharmacokinetics
2	Satisfy the criteria regarding solubility and permeability
3	excipient differences exist: need consideration of the drug substance properties as well as excipient effects, the sponsor should justify why the proposed excipient differences will not affect the absorption profile of the drug substance under consideration, i.e., rate and extent of absorption, using a mechanistic and risk-based approach
3	Change in Formula Composition but It's depend on the composition change level. Refer to SUPAC USFDA Guideline
4	In principle, BE study is not required for the site manufacturer change. The requirements as Follows : There is no change in API manufacturer, Specification of Product, Formula, Production Process, Equipment specification, Environment Condition, PIC and Competencies of the Employee who involved. (Refer to SUPAC USFDA Guideline)

Could you please show your local guideline based on BCS-based Biowaiver approach?
– There is no spesific local GL for BCS based Biowaiver

ICH-M9 guideline (BCS Biowaiver) was agreed among major regulatory agencies at the Singapore meeting in Nov.2019.

Question 2: ***Does your country has a plan to expand the application of "BCS based biowaiver approach" following to the ICH recommendation in the future?***

Please click "YES" or "NO",

YES
In the future, we plan to implement BCS-based biowaiver

YES

NO

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If Yes,

Please provide your opinion what your country can expand “BCS based biowaiver approach” based on the ICH-M9 guideline.
1 For BCS 3, in accordance with the requirements and fulfillment of the requirements of the BCS Based biowaiver

Any other comments regarding the <u>future</u> requirements for (if any)

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☞ END

If No,

What obstructions will you not expand “BCS based biowaiver approach” following the ICH recommendation in the future?
1
2
3

Any other comments regarding the <u>future</u> requirements for (if any)

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If No,

Please provide specific example you could not apply BCS-based Biowaiver approach at a PCA review.

1.	Narrow therapeutic index Drugs
2.	Buccal dosage form
3.	Safety reasons
4.	Modified Release
5	Test product contains a different ester, ether, isomer, mixture of isomers, complex or derivative of a drug substance from that of the reference product

Could you please show your local guideline based on BCS-based Biowaiver approach? -