Summary of GMP Compliance Qualification Process in "Thailand"

Question1: ***Among the following proposed change cases "1-4", which case requires "a-c" for GMP qualification of the related manufacturing sites (Yes or No)?***

Assumption: For small molecule API change, proposed change would not create new impurity

(*) Additional document includes Process validation report, copies of analytical raw data, batch record, and submission of GMP certificate at the time of change submission

Change cases and requirements	1) Change of Manufacturing process	2) Change of Test Methods	3) Change of Manufacturing sites	4) Change of Packaging
a) Requirement of on-site inspection	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No
b) Additional documents(*)	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No
c) Review period is longer than 6 months	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No

Please describe other comments on the GMP compliance qualification process (if any).

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Summary of Stability study documents required for the variations in "Thailand"

Question2: ***For the following proposed change cases "1 – 4", does your agency requires to submit stability data at the time of change proposal (Yes or No) ?***

Assumption: For small molecule API change, proposed change would not create new impurity.
For small molecule DP change, API process/site remains the same as original submission.

Change cases and requirements	1) Change of Manuf. process	2) Change of Test Methods	3) Change of Manuf. sites	4) Change of Packaging
a) Real time stability data is required.	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No
b) NLT 6 months data is required for long term stability.	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No
c) Stability Commitment can be applied.	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No
d) Bracketing / Matrixing approach is acceptable.	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No	For API: Yes / No For DP: Yes / No

Any other comments regarding the stability data requirements (if any)

- *Long-term stability data of not less than 3 months can be accepted for Minor variations of conventional dosage form and stable drug substance.*

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Question 3: Please describe required documents in the following variations.

Change of manufacturing process		
Classification	Required documents	Detailed Requirements
Chemical Drug Products	Manufacturing methods	(1) Description of the new manufacturing process and technical justification for the change, (2) Validation scheme and/or report of the manufacturing process as per ASEAN Guideline on Submission of Manufacturing Process Validation
	Spec and test method	(1) Release and shelf-life specification that supports that the new process must lead to an identical or better product regarding all aspects of quality, safety, and efficacy
	Stability studies	(1) Stability data (6 M accelerated and long-term) as per ASEAN Guideline, for minor pharma. manufacturing change, a declaration letter sufficient
	Bioequivalence studies	(1) Comparative dissolution profile data (2) justification for not submitting new BE study (as per ASEAN Guideline)
	Others	Summary /justification of change, comparative batch analysis
Biological Drug Products	Manufacturing methods	Process validation as appropriate
	Spec and test method	Comparative description of batches and summary results for 3 commercial batches of pre- and post- change final products
	Stability studies	Comparative pre- and post-change test results for key stability indicating attributes for 3 commercial batches
	Bioequivalence studies	NONE

Question 3: Please describe required documents in the following variations.

Change (~~Addition~~) of manufacturing site (by the same manufacturing process)		
Classifi Process cation	Required documents	Detailed Requirements
Chemical Drug Products	Manufacturing methods	Validation scheme and repot of the manufacturing process as per ASEAN Guideline on Submission of Manufacturing Process Validation
	Spec and test method	Release and shelf-life specification of drug product
	Stability studies	Stability data as per ASEAN Guideline on Stability Study of Drug Product (6 months and long term study)
	Bioequivalence studies	Comparative Dissolution Profile (in vitro BE study)
	Others	(1) GMP Cert,. And/or CPP, (2) Comparative batch analysis data of drug product, (3) revised draft of packaging insert and labeling, batch numbering system (where applicable), (4) holding time testing of bulk during storage and transportation between the bulk production site and primary packaging (where applicable), (5) summary/justification of change
Biological Drug Products	Manufacturing methods	Process validation as appropriate
	Spec and test method	Comparative description of batches and summary results for 3 commercial batches of pre and post- change final products
	Stability studies	Comparative pre- and post-change test results for key stability

Question 3: Please describe required documents in the following variations.

Formulation Change ~~or Addition of packaging~~		
Classification	Required documents	Detailed Requirements
Chemical Drug Products	Manufacturing methods	(1) Revised batch formula/manufacturing process/manufacturing control (where applicable); (2) validation scheme and report of the manufacturing process as per ASEAN guideline
	Spec and test method	(1) Specification of excipients/declared letter for TSE/BSE of proposed excipients; (2) release and shelf-life specification of drug product
	Stability studies	(1) 6M accelerated and long-term stability study data
	Bioequivalence studies	(1) Comparative dissolution profile data; (2) Justification for not submitting a new BE study (in vivo)
	Others	(1) summary/justification of change be given as appropriate development of pharmaceutics; (2) Comparative batch analysis data of drug product; (3) revised drafts of the package insert and labeling incorporating the proposed variation (where applicable)
Biological Drug Products	Manufacturing methods	Process validation as appropriate
	Spec and test method	Comparative description of batches and summary results for 3 commercial batches of pre and post- change final products

Question 3: Please describe required documents in the following variations.

~~Formulation Change or~~ Addition of packaging (Primary packaging)		
Classification	Required documents	Detailed Requirements
Chemical Drug Products	Manufacturing methods	(1) validation scheme and report of the manufacturing process as per ASEAN guideline
	Spec and test method	(1) Specification of containers
	Stability studies	(1) 6M accelerated and long-term stability study data
	Bioequivalence studies	NONE
	Others	(1) summary/justification of change; (2) proof that no interaction between the content and the packaging material occurs (where applicable); (3) revised ACTD Section on Manufacturing and Container and Closure (where applicable); (4) revised draft of packaging insert and labeling incorporation the proposed variation
Biological Drug Products	Manufacturing methods	Process validation as appropriate
	Spec and test method	Comparative description of batches and summary results for 3 consecutive commercial batches of pre and post- change final products
	Stability studies	Comparative pre- and post-change test results for key stability

Question 3: Please describe required documents in the following variations.

~~Formulation~~ Change ~~or Addition~~ of primary packaging site		
Classification	Required documents	Detailed Requirements
Chemical Drug Products	Manufacturing methods	(1) validation scheme and report of the manufacturing process as per ASEAN guideline
	Spec and test method	NONE
	Stability studies	(1) 6M accelerated and long-term stability study data
	Bioequivalence studies	NONE
	Others	(1) GMP cert. and/or CPP covering GMP certification; (2) revised draft of the packaging insert and labeling; (3) holding time studies testing of the bulk pack during storage and transportation between the bulk production and primary packager (where applicable); (4)summary/justification of change
Biological Drug Products	Manufacturing methods	Process validation as appropriate
	Spec and test method	Comparative description of batches and summary results for 3 consecutive commercial batches of pre and post- change final products
	Stability studies	Comparative pre- and post-change test results for key stability