

Title:

ASEAN Guideline on Analytical Validation – Questions and Answers

1. Based on the Guidelines, the degree of revalidation required depends on the nature of the changes. Certain other changes may require validation as well. What types of changes or variations merit revalidation and what types require validation? Take note that as per ACTD Quality section P5.3, only verification is required for MaV and MiV, not revalidation.

Validation is required when a new method is developed, when an existing validated method is significantly modified, or when an existing validated method is applied to a sample matrix significantly different from that for which the method was developed.

Verification is required for an assessment of suitability under actual conditions of use of standard methods or compendial methods.

2. As per ACTD Quality Overall Summary (QOS) section P5.3 verification of a compendial method involves accuracy and precision. What does ASEAN specifically regard as compendial – USP, BP, EP, JP, IP or other references?

Compendial methods which are recognized by all Members States are specified as USP, EP and BP. Any other Pharmacopoeias may be accepted by individual countries according to national criteria.

3. Is verification of compendial methods, in all cases, confined to accuracy and precision parameters only?

Verification of compendial methods should depend on the type of test to be verified. For example, LOQ should be a key parameter in verifying the quantitative assay of impurities. As stated in USP-NF, Validation of Compendia method, the characteristic of accuracy is not required.

4. What are the recommended acceptance criteria for each performance characteristic/parameter in the validation of analytical procedure?

If the acceptance criteria is available in accepted compendia, use as prescribe but if the acceptance criteria is not available, establish using scientific basis.

5. How to ensure the method transfer from a mother company to the receiving company is efficient? (Original sentence: In transferring a fully validated test method from mother or sister company)

Comparative testing is the most common analytical method transfer option used.

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6. Identify the conditions/scenarios when each of the following is required to be conducted: Full validation : Revalidation : Verification

Refer to 1. for Full validation and Verification. According to ASEAN Guideline, revalidation may be required in the following circumstances:

- Change in the synthesis of the drug substance
- Change in the composition of the finished product
- Change in the analytical procedure

7. Assay procedure of the dosage form in the compendia is for tablets but the company's product is in capsule form. What validation parameters will be performed?

Full validation is required. Please refer to ASEAN Analytical Validation Guideline for the parameters required for validation.