# Column Batch Verification

To ensure a developed HPLC method will be reproducible, it is recommended to verify performance on columns packed from different batches of sorbent.

## Technical Rationale

Most reputable column vendors supply columns with modern technology and specifications of a very narrow range. However, there still necessarily exists a range of material characteristic parameters across multiple production batches. In addition, it is impossible to capture each characteristic that may potentially affect the chromatography. As such, confirming that the method performs as intended on columns from 3 different batches of packing material is recommended to ensure method reproducibility.

## Regulatory Considerations

Typically, 3-batch verification would be performed during method validation, ruggedness, or robustness testing.

During validation, intermediate precision is a logical and common place for confirming method performance on columns from different batches. In many cases, intermediate precision itself involves 2 additional HPLC run sequences. Therefore, the use of two additional columns from two different batches during these sequences would not add any additional work.

During ruggedness or robustness testing, multiple batch verification will often add an additional experiment (possibly many more depending on the particular experimental design chosen and the results from the other parameters being considered).

It should also be noted that method verification across multiple batches is typically not a specific requirement, but more a practical tool to ensure that the actual method requirements can be reproducibly met.

## Risk Management

The decision of when to perform batch verification, across how many batches, and in what depth comes down to the risk and availability.

The risk assessment should be based on the critical nature of the separation (many critical resolving peaks?), the known nature of the sample (neutral and inert, or ionizable and reactive?), and the consequence of method failure.

Possibly during a given period of time, columns from additional batches may not be readily available. In such cases it is recommended to confirm method performance on a new column from the same batch. This is to ensure that the original column has not had any conditioning types of effects from either the multiple sample injections or other reagents used during the method development process that could have unpredictably altered selectivity.

For cases where multiple batches are an internal requirement or otherwise necessary due to the critical nature of a method, it is best to confirm the availability of such from the column vendor(s) during the initial stages of method development.

Phenomenex maintains at least 3 batches for most of their key HPLC products for the purpose of supporting method reproducibility verifications across multiple batches of material.

Key words: HPLC, validation, robustness, ruggedness, batch, lot, material

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