

What are the maximum changes allowed in a USP method- FAQ

This is a question that is always asked and the following are only guidelines. For exact details, consult the FDA, your regulatory department or the USP.

Change of Detector Wavelength	Not Allowed (you can vary up to 3nm in <u>accuracy</u> but you cannot adjust the detector.)
Column ID	+/- 50%
Column Length	+/- 70%
Column Temperature	+/- 20%
Concentration of buffer salts	+/- 10%
Flow Rate	+/- 50%
Particle Size	- 50%
pH of Mobile Phase	+/-0.2 units
Ratio of Mobile Phase Solvents	+/-10% absolute (This adjustment is not suggested)