Allowable Adjustments to United States Pharmacopeia (USP) Methods

As of August 22, 2012

1. Ratio of components in mobile phase: ± *30 % (relative)*

The amount(s) of the minor component(s) (e.g. ≤ 50%) can be adjusted by ± 30 % relative. However a change in any component cannot exceed ± 10 % absolute.

- 60:40 Acetonitrile/Water could be adjusted to ± 12 % water (= 30 % of 40), but this exceeds the ± 10 % maximum absolute change. Therefore the amount of water can range from 30 % to 50 % in this case.

2. Mobile phase pH: ± *0.2 units*

- pH of 7.6 can be adjusted from 7.4 – 7.8

3. Concentration of salts in buffer: ± *10 %*

- 20 mM Potassium phosphate can be 18 – 22 mM, as long as proper pH is maintained as above

4. Particle size: *Can be reduced as much as 50 %, but cannot be increased*

- 10 µm particles can be switched with 5 µm particles

5. Column length: ± *70 %*

- A 150 x 4.6 mm column can be varied from 45 – 255 mm in length

6. Column inner diameter:

- Can be adjusted if the linear velocity is kept constant

7. Flow rate: ± *50 %*

- 1 mL/min can be varied from 0.5 to 1.5 mL/min

8. Column temperature: ± *10° C*

9. Wavelength of UV-visible detector: *No deviations permitted*

10. Injection volume: *Can be reduced as long as precision and detection limits are achieved (no increase is permitted)*

Source: United States Pharmacopeia General Chapter <621> Chromatography USP35-NF30, page 258