

Allowable HPLC Adjustments for United States Pharmacopeia (USP) Methods

Shodex™



HPLC Columns

SHOWA
DENKO
EUROPE

USP Chapter 621

1. Column length: $\pm 70\%$
2. Column inner diameter: *Can be adjusted if the linear velocity is kept constant*
3. Particle size: $- 50\%$
4. Flow rate: $\pm 50\%$
5. Ratio of components in mobile phase: $\pm 30\%$ (relative for less one) or $\pm 10\%$ absolute
6. Mobile phase pH: ± 0.2
7. Concentration of salts in buffer: $\pm 10\%$
8. Column temperature: $\pm 10^\circ\text{C}$
9. Wavelength of UV-visible detector: $\pm 3\text{ nm}$
10. Injection volume: *Can be reduced as long as precision and detection limits are achieved*