

# Allowable HPLC Adjustments for European Pharmacopoeia (EP) Methods

Shodex™



HPLC Columns

SHOWA  
DENKO  
EUROPE

European Pharmacopoeia Ph. Eur., Chapter 2.2.46

## ISOCRATIC ELUTION

1. Column length:  $\pm 70\%$
2. Column inner diameter:  $\pm 25\%$
3. Particle size:  $- 50\%$
4. Flow rate:  $\pm 50\%$
5. Ratio of components in mobile phase:  $\pm 30\%$  (relative for larger one) or  $\pm 2\%$  absolute
6. Mobile phase pH:  $\pm 0.2$
7. Concentration of salts in buffer:  $\pm 10\%$
8. Column temperature:  $\pm 10^\circ\text{C}$
9. Wavelength of detector:  $\pm 3\text{ nm}$
10. Injection volume: *Can be reduced as long as precision and detection limits are achieved*

## GRADIENT ELUTION

1. Column length:  $\pm 70\%$
2. Column inner diameter:  $\pm 25\%$
3. Particle size: *No adjustment permitted*
4. Flow rate: *Adjustment is acceptable when changing column dimensions*
5. Ratio of components in mobile phase and gradient  
*Minor adjustments of the composition of the mobile phase and the gradient are acceptable, if the system suitability requirements are met.*
6. Dwell volume  
*Gradient time points (t in min) can be adapted to compensate differences in dwell volume between systems.*
7. Mobile phase pH: *No adjustment permitted*
8. Concentration of salts in buffer: *No adjustment permitted*
9. Column temperature:  $\pm 5^\circ\text{C}$
10. Wavelength of detector: *No deviations permitted*
11. Injection volume: *Can be reduced as long as precision and detection limits are achieved*