

Figure 11.6 Separation of peaks as indicated by R_s . (From Ref. 40.)

Tailing factor = 1.3

Tailing factor = 3.7

Tailing factor = 4.4

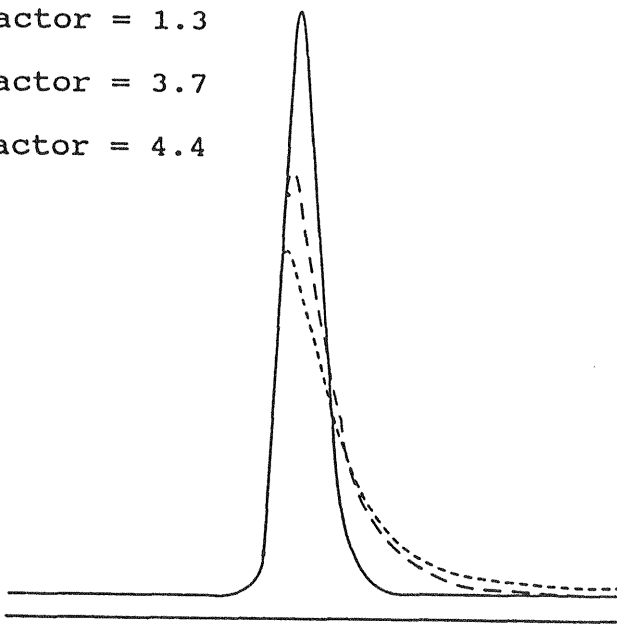


Figure 11.7 HPLC peak with various tailing factors. (From Ref. 40.)

18. POST VALIDATION ISSUES

The validation process does not end after experimental evaluation of the analytical parameters. Data must be evaluated to determine whether validation was successful or not. Does all the data generated meet the specified requirements or not? In the following subsections, steps required to finalize the validation process will be discussed.