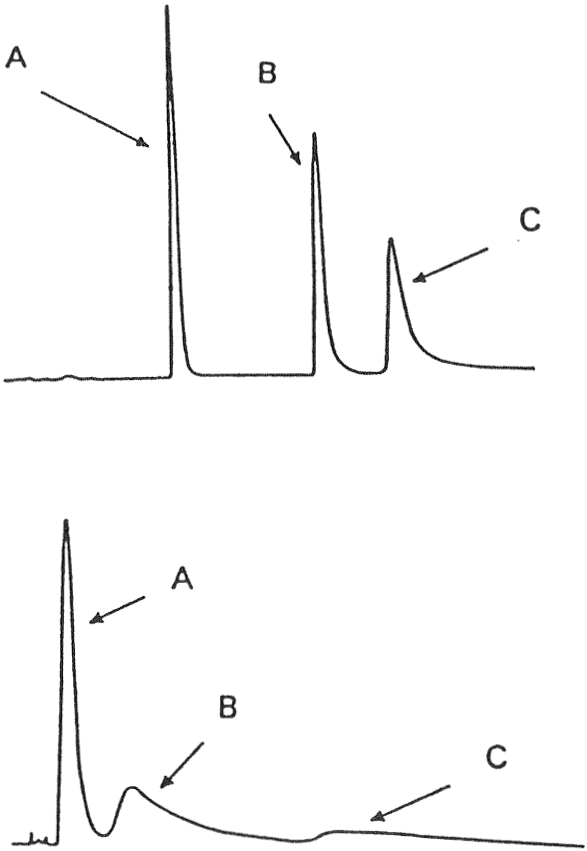

Figure 11.8 Effect of peak tailing on quantitation. (From Ref. 40.)

18.1. After the Laboratory Work

After completion of the laboratory work and documentation of the data in the analyst's notebook, it is very important that all data be carefully reviewed and audited by a qualified person. This process will ensure that data generated through the validation process is correct and meets all the requirements. Only after this step is completed can the next phase of the validation process be implemented.

18.1.1. Validation Report

The method validation report is a regulatory requirement and needs to be submitted to the FDA. The method validation report should be written by the method development group. The format for the report should be agreed upon at the onset of the validation process. This report must describe all the experimental procedures including equipment used, detector type, columns, information on reference standard, chemicals and composition of placebo for accuracy studies. All chromatograms and figures should be labeled properly. For forced degradation studies, conditions used and how this was performed must be explained.