

What is the difference between a peak area comparison and a quantitative limit for related substances?



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Answer:

Most current monographs describe quantitative determinations: a content calculation is necessary for establishing compliance with the monograph.

In older monographs, the acceptance criteria for related substances are expressed relative to the area of a reference peak of known concentration (limit test, area comparison). Without providing a numerical result, the comparison of peak areas leads to a pass/fail decision. The approximate content of impurity tolerated, or the sum of impurities, is indicated in brackets for information only.