

How can I determine the total impurities? Which peaks can be disregarded?



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Answer:

In chromatographic tests, the disregard limit/reporting threshold is defined as the nominal content at or below which peaks/signals are not taken into account for calculating a sum of impurities.

Peaks corresponding to the blank or the sample matrix are to be disregarded, as well as other peaks that the monograph explicitly states are to be disregarded.

In other words, if the peak areas of impurities (specified or unspecified) correspond to amounts that exceed the disregard limit/reporting threshold, they should be taken into account for the calculation of the total impurities.