Does the system sensitivity requirement apply to both tests and assays?

Answer:

This requirement does not concern analytical procedures included under the ASSAY section of a monograph. It concerns any LC or GC purity tests stated in the TESTS section of a monograph and which include a reporting threshold (or disregard limit).

In monographs, a reporting threshold is only stated in tests:

- where the total of impurities is limited,
- when normalisation is applied for the quantitation of only one impurity, or
- when there is a potential sensitivity issue.

Therefore, this requirement is not to be applied to assays or tests that do not include a defined reporting threshold/disregard limit.

It should be emphasised that Ph. Eur. 10th Edition version of the general chapter mentioned ‘in a related substances test, the limit of quantification (corresponding to a signal-to-noise ratio of 10) is equal to or less than the disregard limit.’
Past experience showed that this statement was sometimes misunderstood, as it was wrongly interpreted to apply only to tests under the heading ‘Related substances’, although it was meant to apply to any LC or GC test in the TESTS section of monographs. The term ‘in a related substances test’ was therefore omitted in the course of the international harmonisation work.