

Identity confirmation by LC

LC data for identity confirmation

- LC data alone is not sufficient for analyte identity confirmation.
- Without adequate chromatography the identity confirmation can't be completed.
- Identity confirmation data from LC:
 - Retention time.
 - Peak shape.
 - Altered chromatographic conditions.

Retention time

- The retention times of the analyte in sample and in standard solution must not differ by more than 0.1 min. (SANTE, 2021/808)
- The ratio of the retention times of analyte and internal standard must correspond to that of standard solution within a tolerance of 1%. (2021/808)
- The retention time of the analyte must be at least twice the system dead time, i.e. retention factor $k \geq 1$. (SANTE, 2021/808)

Peak shape

- The peak shape of the analyte in sample must correspond to the peak shape of analyte in standard solution.
- The peak shape of isotopically labelled internal standard shall match the peak shape of the analyte.
- To account for the matrix dependent changes in the peak shape and/or retention time of the analyte use ...
 - Matrix matched standard solutions
 - Isotopically labelled internal standards

Altered chromatographic conditions

- When chromatographic conditions are altered , the retention times and peak shapes of the analyte in sample and in standard solution should remain similar.
- Chromatographic conditions to alter:
 - Different column (ideally, different separation principle).
 - Solvents (including pH variation).
 - Gradient.
 - Temperature.