

Confirmation of identity

# Introduction

- Millions of compounds exist.
- Several compounds have chromatographic behavior similar to the analyte.
- **Identity confirmation** provides evidence that the analytical signal registered from the sample is due to the analyte.
- Information required for identity confirmation is collected during validation.

# Ways of confirming identity

- Comparison of retention times.
  - Analyte retention time should be equal in sample and in standard solution.
  - But several structurally different compounds can have similar retention times.

# Ways of confirming identity

- Spectroscopic methods.
  - Provide evidence that chemical structure of the detected compound is the same as of the intended analyte.
  - On-line (as chromatographic detectors) or off-line.
  - Fluorescence and UV-Vis absorption spectra provide some evidence, but usually not enough for identity confirmation.
    - But enable exclusion – if spectra are different, then the compound can't be the analyte.
- Mass spectrometry is the most powerful method for identity confirmation.

# Identity confirmation by ICH guidelines

- Demonstrate that the method is able to discriminate between compounds of closely related structures.
  - Positive results from samples containing the analyte (true positive).
  - Negative results from samples, which don't contain the analyte (true negative).
  - Negative results from compounds, which are structurally similar or closely related to the analyte (true negative).
- Consider, which compounds could potentially interfere – experience.
- Scientific judgement of properties of the sample components, analyte and analytical method – knowledge.