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# LCMS in the Quality Assessment of Herbal Medicine: an Industrial Perspective

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## Topics

- **Fields of Applications**
- **Comparison of LCMS with Common Techniques**
- **Advantages / Disadvantages of LCMS**
- **Costs of LCMS Application**
- **LCMS in Quality Control / Release / Stability Testing**
- **LCMS and Drug Regulatory Affairs**

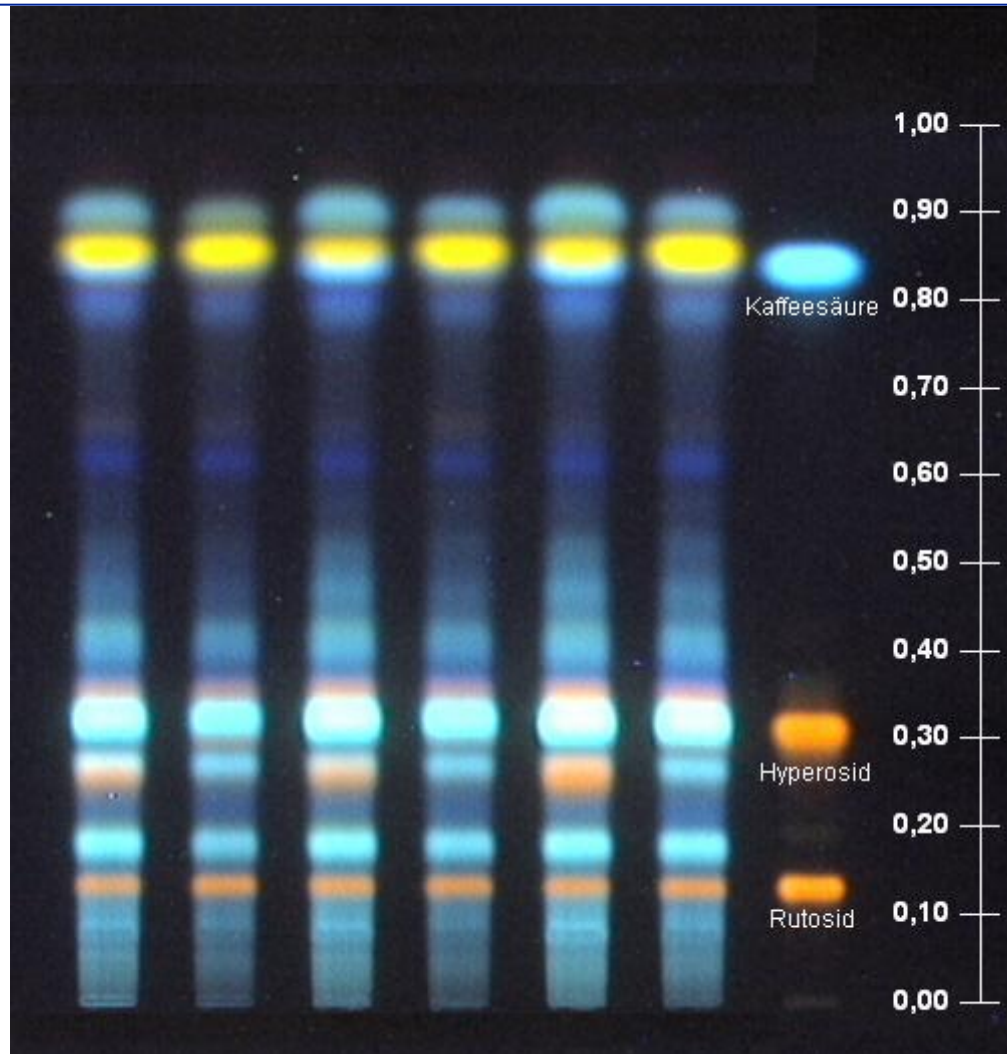
## **Fields of Applications**

- Control of Contaminants, e.g. Established for Pesticides**
- In-House Methods in Quality Control, e.g. to Check Supplies**
  
- Quality Control – Release / Stability Testing**
  
- Assay for Individual Compounds in Herbals**
- Identity Testing of Herbals**

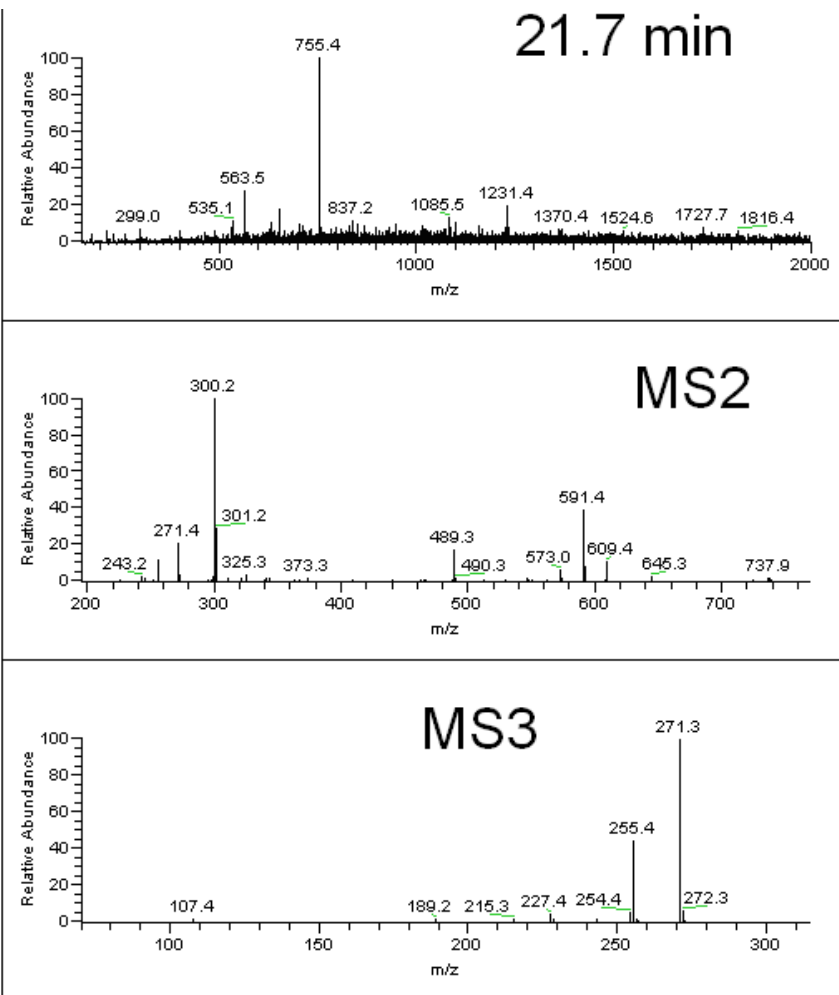
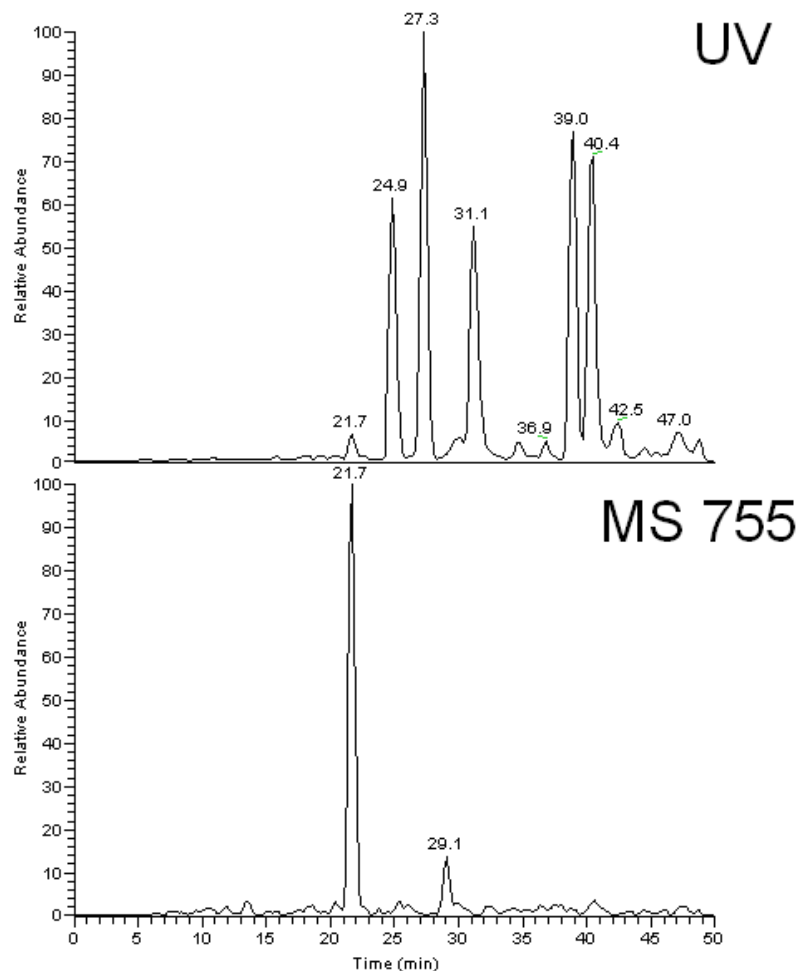
## **Comparison of LCMS with Common Techniques**

- Selectivity / Specificity**
- Sensitivity**
- Spectra**
- Working Range / Linearity**
- Reproducibility / Robustness**
- Reference Compounds**
- Method Validation**
  
- Costs**
- Everyday Usability / Alternatives / Fallback Option**
- GLP / GMP**
- Acceptance**

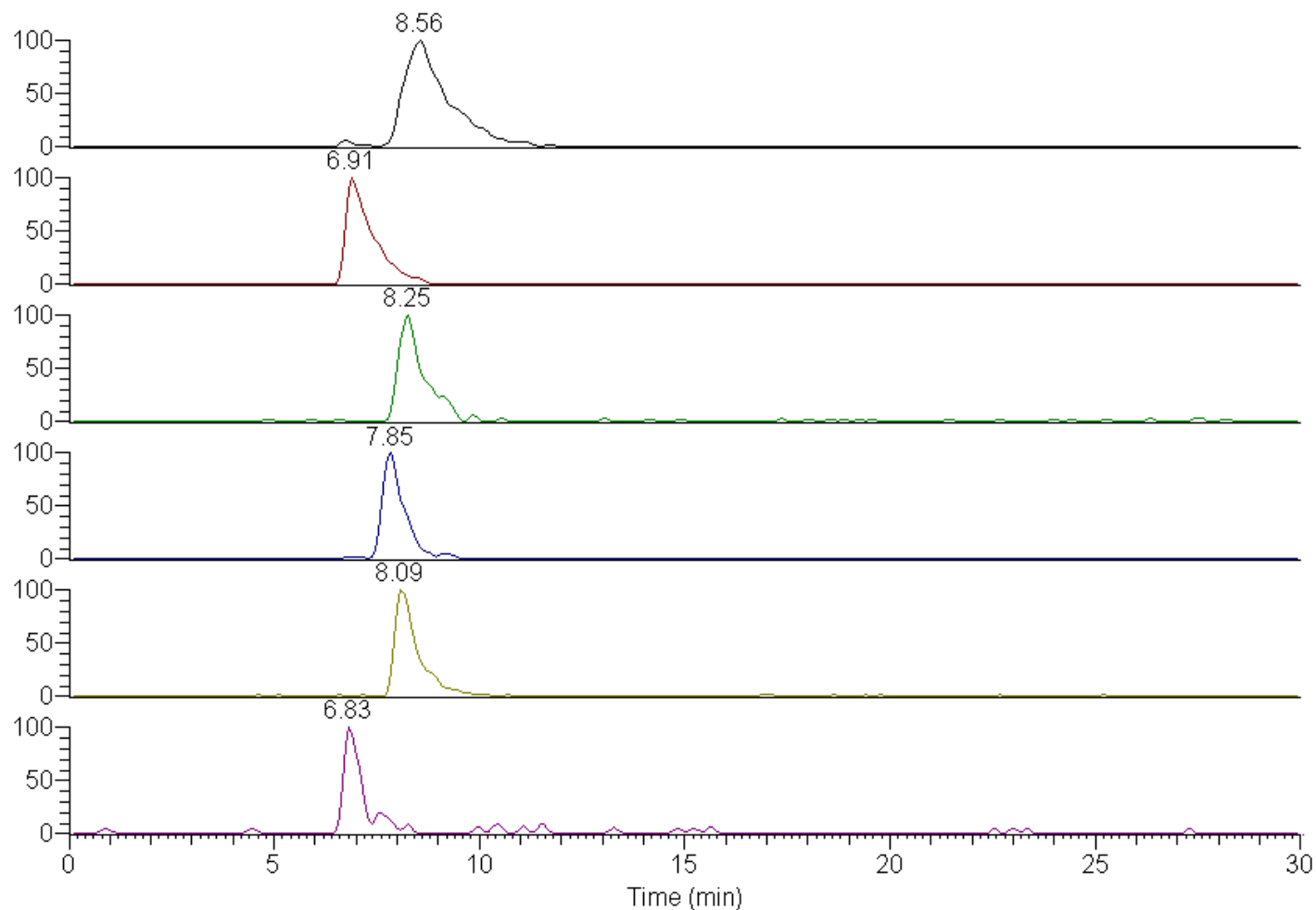
## Classic TLC



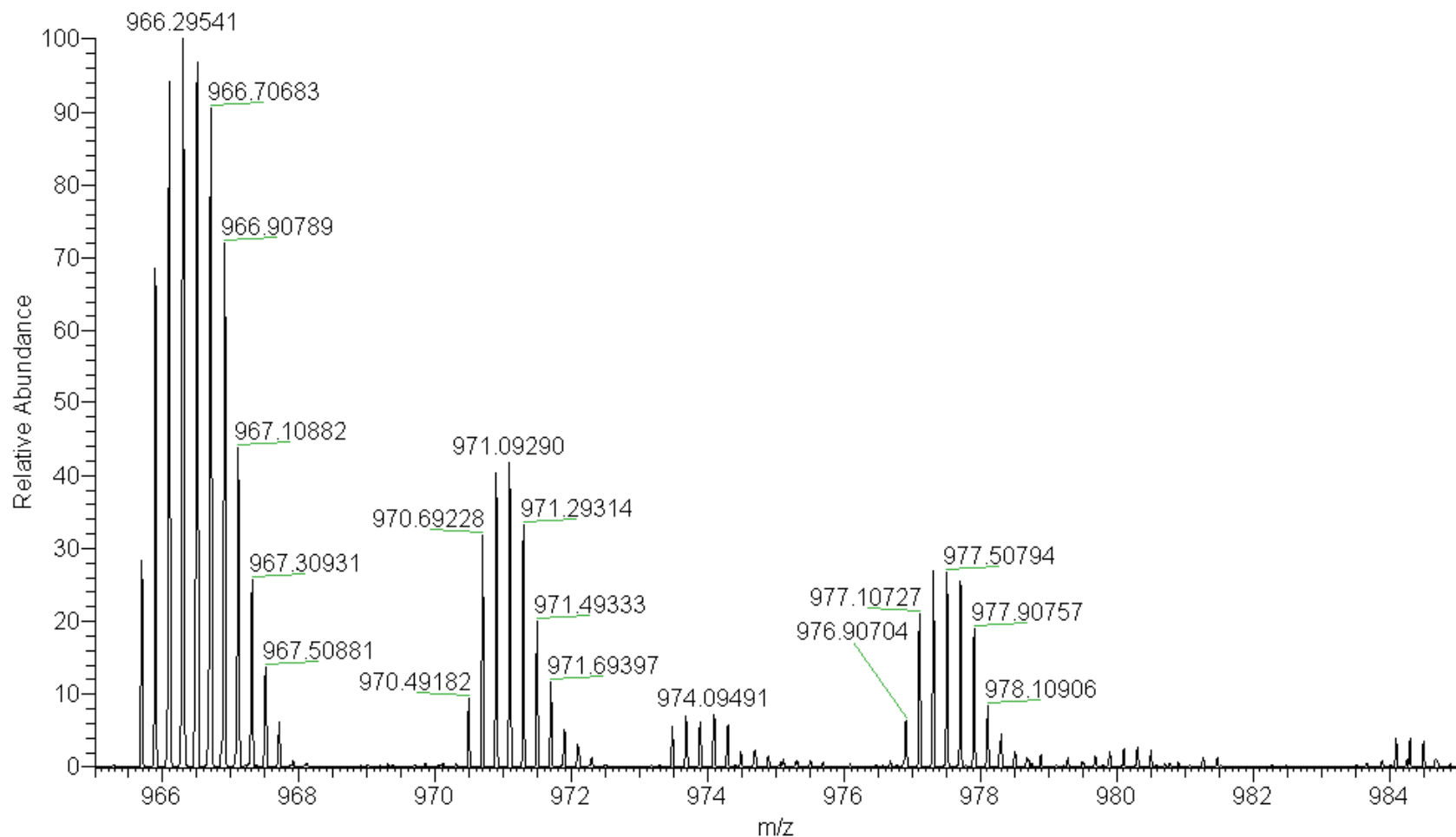
# HPLC-UV / -MS



## HPLC-MS Chromatogram of Peptides (Mass Traces)



## FT-MS Spectrum of Peptides





## **Advantages / Disadvantages of LCMS**

- Selectivity / Specificity**
- Sensitivity**
- Spectra**
- Working Range / Linearity**
- Reproducibility / Robustness**
- Reference Compounds**
  
- Costs**
- Everyday Usability / Alternatives / Fallback Option**
- GLP / GMP**
- Acceptance**

## **Costs of LCMS Application**

- Investment: Machinery, Facilities, Personnel / Training, ...**
- Maintenance and Consumables**
- Instrument Qualification**
- Risk Assessment of Alternatives / Fallback Options**
  
- Costs in Development / Validation**
- Costs in Quality Control / Release**
- Costs in Stability Testing**

## **LCMS in Quality Control / Release / Stability Testing**

- Selectivity / Specificity**
- Sensitivity / Spectra**
- Reproducibility / Robustness**
  
- Costs**
- Everyday Usability / Alternatives / Fallback**
- GLP / GMP / Instrument Qualification**
- Timeline Compliance**

## **LCMS and Drug Regulatory Affairs**

- Presentation of LCMS Data**
- Acceptance for different purposes**
- LCMS for Assays**
- LCMS in Identity Tests**
- Stability Assessment**
- LCMS and ICH-Guidelines**