IMPURITIES AND CHROMATOGRAPHY

- Can you provide relative retentions for ‘Other detectable impurities’ cited in the ‘Impurities’ section of a monograph?
- Can the EDQM provide typical chromatograms for tests described in the monographs?
- I have observed a slight difference in retention times/retardation factors compared with the monograph. What deviation is considered acceptable?
- What is the limit for specified/unspecified/unknown impurities?
- How can I determine the total impurities? Which peaks can be disregarded?
- The limit for unspecified impurities in the monograph is higher than the values defined in general monograph Substances for pharmaceutical use (2034) (Table 2034.-1) and general chapter 5.10. Control of impurities in substances for pharmaceutical use.
- How are limits for impurities defined in monographs?
- I observe baseline separation when the monograph describes a peak-to-valley ratio.
- I cannot achieve the system suitability or signal-to-noise criteria with the described chromatographic method. Can I make any adjustments?
- The monograph does not specify a correction factor for a specified impurity.
- The monograph does not include chemical reference substances or relative retentions for specified impurities.
- What is the difference between a peak area comparison and a quantitative limit for related substances?
- How should the test requirements be applied in related substances tests?