General Chapters and Monographs

ELABORATION AND REVISION

- How are monographs selected for inclusion in the European Pharmacopoeia?
- How can I submit a draft monograph for inclusion in the European Pharmacopoeia?
- How can I propose a revision of a monograph?
- How long does the revision of a monograph take?
- How can I find out why revisions were made to the European Pharmacopoeia?
- How can I comment on a text published in Pharmeuropa?
- How can I order a qualified sample that is proposed in a Pharmeuropa draft text?

COMPLIANCE WITH A MONOGRAPH

- When is an article considered to be of Ph. Eur. quality?
- How can I find the reference number, exact name or status of a European Pharmacopoeia monograph for a particular substance?
- How can I find out if a monograph/a general chapter is included in the Ph. Eur.?
- How can I obtain the official analytical procedures of the European Pharmacopoeia? Could you send me a PDF file, for example?
- What measures do I need to take before using an analytical procedure that is given in Ph. Eur. monographs?
- Can I use a reagent or analytical procedure other than the one published in the Ph. Eur.?
- When can I apply the specification of a new or revised monograph?
- What is a ‘nominal value’ in Ph. Eur. texts?
- What is ‘stated potency’?

MEASURING QUANTITIES

- What accuracy is required for measuring quantities stated in Ph. Eur. texts?
- Am I allowed to round off measurements?

REAGENTS AND SUPPLIERS

- Can you provide details of suppliers of monograph substances?
- How can I find out which chromatography column or other equipment or reagent was used during the elaboration of a monograph?
- Do you recommend using any particular reagent for a monograph/general chapter?
- How long can I store a reagent or a solution before using it?
- Volumetric solutions (4.2.2): I have trouble achieving the repeatability criterion of 0.2% relative standard deviation (RSD).
- How can I standardise a volumetric solution?
- How should I prepare a more dilute volumetric solution than the one described?

CHARACTERS AND IDENTIFICATION

- I have trouble meeting the criteria under ’Characters’.
- Do I have to perform all the tests described in the ‘Identification’ section of a monograph?
- Is it possible to perform a type of measurement (such as ATR) different from that described in the monograph?

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?

GENERAL CHAPTER 2.2.46 (11.0)

- SYSTEM SENSITIVITY
  - What does it mean?
  - Does the system sensitivity requirement apply to both tests and assays?
  - How is the S/N ratio calculated?
- PEAK SYMMETRY

WATER - LOSS ON DRYING - SOLVENTS

PHARMACEUTICAL TECHNICAL PROCEDURES

MICROBIOLOGY

ELEMENTAL IMPURITIES

MEDICINAL PRODUCT MONOGRAPHS

MISCELLANEOUS