General Chapters and Monographs

ELABORATION AND REVISION

- How are the 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?

COMPLIANCE WITH A MONOGRAPH

- When is a material considered to be of pharmacopoeial quality?
- How can I find the reference number, exact name or status of a European pharmacopoeia monograph for a particular substance?
- How can I obtain the official analytical methods of the European Pharmacopoeia? Could you send me a PDF file, for example?
- Do I need to validate a method that is published in the Ph. Eur.?
- Can I use a reagent or method other than the one published in the Ph. Eur.?
- When can I apply the tests and specification of a new monograph and those of a revised monograph?
- What is a ‘nominal value’ in the Ph. Eur. texts?
- What is a ‘stated potency’?

QUANTITIES MEASUREMENTS

- What precision is required for weighing or measuring?
- 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 development of a monograph?
- Do you recommend any particular reagent to be used for a monograph?
- 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 % 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 2034, Substances for pharmaceutical use (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?

WATER - LOSS ON DRYING - SOLVENTS

- What is the difference between “dried” and “anhydrous” substances?
- The definition of substance X gives the content on dried or anhydrous basis. What about the solvents, are they to be taken into account when determining the assay?
- How do I apply general chapter 2.5.12 if the water content of my sample is below 2.5 mg?
- In general chapter 2.5.12, what solvent should I use for the water determination?
- How can I perform the suitability test described in general chapter 2.5.12?
- Does the suitability requirement described in general chapter 2.5.12 apply to both method A and B?
- Does the suitability test described in general chapter 2.5.12 have to be run every time?
- Are methods 2.5.12 and 2.5.32 interchangeable?

PHARMACEUTICAL TECHNICAL PROCEDURES

- When should I apply general chapter 2.9.40 Uniformity of dosage units?
- Dissolution test for solid dosage forms: what is the quantity Q?
- Dissolution test for solid dosage forms: I don’t understand how to calculate the acceptance criteria. Could you give an example?

MICROBIOLOGY
- General chapter 2.6.12, section 4-4 ‘GROWTH PROMOTION OF THE MEDIA’, factor not greater than 2 - Does the statement mean that the difference can be twice or half the calculated value of inoculum?
- General chapters 2.6.12 and 2.6.13, use of other strains & other questions

ELEMENTAL IMPURITIES
- The heavy metals test (2.4.8) has been deleted in many monographs of the European Pharmacopoeia. Why?

MISCELLANEOUS
- Should we use “sulf...” or “sulph...” for our substance in English?
- My question about the content of the European Pharmacopoeia monographs and general chapters is not in the FAQs, therefore I would like to contact the EDQM.