

EUROPEAN PHARMACOPOEIA & INTERNATIONAL HARMONISATION

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**
 - Does the peak symmetry requirement apply to all chromatographic procedures?
 - What does 'Unless otherwise stated' mean in this context?
 - **IMPLEMENTATION OF GENERAL CHAPTER 2.2.46 FOR EXISTING MONOGRAPHS**
 - **IMPLEMENTATION OF GENERAL CHAPTER 2.2.46 FOR IN-HOUSE PROCEDURES**
- **WATER - LOSS ON DRYING - SOLVENTS**
 - What is the difference between 'dried' and 'anhydrous' substances?
 - The definition of substance X gives the content as dried or anhydrous. Do the solvents need 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 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 procedures 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 do not understand how to interpret the acceptance criteria. Could you provide an example?
- **MICROBIOLOGY**
 - Microbiology texts (e.g. chapters 2.6.1, 2.6.12, 2.6.13, 2.7.2, monograph 0008): can microbial strains other than those that are cited in the Ph. Eur. be used?
 - Other questions on general chapters 2.6.12, 2.6.13, 5.1.1, 5.1.2, 5.1.3 and 5.1.4
- **ELEMENTAL IMPURITIES**
 - Why has the heavy metals test (2.4.8) been deleted from many Ph. Eur. monographs?
- **MEDICINAL PRODUCT MONOGRAPHS**
 - Does a monograph on a medicinal product containing a chemically defined active substance apply to all strengths and formulations?
 - What principles apply to disintegration tests described in medicinal product monographs?
 - Why can the limit for total impurities in a monograph on medicinal product containing a chemically defined active substance be lower than the limit for total impurities in the corresponding active substance monograph?
- **MISCELLANEOUS**
 - Should we use “sulf...” or “sulph...” for the English name of our substance?
 - What is the status of the monograph on Gonadotrophin, equine serum, for veterinary use (0719)?
 - My question about the content of the European Pharmacopoeia monographs and general chapters is not in the FAQs – how can I contact the EDQM?

Pharmacopoeial Harmonisation (Pharmacopoeial Discussion Group (PDG))

- In the case of a harmonised monograph, is it possible to use a reference standard from a different pharmacopoeia?
- My question about the Pharmacopoeial Harmonisation is not in the FAQs – how can I contact the EDQM?