# 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?
- CHROMATOGRAPHY: IMPURITIES AND ASSAY
  - 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?
  - System suitability test for LC and GC assays: what does ‘as described… with the following modifications’ imply for chromatographic procedures described under Assay?
- 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?
    - Monograph 0861 (implementation date: 1 January 2026) now also covers solutions for haemofiltration and haemodiafiltration prepared on-line by diluting a concentrated solution with “water of suitable quality”. What does “suitable quality” mean?
- 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
    - The name of a micro-organism in the Ph. Eur. does not match the ones used by culture collections (e.g. ATCC 6633 is named Bacillus subtilis in the Ph. Eur. and Bacillus spizizenii on the ATCC website). Which strain should I use?
- 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?