THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

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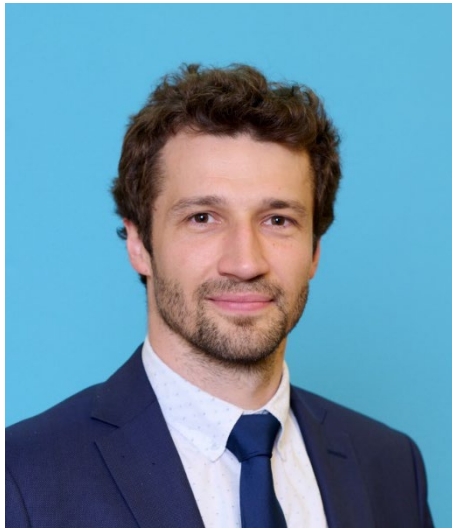
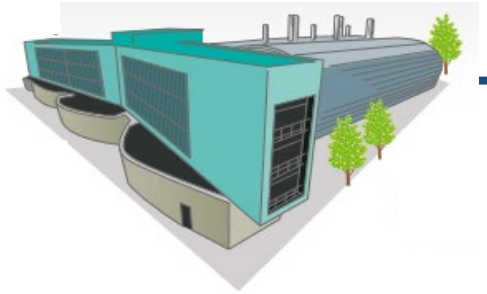
Recent developments in Ph. Eur. general texts regarding analytical methods

FIMEA
(Live Webinar)
Date: 31 October 2023

Who's talking ?

Mr Bruno SPIELDENNER





Great team of 10 scientific programme managers and 4 administrative support assistants

Studied Phys-Chem
MSc in Analytical Chemistry
Strasbourg/Marseille

Joined EDQM in 2013
European Pharmacopoeia Department

Since 2022:
Head of Division A
(Chemicals, herbals and general methods)

French
Strasbourg

7 years in Pharmaceutical industry in Switzerland
Specialised in Mass spectrometry

Work on transversal projects:
General methods chapters, implementation ICH Q3D

Structure of the Ph. Eur.

Ph. Eur.: Content and structure

Ph. Eur. Reference standards / preparations & reagents

General chapters & general texts

- avoid repeating standard procedures or requirements in each monograph; aspects that cannot be treated in each monograph
- become mandatory when referred to in a monograph
- provide standard analytical procedures; guidance

Individual monographs

- Specific but not a stand alone text
- Analytical procedures and acceptance criteria represent required quality standards
- Based on approved specifications backed up by batch data
- Reliance on manufacturers' feedback (public consultation)

General notices

- Essential reading
- Apply to all texts
- Address general topics
- Provide basic information
- Include rules to understand texts, conventional expressions

General monographs

Dosage form monographs

- Classes of substances/medicinal products
- Mandatory for all substances/products within scope of their definition
- Aspects that cannot be included in each individual monograph
- Not cross-referenced in individual monographs (exceptions)

General Notices – answers to a lot of questions!

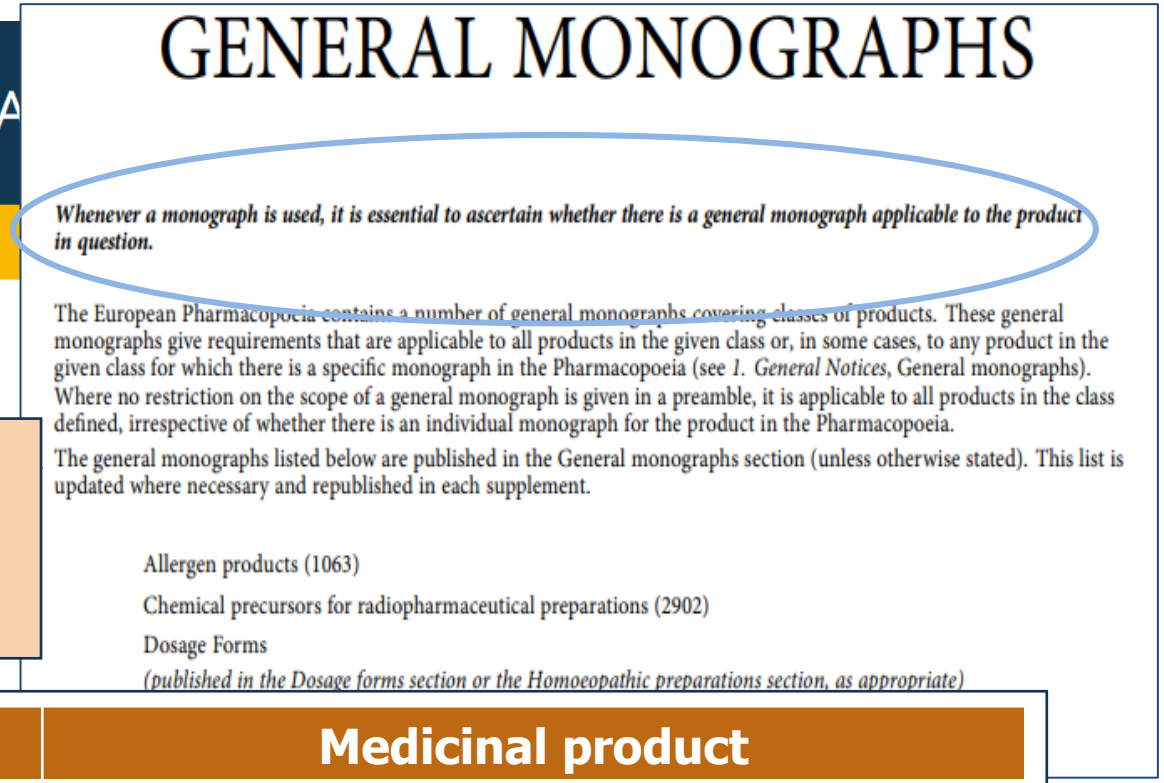
- Such as:
  - What does compliance mean?
  - What is mandatory?
  - What to do when implementing a pharmacopoeial procedure?
  - What about alternative analytical procedures?
  - What about waiving of tests?
  - Why two identification tests … sometimes?
  - Human and/or veterinary use?

And many more…

On demand webinar is available for learning more on the recent changes
https://www.edqm.eu/en/-/getting-the-big-picture-what-has-changed-in-the-ph.-eur.-general-notices

General monographs

Check which general monograph(s) applies!



GENERAL MONOGRAPHS

Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question.

The European Pharmacopoeia contains a number of general monographs covering classes of products. These general monographs give requirements that are applicable to all products in the given class or, in some cases, to any product in the given class for which there is a specific monograph in the Pharmacopoeia (see *1. General Notices*, General monographs). Where no restriction on the scope of a general monograph is given in a preamble, it is applicable to all products in the class defined, irrespective of whether there is an individual monograph for the product in the Pharmacopoeia.

The general monographs listed below are published in the General monographs section (unless otherwise stated). This list is updated where necessary and republished in each supplement.

Allergen products (1063)

Chemical precursors for radiopharmaceutical preparations (2902)

Dosage Forms

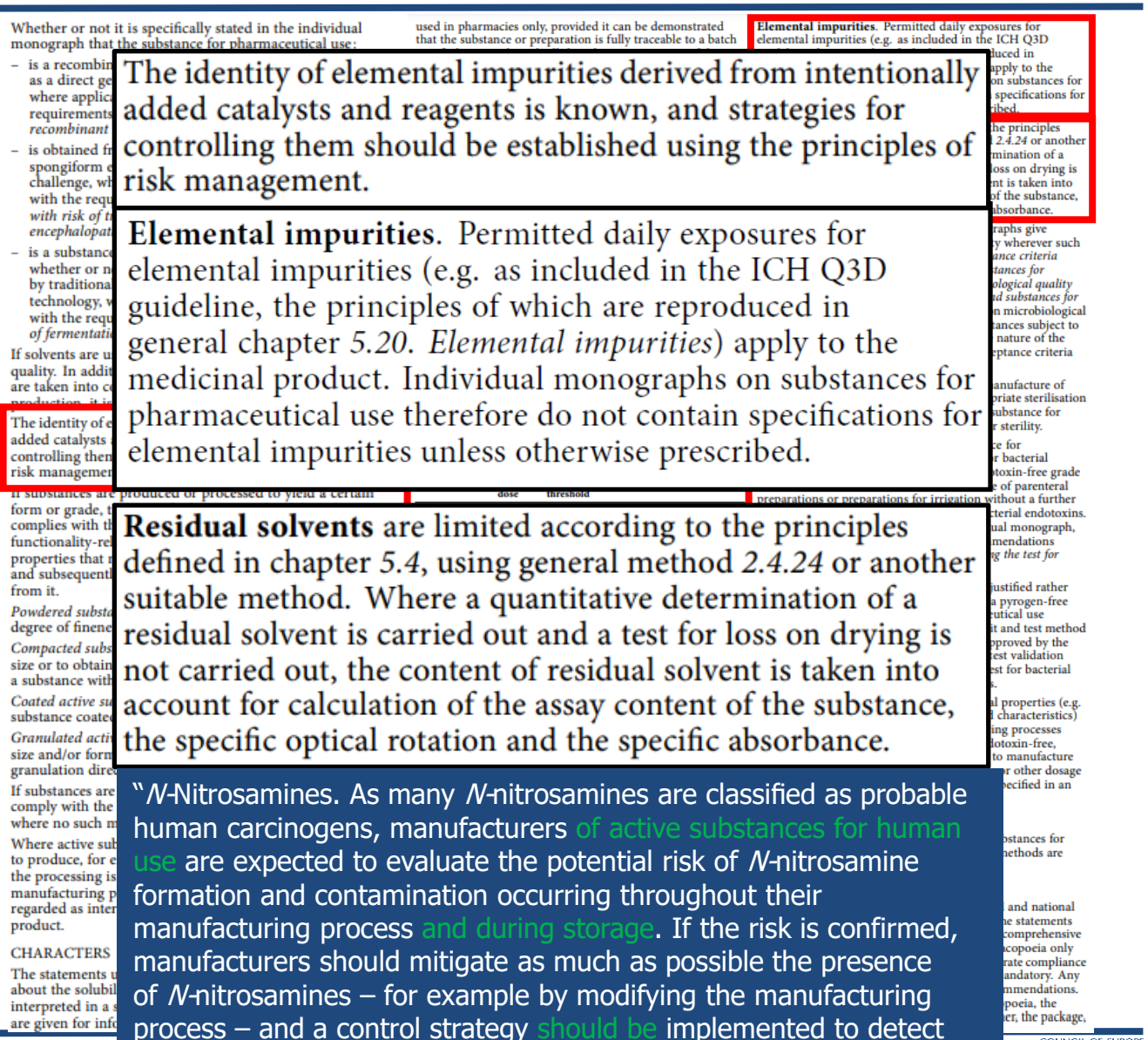
(published in the Dosage forms section or the Homoeopathic preparations section, as appropriate)

EXAMPLES

	API	Medicinal product
Ibuprofen (0721)	Substances for pharmaceutical use (2034)	Pharmaceutical preparations (2619) *Capsules (0016)*
Azithromycin (1649)	Substances for pharmaceutical use (2034) + Products of fermentation (1468)	Pharmaceutical preparations (2619) *Tablets (0478)*

Example: General monograph 2034

- Related substances: defining thresholds and refering to 5.10. Control of impurities in substances for pharmaceutical use (ICH Q3A)
- Elemental impurities: considered during production with risk management. 5.20 Elemental impurities (= principles of ICH Q3D guideline) applies for medicinal products
- Residual solvents: refers to 5.4 Residual solvents (=ICH Q3C); the chapter applies to APIs and excipients in scope of *2034*
  ➔*often no specific test in monograph*
- **NEW**: *N*-Nitrosamines



SUBSTANCES FOR PHARMACEUTICAL USE

The identity of elemental impurities derived from intentionally added catalysts and reagents is known, and strategies for controlling them should be established using the principles of risk management.

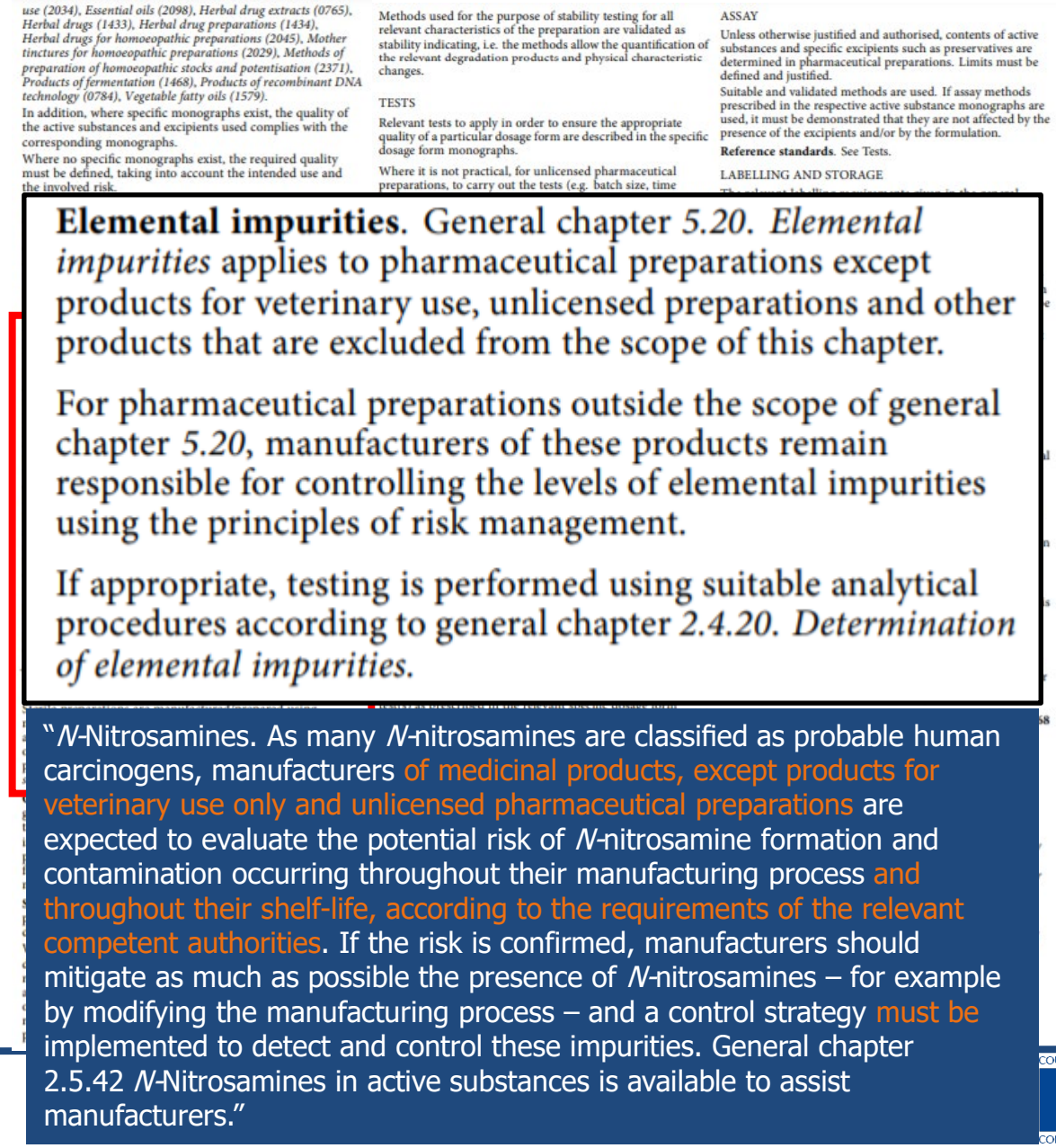
Elemental impurities. Permitted daily exposures for elemental impurities (e.g. as included in the ICH Q3D guideline, the principles of which are reproduced in general chapter *5.20. Elemental impurities*) apply to the medicinal product. Individual monographs on substances for pharmaceutical use therefore do not contain specifications for elemental impurities unless otherwise prescribed.

Residual solvents are limited according to the principles defined in chapter *5.4*, using general method *2.4.24* or another suitable method. Where a quantitative determination of a residual solvent is carried out and a test for loss on drying is not carried out, the content of residual solvent is taken into account for calculation of the assay content of the substance, the specific optical rotation and the specific absorbance.

"*N*-Nitrosamines. As many *N*-nitrosamines are classified as probable human carcinogens, manufacturers of active substances for human use are expected to evaluate the potential risk of *N*-nitrosamine formation and contamination occurring throughout their manufacturing process and during storage. If the risk is confirmed, manufacturers should mitigate as much as possible the presence of *N*-nitrosamines – for example by modifying the manufacturing process – and a control strategy should be implemented to detect and control these impurities. General chapter 2.5.42 *N*-Nitrosamines in active substances is available to assist manufacturers."

Example: General monograph 2619

- reference source of standards in the European Pharmacopoeia on active substances, excipients and dosage forms, which are to be applied in the manufacture/preparation of pharmaceuticals
- Microbiological quality: links given to the relevant general texts (5.1.1, 5.1.3, 5.1.4, 5.1.8)
- Elemental impurities: refers to general text 5.20 (= principles of ICH Q3D guideline) rendered mandatory according to its scope. For products outside scope, EI are a risk that needs to be managed
- **NEW**: *N*-Nitrosamines



use (2034), Essential oils (2098), Herbal drug extracts (0765), Herbal drugs (1433), Herbal drug preparations (1434), Herbal drugs for homoeopathic preparations (2045), Mother tinctures for homoeopathic preparations (2029), Methods of preparation of homoeopathic stocks and potentisation (2371), Products of fermentation (1468), Products of recombinant DNA technology (0784), Vegetable fatty oils (1579).

In addition, where specific monographs exist, the quality of the active substances and excipients used complies with the corresponding monographs.

Where no specific monographs exist, the required quality must be defined, taking into account the intended use and the involved risk.

Methods used for the purpose of stability testing for all relevant characteristics of the preparation are validated as stability indicating, i.e. the methods allow the quantification of the relevant degradation products and physical characteristic changes.

TESTS

Relevant tests to apply in order to ensure the appropriate quality of a particular dosage form are described in the specific dosage form monographs.

Where it is not practical, for unlicensed pharmaceutical preparations, to carry out the tests (e.g. batch size, time

ASSAY

Unless otherwise justified and authorised, contents of active substances and specific excipients such as preservatives are determined in pharmaceutical preparations. Limits must be defined and justified.

Suitable and validated methods are used. If assay methods prescribed in the respective active substance monographs are used, it must be demonstrated that they are not affected by the presence of the excipients and/or by the formulation.

Reference standards. See Tests.

LABELLING AND STORAGE

Elemental impurities. General chapter *5.20. Elemental impurities* applies to pharmaceutical preparations except products for veterinary use, unlicensed preparations and other products that are excluded from the scope of this chapter.

For pharmaceutical preparations outside the scope of general chapter *5.20*, manufacturers of these products remain responsible for controlling the levels of elemental impurities using the principles of risk management.

If appropriate, testing is performed using suitable analytical procedures according to general chapter *2.4.20. Determination of elemental impurities.*

"*N*-Nitrosamines. As many *N*-nitrosamines are classified as probable human carcinogens, manufacturers of medicinal products, except products for veterinary use only and unlicensed pharmaceutical preparations are expected to evaluate the potential risk of *N*-nitrosamine formation and contamination occurring throughout their manufacturing process and throughout their shelf-life, according to the requirements of the relevant competent authorities. If the risk is confirmed, manufacturers should mitigate as much as possible the presence of *N*-nitrosamines – for example by modifying the manufacturing process – and a control strategy must be implemented to detect and control these impurities. General chapter 2.5.42 *N*-Nitrosamines in active substances is available to assist manufacturers."

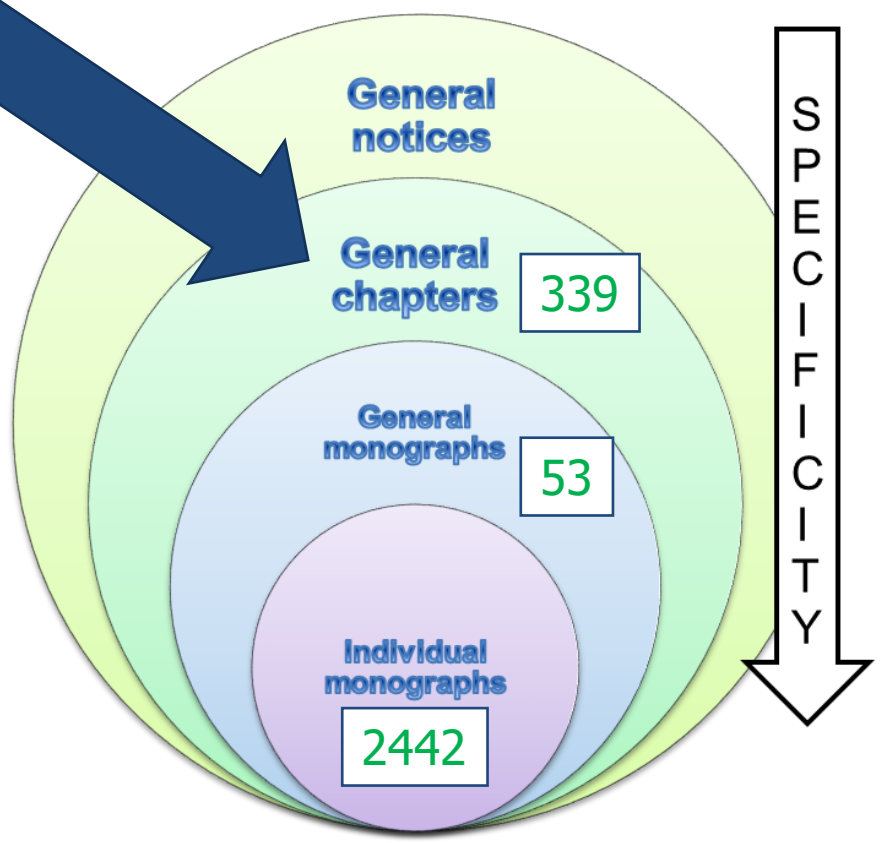
General chapters

Table of contents

- European Pharmacopoeia 10.0
  - European Pharmacopoeia 10.0
    - 00 Introduction
    - 01 General notices
    - 02 Methods of analysis
      - 2.1. Apparatus
      - 2.2. Physical and physicochemical methods
      - 2.3. Identification
      - 2.4. Limit tests
      - 2.5. Assays
      - 2.6. Biological tests
      - 2.7. Biological assays
      - 2.8. Methods in pharmacognosy
      - 2.9. Pharmaceutical technical procedures
    - 03 Materials for containers and containers
    - 04 Reagents

- 05 General Texts
  - 5.1. General texts on microbiology
  - 5.2. General texts on biological products
  - 5.3. Statistical analysis of results of biological assays and tests
  - 5.4. Residual solvents
  - 5.5. Alcoholimetric tables
  - 5.6. Assay of interferons
  - 5.7. Table of physical characteristics of radionuclides mentioned in
  - 5.8. Pharmacopoeial harmonisation
  - 5.9. Polymorphism
  - 5.10. Control of impurities in substances for pharmaceutical use
  - 5.11. Characters section in monographs
  - 5.12. Reference standards
  - 5.14. Gene transfer medicinal products for human use
  - 5.15. Functionality-related characteristics of excipients
  - 5.16. Crystallinity
  - 5.17. Recommendations on methods for dosage forms testing
  - 5.18. Methods of pretreatment for preparing traditional Chinese d
  - 5.19. Extemporaneous preparation of radiopharmaceuticals
  - 5.20. Elemental impurities
  - 5.21. Chemometric methods applied to analytical data
  - 5.22. Names of herbal drugs used in traditional Chinese medicine
  - 5.23. Monographs on herbal drug extracts (information chapter)
  - 5.24. Chemical imaging
  - 5.25. Process analytical technology
  - 5.28. Multivariate statistical process control

(number of texts from Suppl. 11.2)



General chapters

Section 2: Methods of analysis

- Give general requirements for equipment and procedures
- Editorial convenience: avoid repetition in each monograph
- Provide standard procedures that can be used where there is no monograph (with product specific validation)

Section 5: General texts

- Informative texts
- Specific to certain topics (e.g. microbiology, chemometrics)
- In some cases, reproduces the principles of regulatory guidelines

➔ Not mandatory on their own

➔ When referred to in a (general or individual) monograph, they become part of the standard

✓ *2.2.24 IR spectrophotometry,* referred in many ID tests ⟹ Mandatory application

✓ *2.2.48 Raman spectroscopy,* no monograph reference ⟹ For guidance
can be mentioned in applications but has no mandatory character

➔ Some chapters are only informative or provide examples ➔ This is clearly indicated

General Chapters in the Ph. Eur.

WORK PROGRAMME UPDATE

Recent achievements : revised/new GMs

(Not exhaustive)

- N-Nitrosamines in active substances, 2.5.42
- Balances for analytical purposes, 2.1.7
- Raman spectroscopy, 2.2.48
- ★ Chromatographic separation techniques, 2.2.46
- Cell-based assays for potency determination of TNF-alpha antagonists, 2.7.26
- Osmolality, 2.2.35

★ International harmonisation

Balances for analytical purposes, 2.1.7

SUPPL. 10.6, 01/2022

- Applicable for all weighings described in Ph. Eur. texts
- Fitting in the international regulatory landscape (aligned with USP <41> & <1251>)
- Giving recommendations for installation and location
- Including lifecycle management of balances:
  - Qualification;
  - Performance checks, i.e. routine tests for evaluating its error (sensitivity and repeatability tests);
  - internal adjustments.
- Introducing the concepts of smallest net weight (user) and minimum weight (instrument)

Further reading available: https://pbiosn.edqm.eu/app/pbiosn/content/default/2022-1_Weighing_according_to_the_European_Pharmacopoeia.pdf

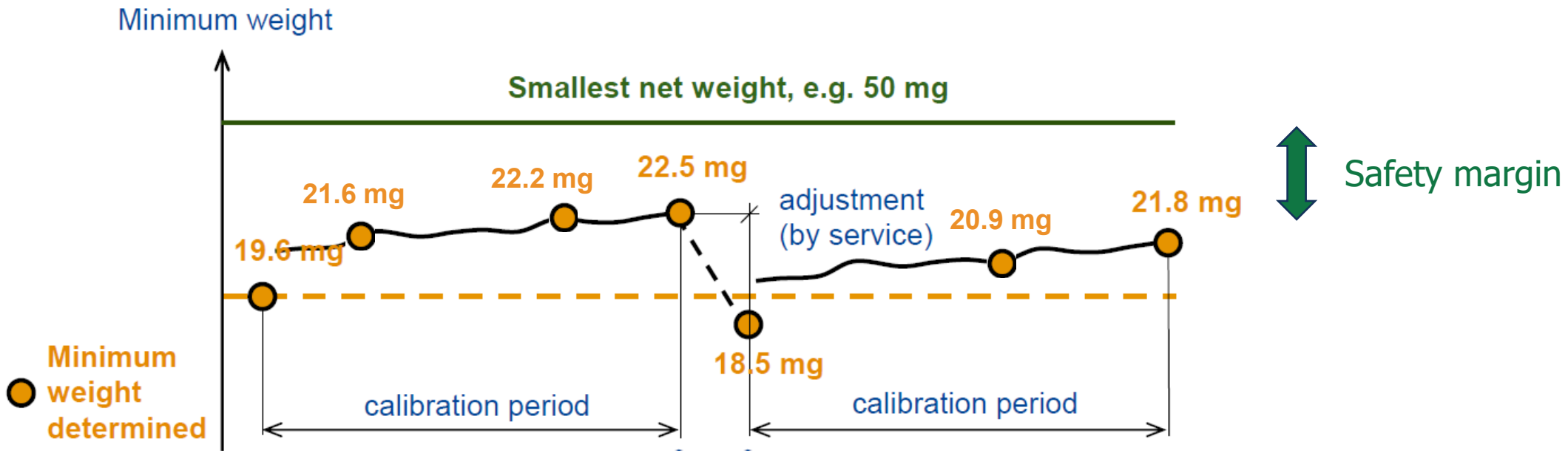
Balances for analytical purposes, 2.1.7: Minimum weight

- Instrument parameter; linked to repeatability performance (st. dev.)

➔Varies with time and external factors

➔m_{snw} must be superior to m_{min} (at least equal=high risk)

In an ideal case: $m_{min} = 2000 \times s = 820 \times d$ (readability)



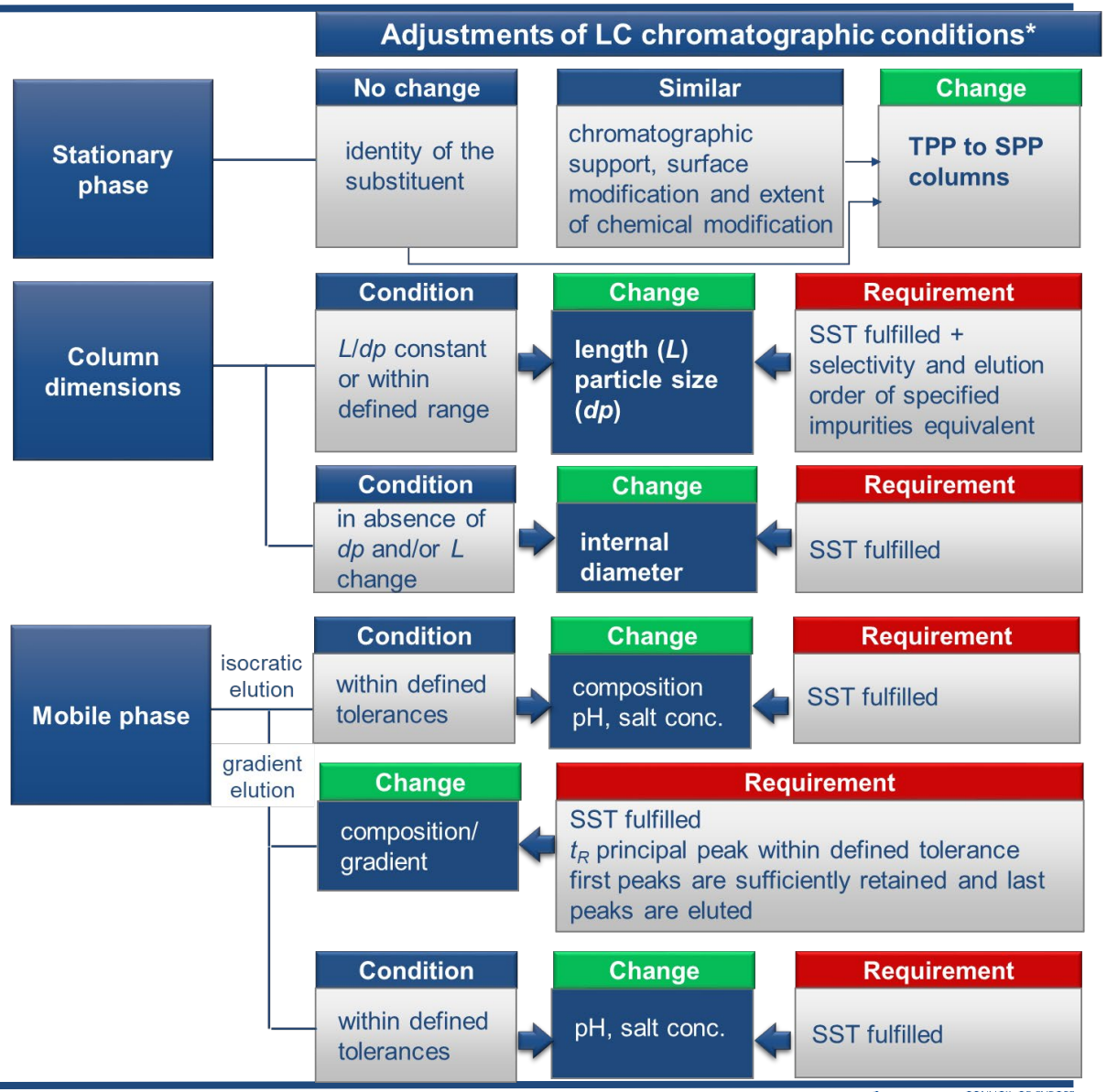
Chromatographic separation techniques (2.2.46)

Widely applicable across chromatography chapters

- Definitions and calculation methods for common parameters (peak, retention time, resolution, etc.)
- System suitability requirements for LC and GC procedures:
  - system repeatability (assay)
  - system sensitivity (tests)
  - peak symmetry [≠ normalisation] (tests and assays)

  complementing those given in the individual monographs.
- **Describes framework for adjustments of chromatographic conditions**

Revised chapter (harmonised with USP and JP), Ph. Eur. 11th Edition, July 2022



*list not exhaustive (further adjustments: flow rate, injection volume)

Adjustments and requirements-compromise at PDG

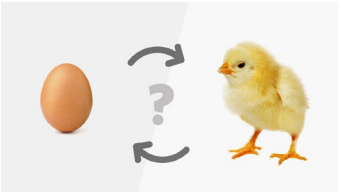
Chapter 2.2.46 provides the framework for adjustments that can be performed without revalidation

- *Column dimensions, permitted modifications* (11.0)
  - For TPP: L/dp within -25 % to +50 % of the prescribed L/dp ratio

  (change from HPLC to UHPLC possible)
  - For SPP: other L/dp provided *N* within – 25 % to + 50 % of the original *N*
- *Stationary phase of column*
  - no change to identity of substituent e.g. no replacement C18 ↔ C8 (older text)
  - similar physico-chemical characteristics + similar surface modification and extent of modification (11.0)

Requirements

- **Former text:** SST requirements must be fulfilled when chromatographic conditions are adjusted and adjustments possible to comply with SST



- **Revised text (11.0):**

SST compliant :
- symmetry (A_s) of peak used for quantitation OK (general SST)
- sensitivity (S/N) at reporting threshold OK (general SST)

+ ADDITIONAL REQUIREMENTS:
- selectivity of specified impurities equivalent
- elution order

➢Valid for isocratic and gradient systems

More flexibility but more safeguards

Key principle of the Ph. Eur.: no successive changes

Ph. Eur. procedure = Reference procedure

- "In the event of doubt or dispute, the analytical procedures of the Pharmacopoeia are alone authoritative."

Adjusted procedure

- Adjustments based on chapter 2.2.46

Adjusted procedure no. 2

- New procedure ➔requires validation

Q&A (1/2)

IMPLEMENTATION OF GENERAL CHAPTER 2.2.46 FOR EXISTING MONOGRAPHS

Revised chapter *(i.e. 2.2.46)* applies to all individual monographs since 1.01.2023.

(Via cross references in the instrumental chapters on LC (2.2.29), GC (2.2.30), etc.)

As mentioned in the *General Notices*, 'General chapters become mandatory when referred to in a monograph, unless the wording clearly indicates that it is not the intention to make the text referred to mandatory but rather to cite it for information.'

[…]

Reference procedure = Ph. Eur. procedure

Q&A (2/2)

IMPLEMENTATION OF GENERAL CHAPTER 2.2.46 FOR IN-HOUSE PROCEDURES

When using an in-house analytical procedure, i.e. a non-pharmacopoeial analytical procedure, general chapter *2.2.46* is not mandatory.

Any reference to and/or application of general chapter *2.2.46* for quality control of substances or medicinal products using chromatographic procedures not described in relevant Ph. Eur. monographs is subject to approval by the competent authority as part of the assessment of a marketing authorisation application.

Ph. Eur. Concepts Related to Analytical Procedures

The analytical procedures given in an individual monograph have been **validated** in accordance with accepted scientific practice and recommendations on analytical validation. Unless otherwise stated in the individual monograph or in the corresponding general chapter, validation of these procedures by the user is not required.

When **implementing** a Ph. Eur. analytical procedure, the user must assess whether and to what extent its suitability under the actual conditions of use needs to be demonstrated according to relevant monographs, general chapters and quality systems.

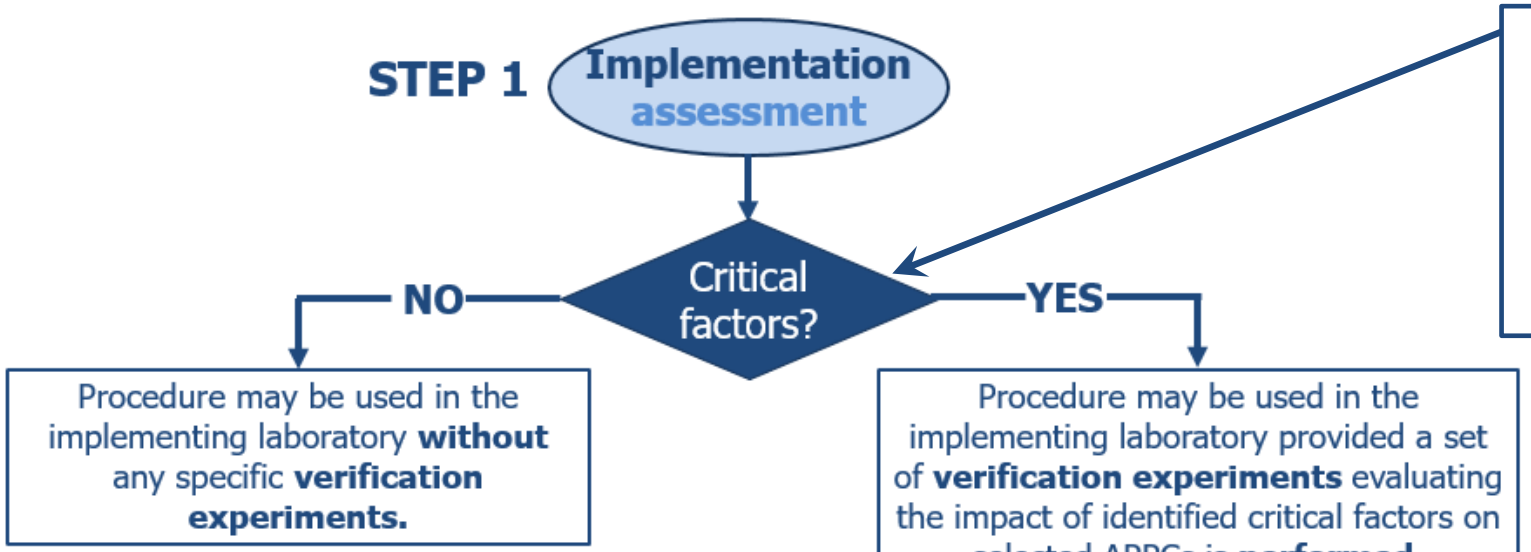
The tests and assays described are the official analytical procedures upon which the standards of the Ph. Eur. are based. With the agreement of the competent authority, **alternative analytical procedures** may be used for control purposes, provided that they enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official procedures were used. In the event of doubt or dispute, the analytical procedures of the Ph. Eur. are alone authoritative.

Ph. Eur. General Notices

Implementation of pharmacopoeial procedures, 5.26

- **Aim**: to provide guidance on setting up an approach for implementation
- « **For information** » chapter; other approaches may be appropriate

NEW 11th Ed., 01/2023



= experiments to verify **relevant APPCs** depending on **intended use** wrt defined **acceptance criteria**

- composition of the article under test ;
- complexity of the sample preparation ;
- reagents required to run the procedure ;
- laboratory equipment required to run the procedure ;
- laboratory environment.

Intended use / APPCs	Identification	Testing for impurities		Assay - content/potency - dissolution (measurement only)	Other quantitative tests
		limit	quant.		
Accuracy	○	○	○	◗	◗
Precision					
Repeatability	○	○	●	●	●
Interm. prec.	○	○	◗	◗	◗
Specificity/ Selectivity	◗	●	●	●	◗
Sensitivity	○	●	●	○	◗
Linearity	○	○	○	◗	◗
Range	○	○	○	◗	◗
Robustness	○	○	◗	◗	◗

5.26 IMPLEMENTATION EXAMPLES

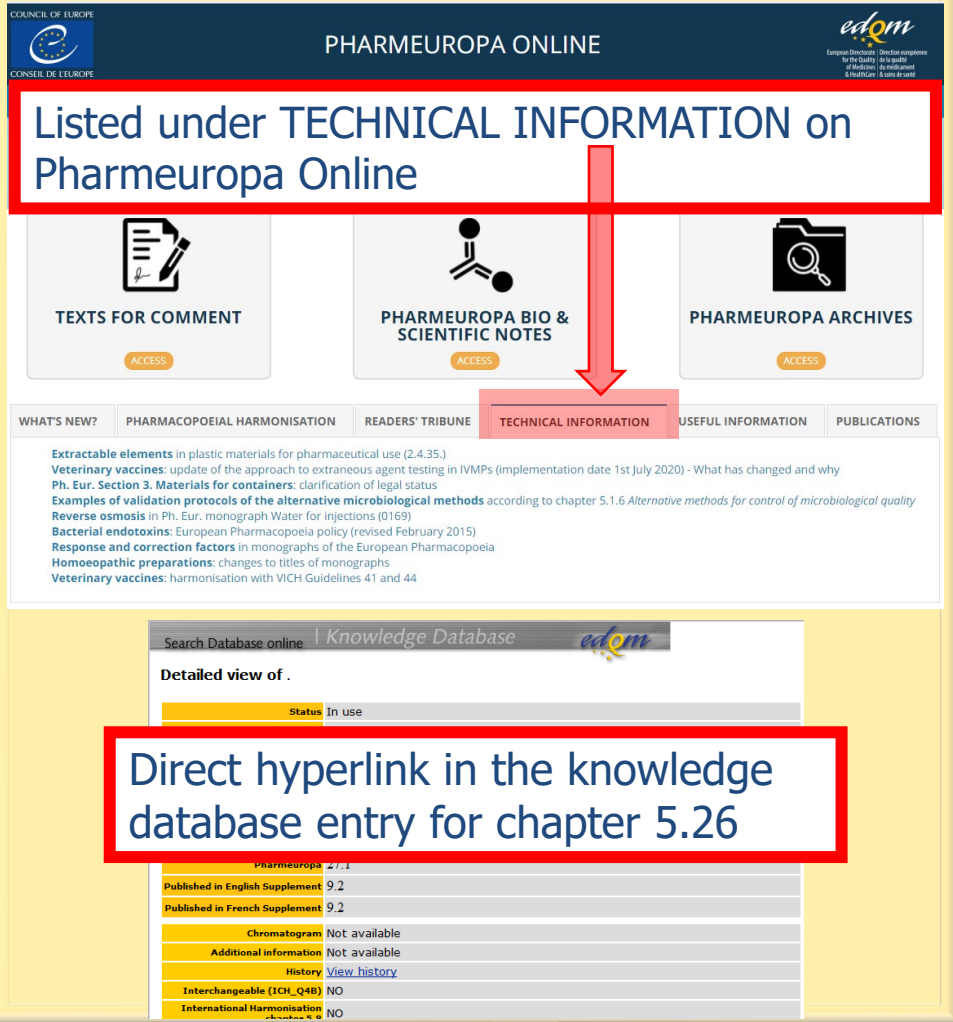
AVAILABLE ONLINE

WHY

WHAT

- Assay for an active substance (by LC-UV)
- Impurity test for a medicinal product (by LC)
- Cell based assay
- Identification by IR spectroscopy
- Simple procedure : Sulfated Ash
- Microbial enumeration tests

WHERE



Comparability of alternative analytical procedures, 5.27

✓Flexibility in the Ph. Eur., extract of the General Notices (1.1.2.5)

"The tests and assays described are the official analytical procedures upon which the standards of the Ph. Eur. are based. With the agreement of the competent authority, alternative analytical procedures may be used for control purposes, provided that they enable an unequivocal decision to be made as to whether compliance with the standards of the monographs would be achieved if the official procedures were used. In the event of doubt or dispute, the analytical procedures of the Ph. Eur. are alone authoritative."

✓Users' responsibility to demonstrate comparability to the satisfaction of the *competent authority*

✓Compliance required, but alternative procedures may be used: same pass/fail decision

✓The pharmacopoeial procedure is the reference procedure

Just recently adopted by the European Pharmacopoeia Commission

Principle

- Published for information
- Guidance on some possible approaches
- Thin line between sufficient guidance and restrictive requirements

Scope

- **Cases where a pharmacopoeial (official) analytical procedure, as referenced in an individual monograph, would be replaced by an alternative ("in-house") analytical procedure**

Not in scope

- Development of new analytical procedures
- Application of pharmacopoeial analytical procedures to articles not covered by Ph. Eur.

Process for comparability, 5.27

Comparison of data obtained in the implementation of the phar.AP and validation of the alt.AP in terms of APPCs

Validation of the alternative procedure

Prerequisites

Implementation of the pharrmacopoeial procedure

Step 1: Comparability assessment

Study design

Step 2: Comparability study

Head-to-head testing, with the aim of reaching the same analytical decision
→ particularities: same experiments, same samples

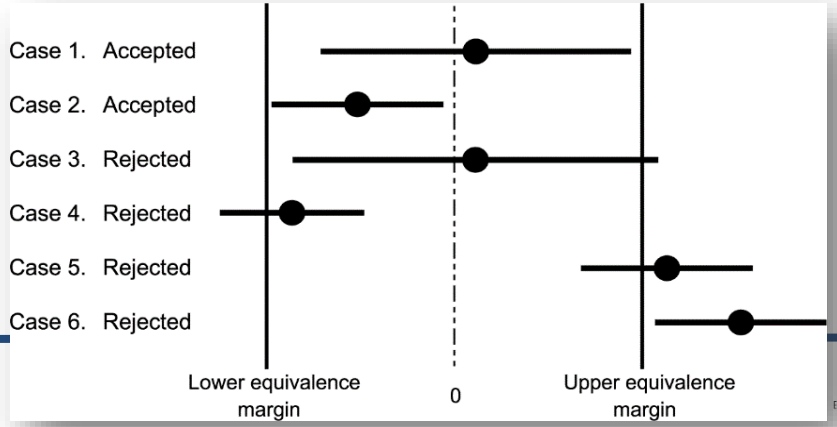
Study report

summarises the results and conclusion of the study, as well as other relevant information (e.g. deviations from study protocol, newly obtained information on the procedure(s) and or tested samples)

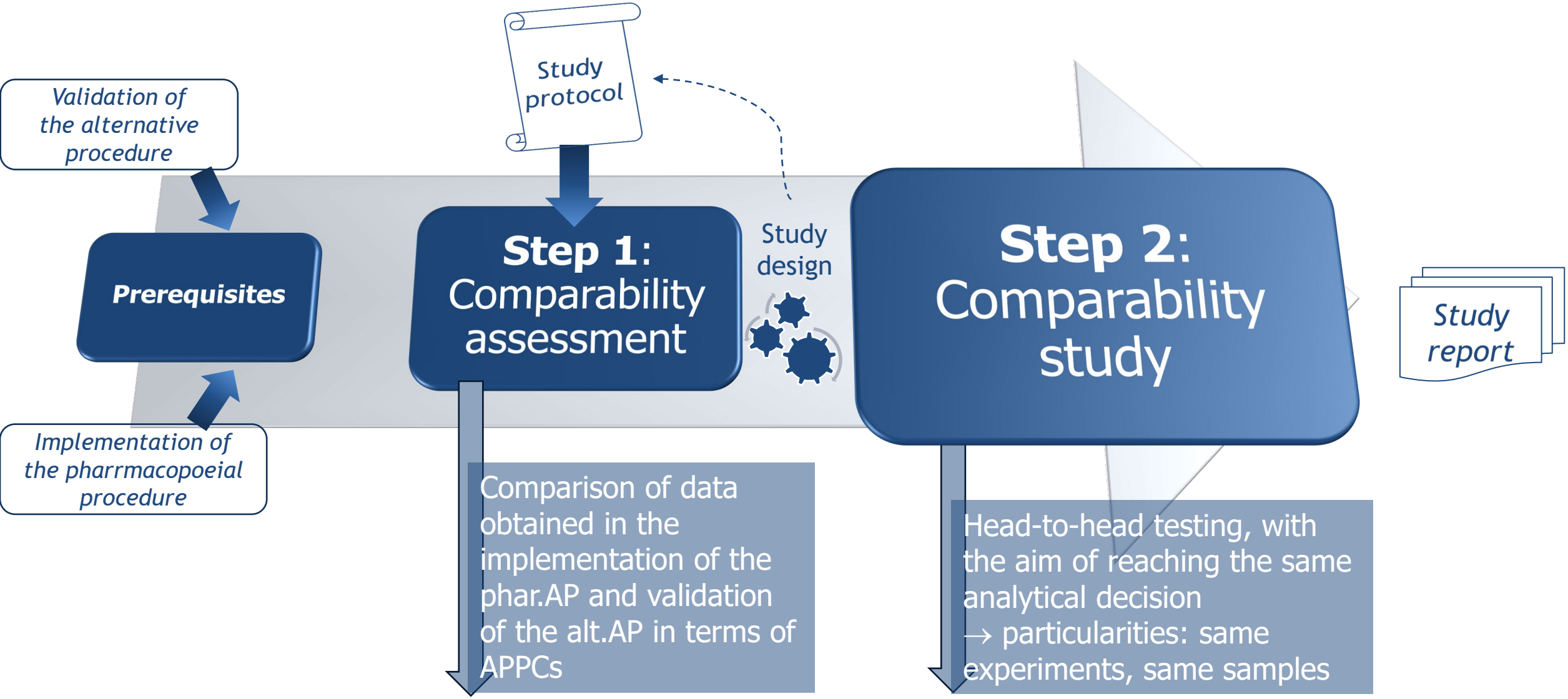
Study protocol

Covers selection of samples and sample size, APPCs to be included and method for statistical evaluation of data
Includes definition of comparability through setting of **equivalence margin(s)** and **acceptance criteria**

Typical outcomes of a comparability study

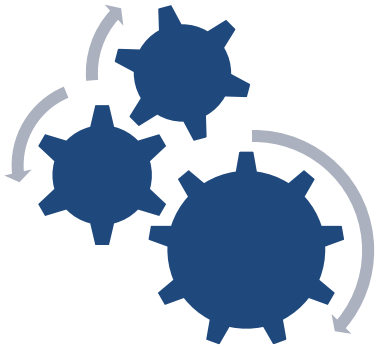


Process

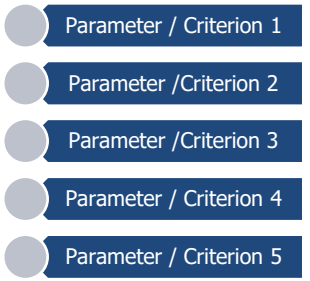


Study design

- Based on the outcome of the comparability assessment
- Considers special cases where testing in a head-to-head format is not feasible



- **Study protocol**
  - Is established on the basis of the study design
  - Covers selection of samples and sample size, APPCs to be included and method for statistical evaluation of data
  - Includes definition of comparability through setting of **equivalence margin(s)** and **acceptance criteria** and their justification

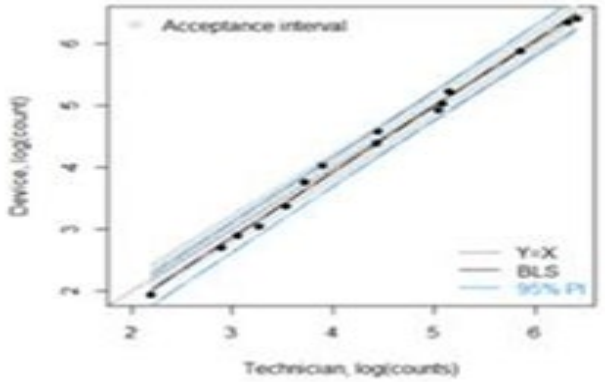


- **Study report**:
  - summarises the results and conclusion of the comparability study, as well as other relevant information (e.g. deviations from study protocol, newly obtained information on the procedure(s) and or tested samples)

Data evaluation

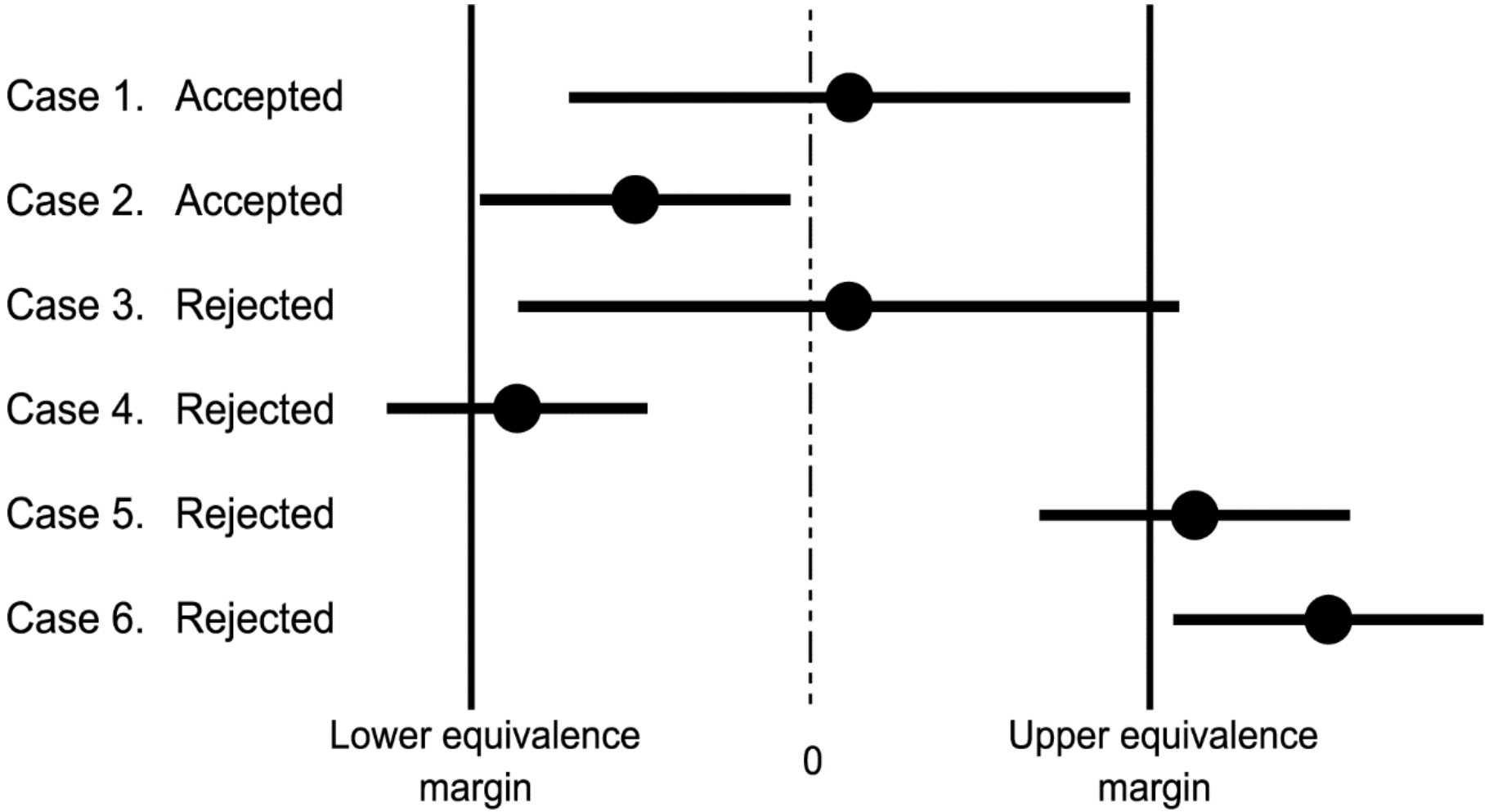
Statistical evaluation of results

- *Step 1. Data description*
- *Step 2. Statistical assumptions*
- *Step 3. Equivalence testing*

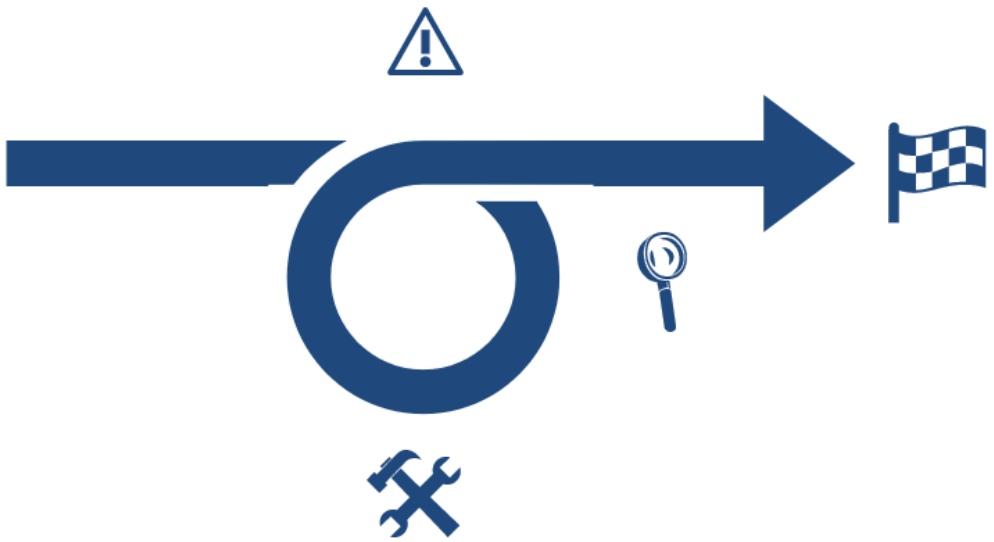


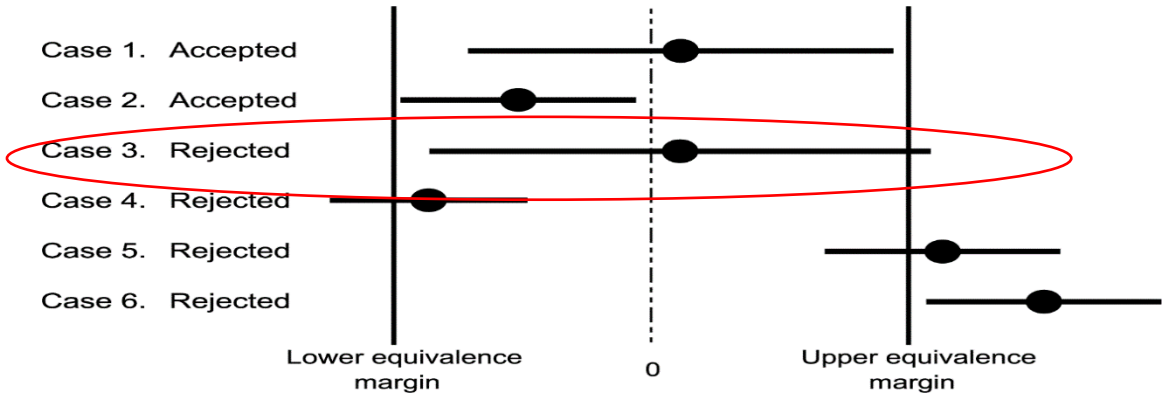
- For quantitative results - Comparison of two group means: two one-sided t-tests (TOST) method
- For results spreading over a wider range than those obtained at a single level, a regression approach (e.g. Deming regression, bivariate least squares regression)
- Other approaches may be appropriate
- Pass/Fail criterion is key

Typical outcomes of a comparability study



Statistical evaluation of results



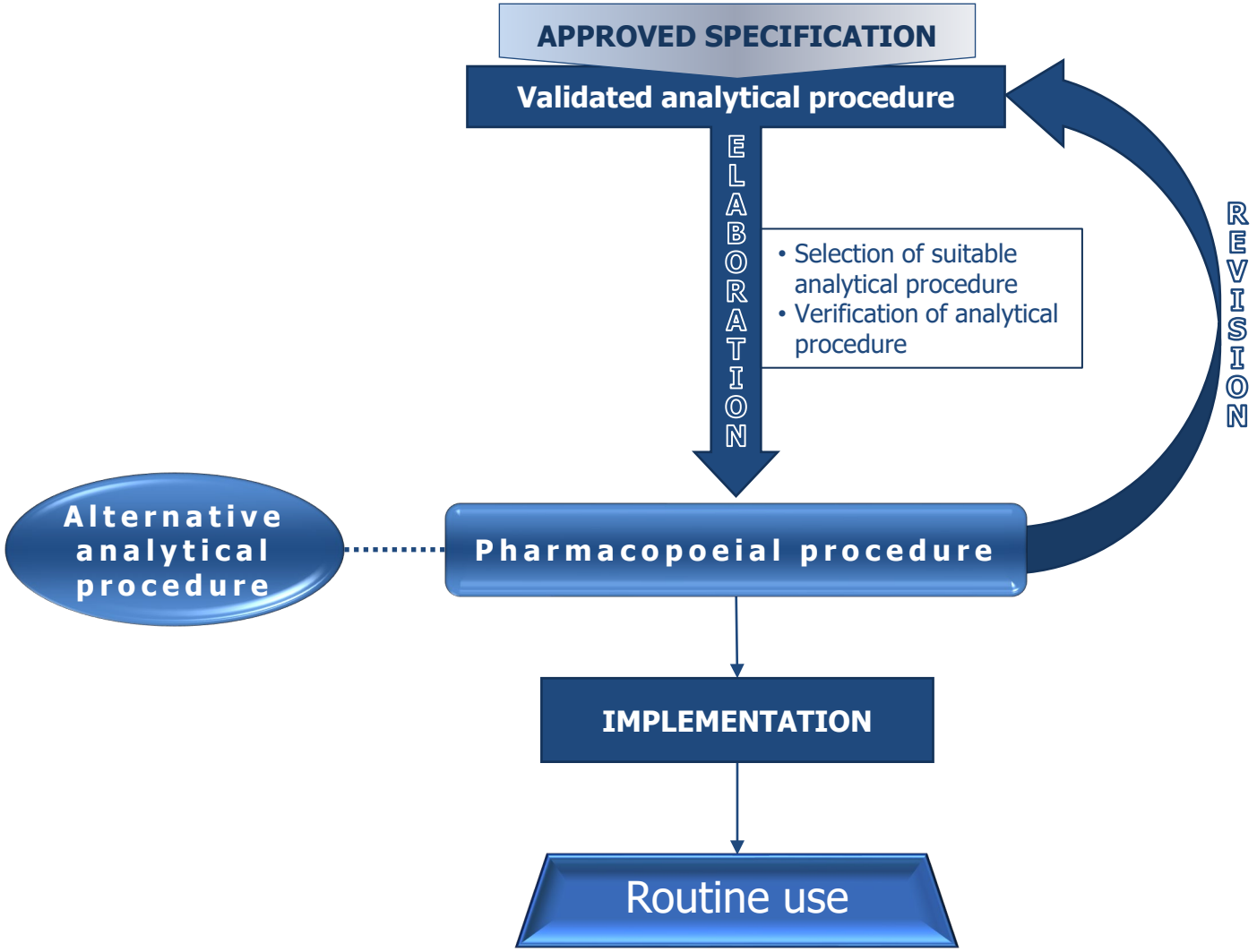


In cases where the comparability cannot be accepted directly, certain flexibility is present:
- available data may be reviewed and if bias and/or variability is observed and steps taken to reduce it, the assessment may be relaunched, including e.g. performing additional experiments.

This possibility needs to be clearly defined in the study protocol

E.g. Case 3: If the root cause for the spread of the results can be found, and better precision reached in a repeated test, the outcome would change to accepted.

Lifecycle of the pharmacopoeial procedure



- If a user considers the alternative analytical procedure to bring significant improvement for the quality of the article, they are encouraged to contact EDQM and/or submit a request for a **revision**
- In the event of a problem with a pharmacopoeial procedure (e.g. implementation difficulties), NPA or EDQM should be contacted and if confirmed, this may result in a revision → inadequate method renders comparability impossible, **hence not a case for an alternative procedure**

Some updates in the pipeline

★ International harmonisation

★ Determination of elemental impurities, 2.4.20 (after Pharmeuropa)

★ Particulate contamination: sub-visible particles, 2.9.19 (after Pharmeuropa)

- Design of experiments, 5.33 (after Pharmeuropa)

★ Capillary electrophoresis (in Pharmeuropa 35.3)

★ Disintegration of tablets and capsules, 2.9.1 (in Pharmeuropa 35.2)

- Flow cytometry, 2.7.24 (in Pharmeuropa 35.4)
- *N*-Nitrosamines in active substances **& medicinal products**, 2.5.42 (prepared for Pharmeuropa)

Recent major additions on the work program

NON EXHAUSTIVE

- High Throughput Sequencing for the detection of extraneous agents in biological products (2.6.41)
- Evaporative light scattering detection, 2.2.62
- Charged aerosol detection, 2.2.69
- Identification and control of residual solvents, 2.4.24
  - ➢ *Alignment with ICH Q3C(R8) and general revision*
- Cell-based preparations, 5.32
- Recombinant viral-vectored vaccines for human use, 5.37
- Quality aspects for data analysis, 5.38
  - ➢ Framework to ensure that the data used for analysis, decision making and subsequent actions is reliable

Update on strategy

Medicinal product monographs

Medicinal product monographs (chemically defined API)

2012
Start of the pilot phase:
* 1 single-source product (P4)
* 1 multi-source product (P1)

2014
Scope of the Ph. Eur. widened:
* P4 mono. in Pharmeuropa
* Focus on single-source

2015
* Adoption of the first P4 mono. ***'Sitagliptin tablets'***
* Addition to the WP of the first P1 mono.

2019
* Adoption of the first P1 mono. ***'Rosuvastatin tablets'***
* Creation of group 17 (multi-source products)

2022
* Addition to the WP of the first mono. on combination product

11th Edition

23
monographs adopted
(21 P4 & 2 P1)

2
Expert groups highly involved in the elaboration of
33 monographs
(17 P4 & 13 P1)

2
monographs in Pharmeuropa

Elaboration frame established
(e.g. impurity control, dissolution test, API salts and solvates)
Dedicated Technical Guide

12th Edition
Increase the number of medicinal product monographs in the Ph. Eur.

General policy and approaches

- General policies are captured in the Technical Guide for the elaboration of monographs on medicinal products containing chemically defined active substances (3rd Edition, 2023)
- Recent updates of the guide include:
  - elaboration of combination medicinal products
  - policy on repeatability criterion (Assay/Dissolution) – **RSD value of 1.0% (n=6)** as a general rule confirmed after the trial period (ended in March 2023)
  - indication of the strength(s) of the medicinal product considered during the elaboration of the monograph is provided to users in the EDQM Knowledge database (for information) once a monograph is published (FAQ, March 2023)

- Policy is evolving to best tackle the needs and reflect the regulatory requirements and scientific progress

Update on strategy

Other topics

New activities / new working parties

- AQbD : Assess the **feasibility and impact of incorporating analytical procedures developed using the concepts of AQbD** in Ph. Eur. monographs
- EXS (Excipient strategy): Identify and discuss best possible approach(es) to address the **quality and the standard setting process of excipients** for pharmaceutical use
- mRNAVAC : already 3 new general texts on the work programme, addressing aspects related to the production and control of mRNA vaccines and their components
- Nano(medicines) : Drafting and revision of texts in the field of nanomedicines
- BACT(eriophages) : general text back from public consultation *Phage therapy active substances and medicinal products for human and veterinary use (5.31)*

Numerous technical decisions made and texts approved e.g.:

- Ph. Eur. allows the use of recombinant factor C for control of bacterial endotoxins in water monographs
- EDQM publishes 2nd edition of Herbal Guide
- Ph. Eur. Commission keeps pace with veterinary vaccine development efforts
- Ph. Eur. Commission kicks off elaboration of three general texts on mRNA vaccines and components
- The future of pyrogenicity testing: new approaches discussed at joint EDQM-EPAA event
- Ph. Eur. Commission adopts revised general monographs 2034 and 2619 after inclusion of new paragraph on control of N-nitrosamines
- Revised general chapter on rubber closures published in the Ph. Eur. Supplement 11.1

Join us in paving the way for the future…

Contribute to the protection of public health by:

- Making your comments count !!!

PHARMEUROPA ONLINE

TEXTS FOR COMMENT

ACCESS

- Becoming part of a dynamic scientific community !!!

Thank you for your attention

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