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Module 1:
General Methods, General Chapters & General Monographs

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(Live Webinar)
Date: 1 December 2025

Outline

- The EDQM and the European Pharmacopoeia
- Structure of the Ph. Eur. & general principles
  - General Notices
  - General monographs
  - General chapters
- General chapters work programme update
  - Recently published
  - Major items in the work programme
  - Public consultation items
  - New entries in the work programme
- Update on Ph. Eur. strategy

The EDQM and the European Pharmacopoeia

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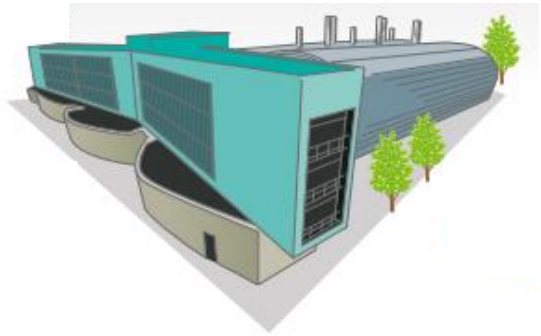
Council of Europe ≠ European Union!

COMMITTEE OF MINISTERS | PARLIAMENTARY ASSEMBLY | CONGRESS OF LOCAL AND REGIONAL AUTHORITIES | EUROPEAN COURT OF HUMAN RIGHTS | COMMISSIONER OF HUMAN RIGHTS | CONFERENCE OF INGOS

- Founded in **1949**
- **Intergovernmental** organisation, Strasbourg
- **46** Member States
- More than **700 Millions** of Citizens

Alain Berset is the 15th Secretary General of the Council of Europe.

The **European Directorate for the Quality of Medicines and HealthCare** (EDQM)



- Founded in 1964
- Work in the framework of a **Partial Agreement, 39 Members & the EU**
- Contribute to **Public Health and access to good quality medicines and healthcare in Europe**
- Publish the **European Pharmacopoeia (Ph. Eur.)**
- Official languages: **English** and **French**

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EDQM

- ★ Founded in **1964**
- ★ Partial agreement
  (39 members states & the EU
  + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities

* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

Our vision

Together for better health, for all

Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders

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The edqm is relevant to you in many ways…

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European Pharmacopoeia:
Documentary and reference standards

Legally binding in the **40 signatory parties** of the Ph. Eur. Convention and used as a reference **worldwide**; **33 observers** from all continents

Almost **3000 documentary standards** for the quality control of medicines covering the whole manufacturing process

All stages of the **life cycle** of a medicine from development to production and market surveillance

About **3 300 reference standards** shipped to **127 countries**

Laboratory, production, storage and distribution

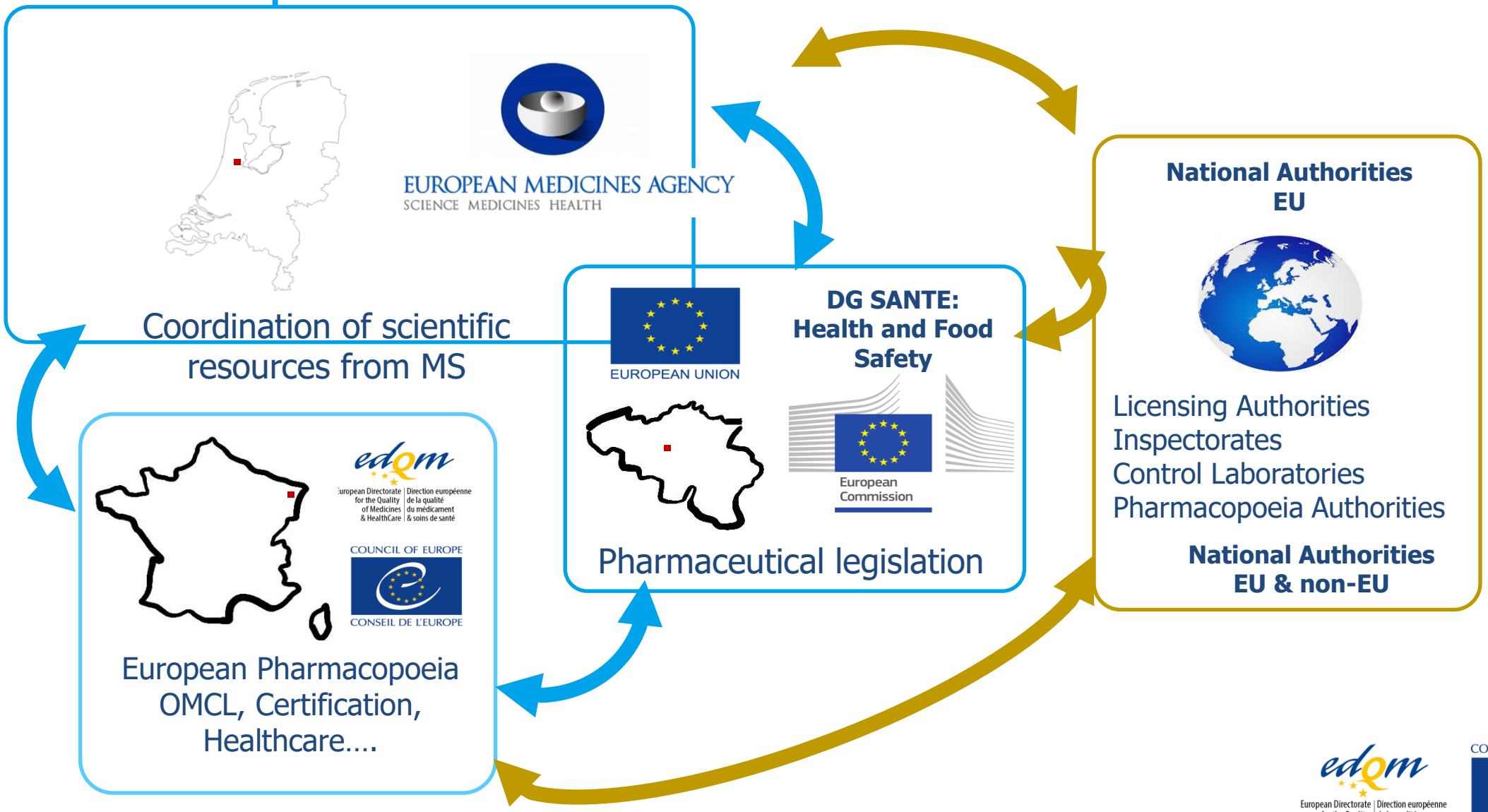
European Pharmacopoeia Commission – treaty-based body - and its experts' groups

Biological Standardisation Steering Committee

PUBLIC HEALTH IMPACT

- Ensures quality and safety of medicinal products
- Facilitates their free movement in Europe and beyond

Relationship with other bodies

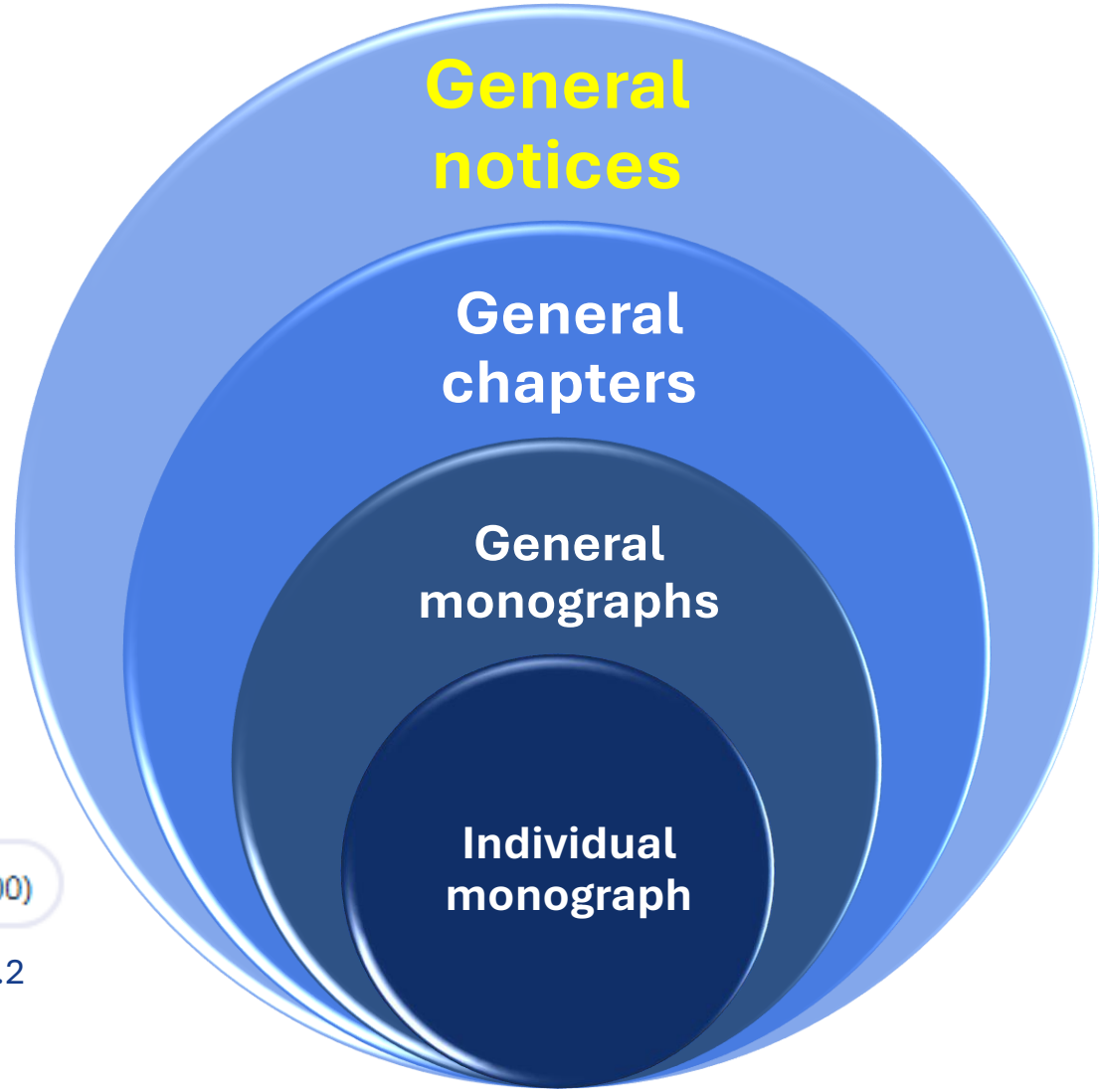


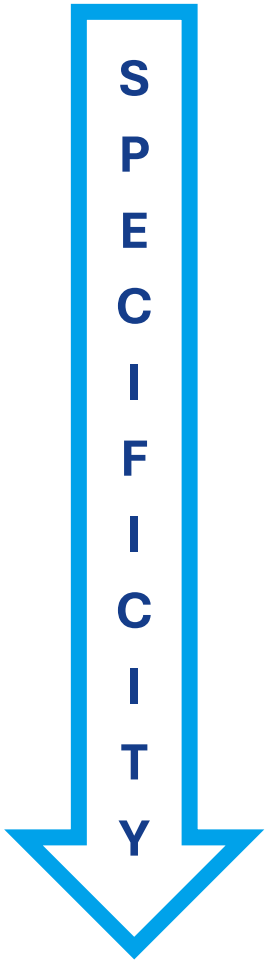
Structure of the Ph. Eur.

Text type

- General information (2)
- General Notices (1)
- General chapter (372)
- General monograph (62)
- Reagent (2936)
- Individual monograph (2500)

In Issue 12.2





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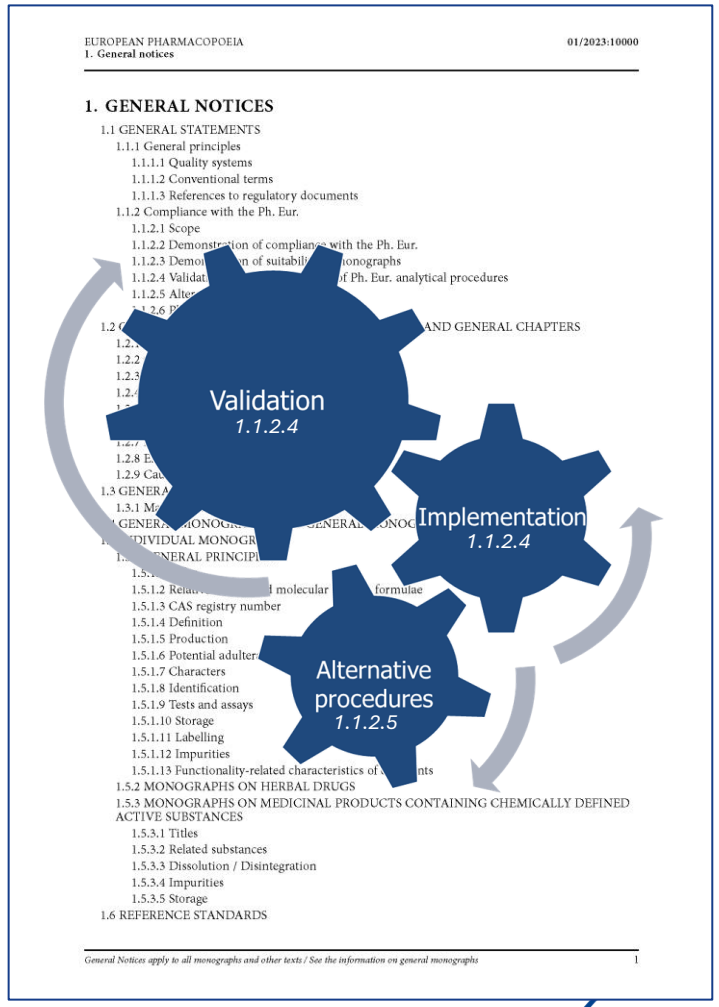
General Notices

New version in 12th Edition

At the very beginning of the Ph. Eur.

- apply to all texts including general chapters and texts
- aim at providing basic information to the user
- address **general topics**
- describes **general principles**, including *flexibility*
- include rules to understand texts, conventional expressions

Essential reading before starting to use monographs and other texts!



Ph. Eur. concepts related to analytical procedures

Find out more about the new Ph. Eur. online platform:
https://www.edqm.eu/en/-/unlocking-the-potential-of-the-european-pharmacopoeia-online

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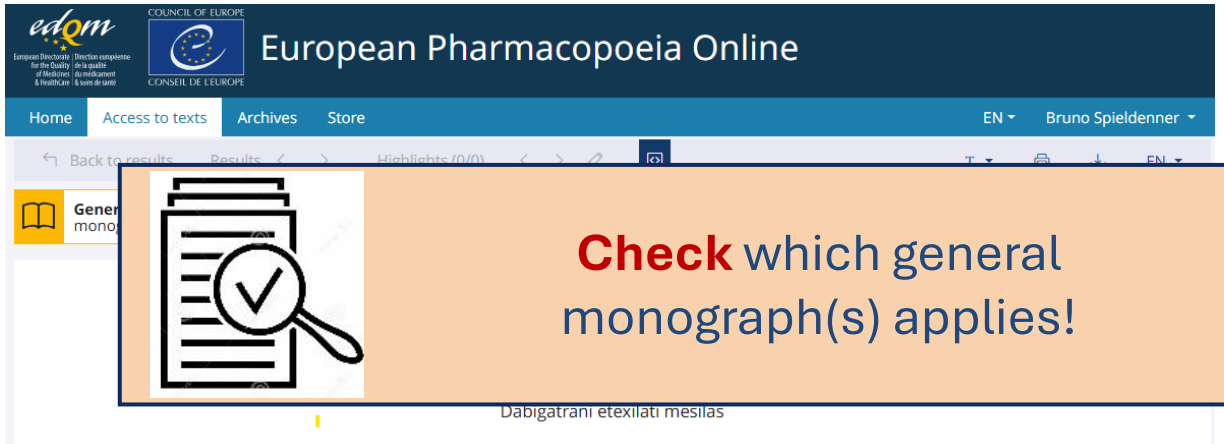
General monographs

Complementary to individual monographs

User's responsibility to consider relevant general monographs



GENERAL MONOGRAPHS

Allergen products (1063)
Chemical precursors for radiopharmaceutical preparations (2902)
Dosage forms *(published in the Dosage forms section)*
Essential oils (2098)
Gene therapy medicinal products for human use (3186)
Herbal drug extracts (0765)
Herbal drug preparations (1434)
Herbal drugs (1433)
Herbal drugs for homoeopathic preparations (2045)
Herbal teas (1435)
Herbal teas, instant (2620)
Homoeopathic preparations (1038)

EXAMPLES

	Active substance	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)*

Ph. Eur. General Chapters

Methods of analysis (section 2)

- Provide general requirements for equipment, equipment qualification or calibration
- Avoid repeating standard procedures or requirements in each monograph
- Provide standard analytical procedures that may be used when there is no monograph (with product-specific validation)
- Become mandatory when referred to in a monograph, unless otherwise stated (mandatory also when referred to in another general chapter that is itself referred to in a monograph, unless otherwise stated)
- Provide a harmonized analytical framework, common analytical expectations; widely applicable
- May include product-specific considerations; serve as a starting point for development of product-specific analytical procedures

General texts (section 5)

- Often published for information and guidance
- Become mandatory when referred to in a monograph
- Specific to certain topics (e.g. microbiology, chemometrics)
- Reproduce principles of regulatory guidelines
- May provide a non-mandatory framework of recommendations

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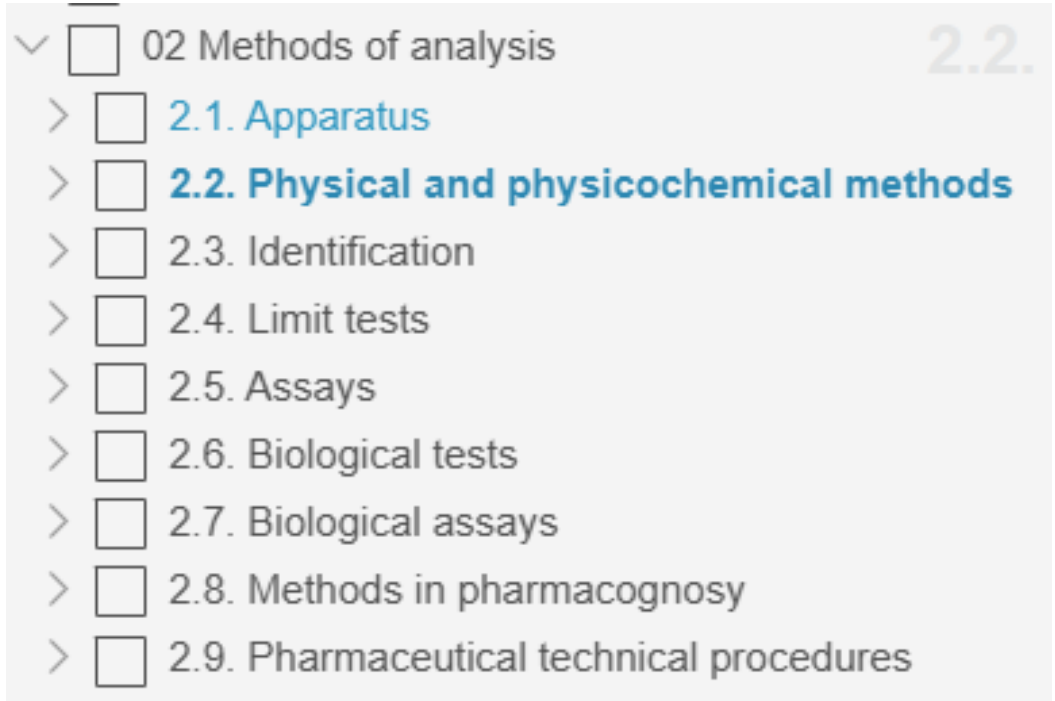
Ph. Eur. Methods of Analysis



2.2.29. LIQUID CHROMATOGRAPHY

PRINCIPLE

Liquid chromatography (LC) is a chromatographic separation technique based on the difference in the distribution of species between 2 non-miscible phases, in which the mobile phase is a liquid that percolates through a stationary phase contained in a column.

2.5.33. TOTAL PROTEIN

Many of the assay methods described in this chapter can be performed using kits from commercial sources.

METHOD 1

2.6.34. HOST-CELL PROTEIN ASSAYS

This general chapter provides guidance for the development and validation of host-cell protein (HCP) assays used to test products obtained by recombinant DNA technology. It does not exclude the use of alternative approaches that are acceptable to the competent authority.

2.7.26. CELL-BASED ASSAYS FOR POTENCY DETERMINATION OF TNF-ALPHA ANTAGONISTS

The assays described (Procedures A, B, C and D) have been validated for the potency determination of specific TNF-alpha antagonist substances (i.e. Procedure A – etanercept; Procedure B – infliximab; Procedure C – certolizumab pegol and Procedure D – adalimumab). Whereas full validation

2.2.46. CHROMATOGRAPHIC SEPARATION TECHNIQUES[1]

INTRODUCTION

Chromatographic separation techniques are multi-stage separation methods in which the components of a sample are distributed between 2 phases, one of which is stationary, while the other is mobile. The stationary phase may be a solid or a

2.5.32. WATER: MICRO DETERMINATION

PRINCIPLE

The coulometric titration of water is based upon the quantitative reaction of water with sulfur dioxide and iodine in an anhydrous medium in the presence of a base with sufficient

2.6.35. QUANTIFICATION AND CHARACTERISATION OF RESIDUAL HOST-CELL DNA

This general chapter describes analytical methods that may be used to measure the content and to characterise the size of residual host-cell DNA in biological products produced in cell substrates. It does not exclude the use of alternative approaches that are acceptable to the competent authority.

Examples

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Ph. Eur. Concepts Related to Analytical Procedures

- **Ph. Eur. Chapter 1 General Notices:**

1.1.2.4 Validation and implementation of Ph. Eur. analytical procedures

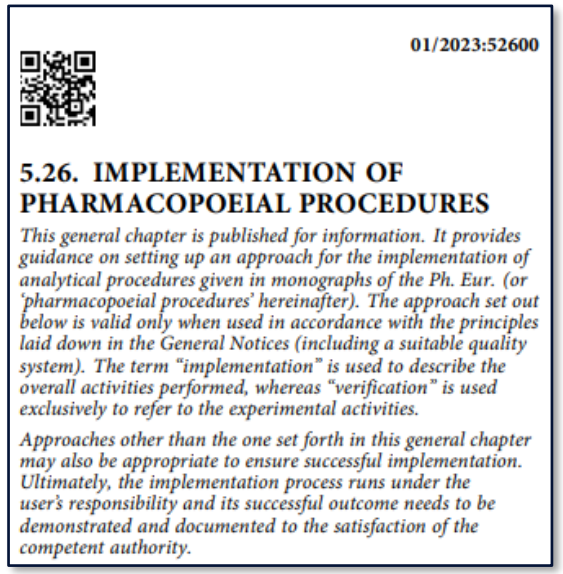
The analytical procedures given in an individual monograph have been **validated** in accordance with accepted scientific practice and recommendations on analytical validation. Unless otherwise stated in the individual monograph or in the corresponding general chapter, validation of these procedures 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.

1.1.2.5 Alternative analytical procedures

*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**.*

General Text 5.26: Implementation Process



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5.26. IMPLEMENTATION OF PHARMACOPOEIAL PROCEDURES

This general chapter is published for information. It provides guidance on setting up an approach for the implementation of analytical procedures given in monographs of the Ph. Eur. (or 'pharmacopoeial procedures' hereinafter). The approach set out below is valid only when used in accordance with the principles laid down in the General Notices (including a suitable quality system). The term "implementation" is used to describe the overall activities performed, whereas "verification" is used exclusively to refer to the experimental activities.

Approaches other than the one set forth in this general chapter may also be appropriate to ensure successful implementation. Ultimately, the implementation process runs under the user's responsibility and its successful outcome needs to be demonstrated and documented to the satisfaction of the competent authority.

STEP 1

Implementation assessment

- To identify any **critical factors** related to the actual conditions of use that may affect the performance of the pharmacopoeial procedure:
  - 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
- Carried out in conjunction with provisions given in monographs and relevant general chapters (e.g. suitability requirements or any other described performance tests)

Critical factors?

NO

Procedure may be used in the implementing laboratory **without** any specific **verification experiments**

YES

Procedure may be used provided a set of **verification experiments** evaluating the impact of identified critical factors on selected APPCs is **performed**

VERIFICATION

STEP 2

General Text 5.26: Implementation Process

STEP 2 - VERFICATION EXPERIMENTS

- To **demonstrate** that the implementation is feasible
- **Relevant APPCs** are assessed and verified depending on the objective of the analytical procedure.

Verification plan

- Experiments required to verify **critical APPCs** together with the corresponding acceptance criteria defined by the user
- Suitability tests prescribed in an individual monograph and/or relevant general chapter can be used as a partial or full verification of the corresponding APPCs

5.26. IMPLEMENTATION OF PHARMACOPOEIAL PROCEDURES

Table 5.26.-1. – *Relevant APPCs to be recommended for verification based on the intended use of the procedure*

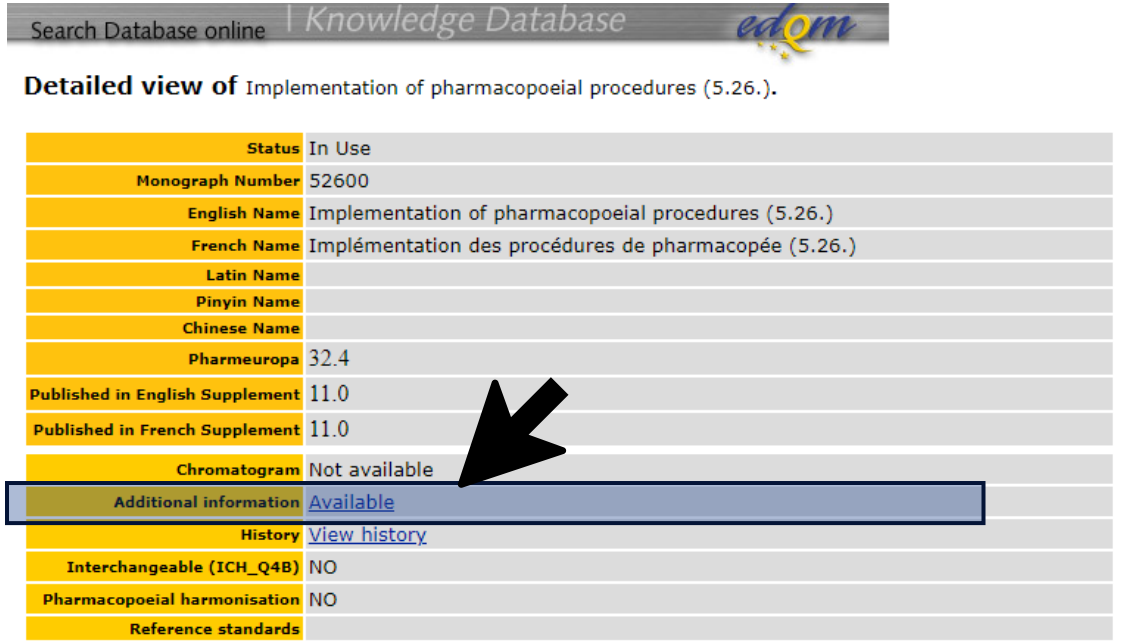
Intended use / APPCs	Identification	Testing for impurities		Assay - content/potency - dissolution (measurement only)	Other quantitative tests
		Limit test	Quantitative test		
Accuracy	○	○	○	◗	◗
Precision					
- Repeatability	○	○	●	●	●
- Intermediate precision	○	○	◗	◗	◗
Specificity/Selectivity	◗	●	●	●	◗
Sensitivity	○	●	●	○	◗
Linearity	○	○	○	◗	◗
Range	○	○	○	◗	◗
Robustness	○	○	◗	◗	◗

● *signifies that this characteristic should be experimentally verified.*
◗ *signifies that this characteristic should be experimentally verified, if impacted by critical factors from the actual conditions of use in the implementing laboratory.*
○ *signifies that this characteristic is typically not relevant for purposes of verification.*

Compliance with pre-defined acceptance criteria demonstrates that implementation of the pharmacopoeial procedure for a given article is feasible.

Implementation of Pharmacopoeial Procedures (5.26)

- **Examples of implementation** of pharmacopoeial procedures according to 5.26:
  - for **illustrative purposes** only
  - "Ultimately, the **implementation process** runs under the **user's responsibility** and its successful outcome needs to be demonstrated and documented to the satisfaction of the competent authority."



Selected examples

Pharmacopoeial procedure	Ph. Eur. monograph	Ph. Eur. General chapter
Identification by IR	0559, Mannitol (07/2019)	2.2.24. Absorption spectrophotometry, infrared
Related substances test by LC-UV	2986, Deferiprone tablets (01/2022)	2.2.29 Liquid chromatography 2.2.46 Chromatographic separation techniques
Potency by cell-based assay	2928, Infliximab concentrated solution (04/2023)	2.7.26 Cell-based assays for potency determination of TNF-alpha antagonists, Procedure B

Key Aspects of General Chapter 5.27

Framework

- Published for information
- Guidance on possible approaches
- No new requirements introduced
- ‘Comparability’ ≠ ‘equality’

Scope

- Cases where a pharmacopoeial (official) analytical procedure, as referenced in an individual monograph, would be replaced by an alternative (“in-house”) analytical procedure
- Applies to qualitative and quantitative analytical procedures

Not in scope

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

5.27. COMPARABILITY OF ALTERNATIVE ANALYTICAL PROCEDURES

This general chapter is published for information. It
an alternative analytical procedure to a pharmacop
demonstrated. Other approaches to demonstrating c
The use of an alternative procedure is subject to autho
The final responsibility for the demonstration of compara
the successful outcome of the process needs to be demonstrated and documented to the satisfaction of the competent authority. Comparability must be maintained over the lifecycle of both the pharmacopoeial and alternative

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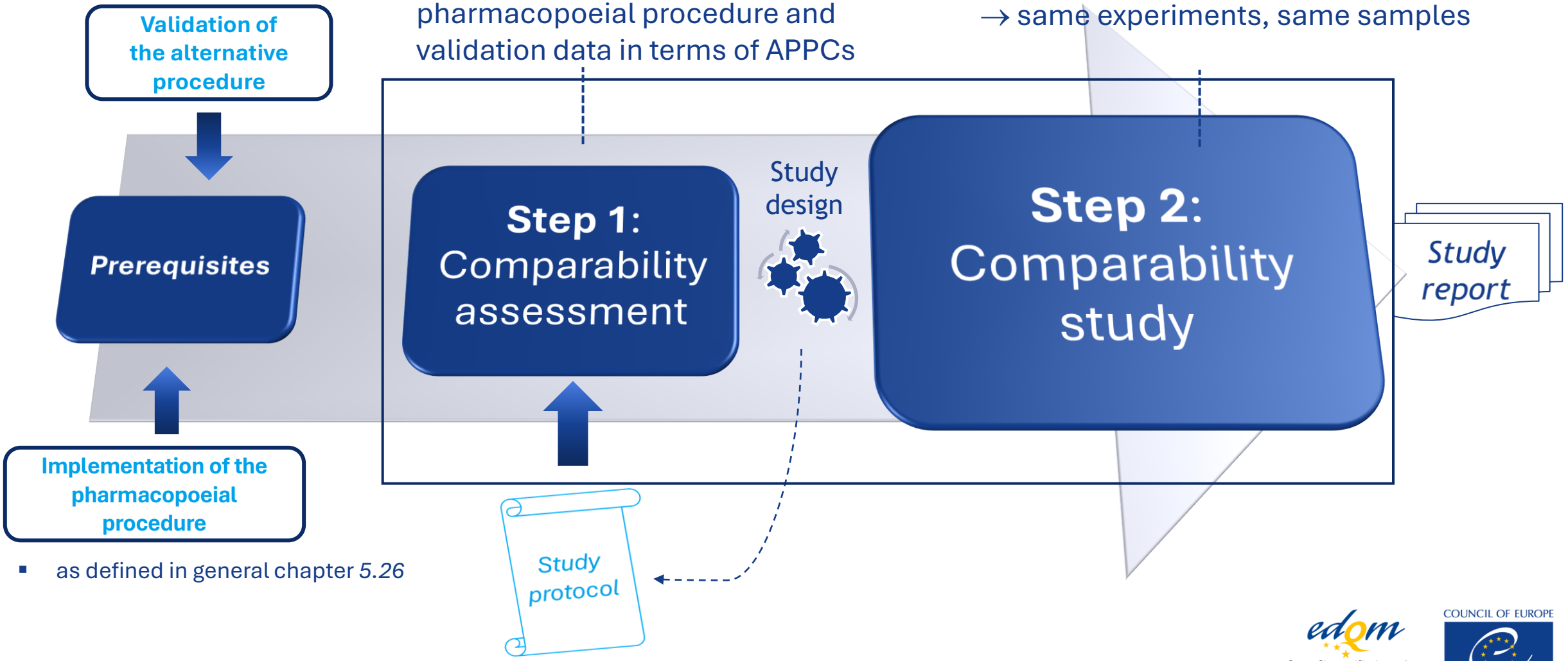
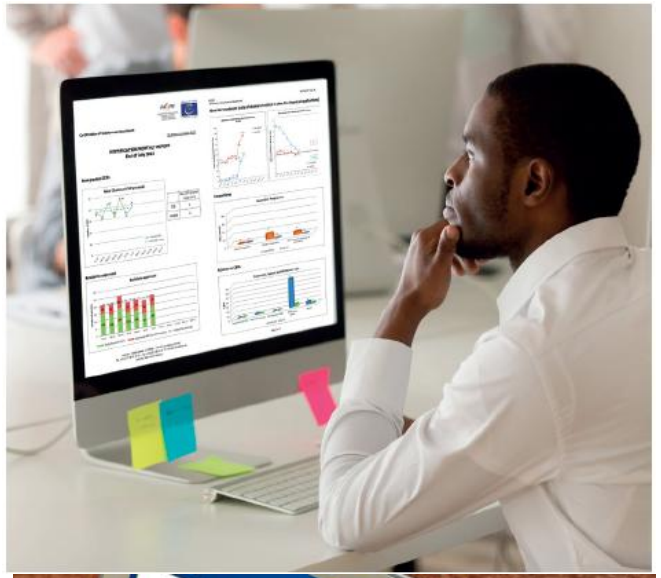
Process

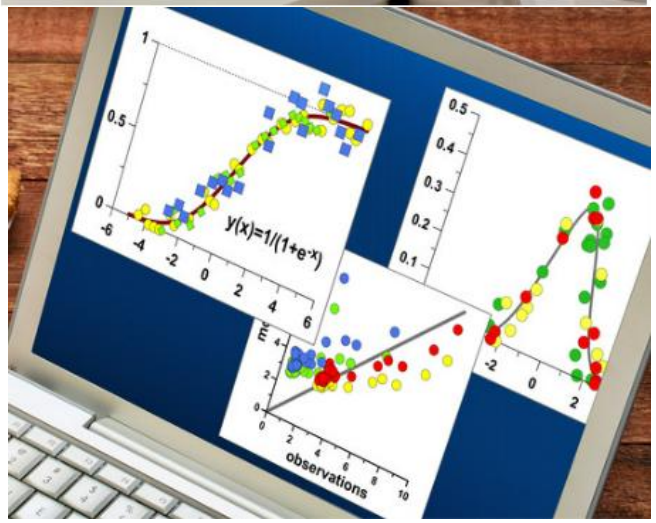
- **Comparison of data** obtained in the implementation of the pharmacopoeial procedure and validation data in terms of APPCs
- **Head-to-head testing**, with the aim of reaching the same analytical decision → same experiments, same samples



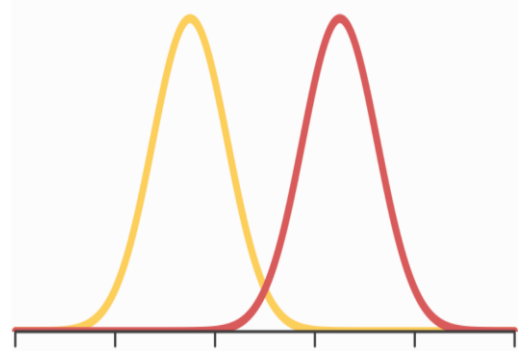
- as defined in general chapter *5.26*

Acceptance Criteria for Comparability





- Defined in the study design phase and stated in the study protocol
- **Equivalence margin:** the acceptable difference between the means of results from two procedures, which includes an acceptable confidence level
- Determined by a combination of scientific knowledge and statistical expertise
- For quantitative results: example (most commonly used approach) - comparison of two group means: TOST method
- **Pass/Fail criterion is key**



Online training

Webinar on new general chapter Comparability of alternative analytical procedures (5.27)

EUROPEAN PHARMACOPOEIA | 17/01/2024 | ON-DEMAND WEBINAR

GENERAL CHAPTERS IN THE Ph. Eur.
WORK PROGRAMME UPDATE

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Challenges for general chapters

- Number (300+) and diversity of domains/techniques
- Build-in of transversal and important concepts: (A)QbD, RTRT, data treatment …
- Generation of representative data, laboratory studies
- High impact on many existing monographs (transversal view)
  - Loss on drying: ~1100 monographs
  - IR: ~1200 monographs
- Revision of some historical methods (many users, few experts)
- Obtaining reliable up-to-date information on instruments
- Getting the additional support from method/instrument specialists
- Finding the right balance to not turn the GM into a textbook while providing enough information for appropriate implementation
- Ensuring maximum visibility before and during the revision/elaboration process
- Communication with all stakeholders (internal and external)

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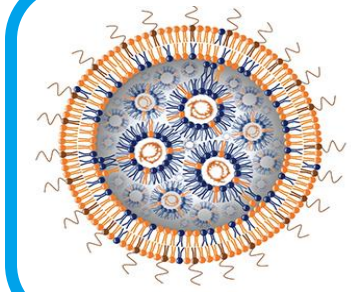
(Not exhaustive)

Ph. Eur. : revised/new texts



3 new general texts around production and control of mRNA vaccines :
5.36. mRNA vaccines for human use

5.39. mRNA substances for the production of mRNA vaccines for human use

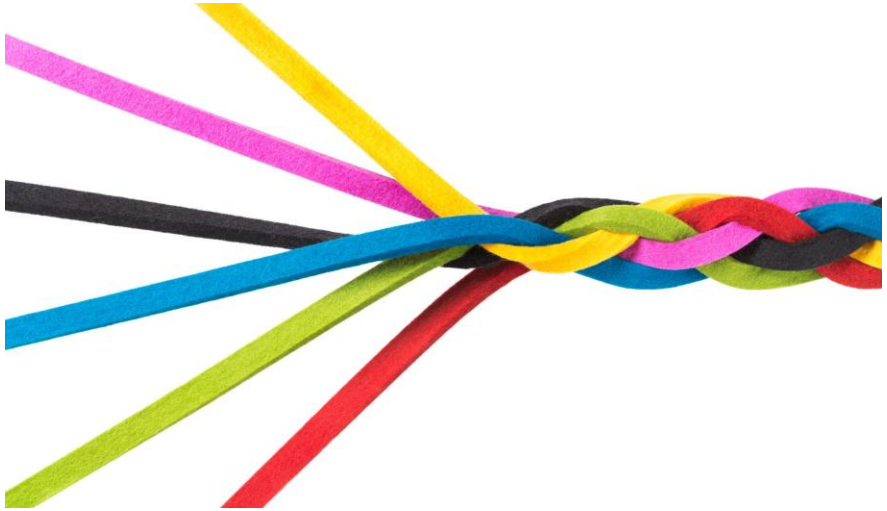
5.40. DNA templates for the preparation of mRNA substances

- 5.27 Comparability of alternative analytical procedures
- 5.33. Design of experiments
- 5.38. Quality of data
- ★ 2.4.20. Determination of elemental impurities
- 2.4.35. Extractable elements in plastic materials for pharmaceutical use
- 3.1.16 Cyclo-olefin polymers, 3.1.17 Cyclo-olefin copolymers and 3.1.18 Styrene block copolymers
- 2.5.42 N-Nitrosamines in active substances and medicinal products (formerly N-Nitrosamines in active substances)
- 5.1.13. Pyrogenicity
- 2.6.41. High-throughput sequencing for the detection of viral extraneous agents

★ International harmonisation

2.4.20. Determination of elemental impurities

- The new harmonised general chapter “Elemental Impurities (G-07)” was signed-off by the Pharmacopoeial Discussion Group (PDG) on 19 June 2024. The coordinating pharmacopoeia was the United States Pharmacopoeia.
- During the development of the harmonised text, the participating pharmacopoeias focused on including the updated requirements described in the ICH Q3D Guideline and also achieved harmonisation on acceptable approaches for analytical procedures, specifically on the following topics:
  - Sample preparation
  - Examples of applicable procedures and detection techniques
  - Requirements for procedure validation



- Complete revision of Ph. Eur. text
- However, the general approach for the determination of elemental impurities is mostly preserved.
- procedures 1 and 2 are provided as examples.

FLEXIBILITY: Any analytical procedure may be used, provided it satisfies the corresponding validation requirements detailed in the general chapter.

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2.4.35. Extractable elements in plastic materials for pharmaceutical use

- This general chapter defines the analytical procedure for determination of extractable elements in plastic materials used for the manufacture of containers for pharmaceutical use.
- Testing in line with this general chapter does not preclude the need to perform a risk assessment of the container according to general chapter 5.20. Elemental impurities.
- Referred to in 3 new general chapters on plastic materials, plastic containers and closures
- Requirements similar to those in 2.4.20. Determination of elemental impurities, where materials for containers are not in scope

3.1.16 Cyclo-olefin polymers, 3.1.17 Cyclo-olefin copolymers and 3.1.18 Styrene block copolymers

- First new texts to be published in section 3.1. Materials used for the manufacture of containers since 2001(4th Edition)
- They are also the first texts in section 3.1 to refer to the general chapter on Extractable elements in plastic materials for pharmaceutical use (2.4.35), published in September 2024.
- Cover important plastic materials already used for several medicinal products in Europe and will help standardise analytical procedures and specifications for these widely employed substances.
- Rendered legally binding through cross-references in the general monograph on *Pharmaceutical preparations (2619)* and in the dosage form monographs in section 7 of the Ph. Eur.
- Published in issue 12.1 in July 2025, with an implementation date of 1 January 2026 (3.1.17 to be corrected January 2026).

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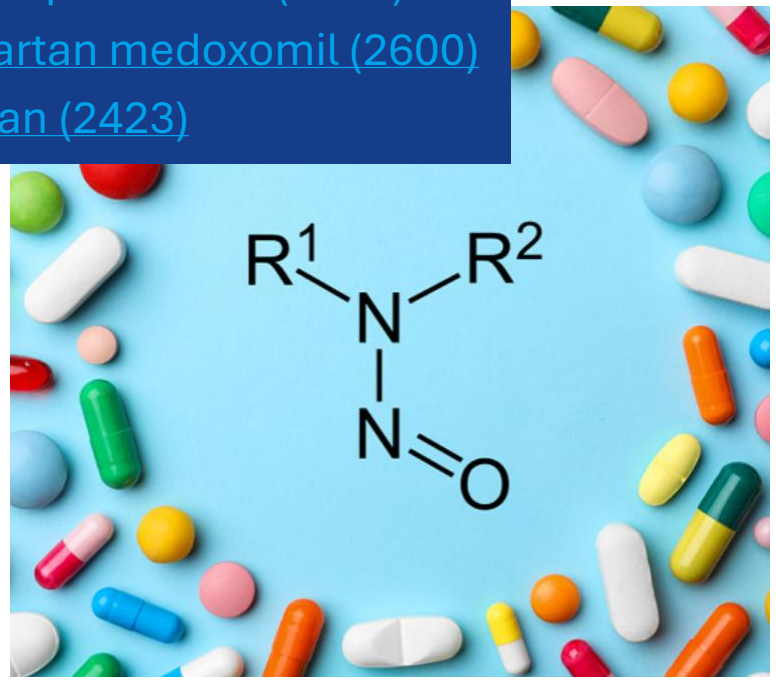
2.5.42 N-Nitrosamines in active substances and medicinal products (formerly N-Nitrosamines in active substances)

- What has changed:
  - **Expansion of scope to sartan-containing medicinal products:**
  - **Procedures A and C can be applied as a quantitative tests**
  - **Addition of the requirement for performing a validation when a procedure is modified beyond the allowable adjustments of chromatographic conditions listed in Chromatographic separation techniques (*2.2.46*)**
- The complexity of the sample matrix is the determining factor for the extent of such modifications.
- The analytical procedures may also be used for other active substances and medicinal products, but in such a case, validation must be performed

- Candesartan cilexetil (2573)
- Irbesartan (2465)
- Losartan potassium (2232)
- Olmesartan medoxomil (2600)
- Valsartan (2423)



General Chapter on Quality of data (5.38)

Introduction of key concepts

Provide guidance for good data management

importance of subject matter experts in decisions

support digital and technological transformation in the pharmaceutical sector, such as chapters on *Chemometric methods applied to analytical data* (*5.21*), *Multivariate statistical process control* (5.28), *Design of* experiments (*5.33*), C*hemical imaging* (*5.24*), and *Process analytical technology* (*5.25*)

Safeguarding that data used in pharmaceutical quality decisions is robust, reliable, and well-governed

Ph. Eur. chapter 2.6.41 – Overview

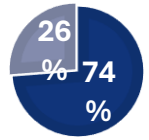
HIGH-THROUGHPUT SEQUENCING FOR THE DETECTION OF VIRAL EXTRANEOUS AGENTS

- ★ Description of HTS methodologies used for the detection of viral extraneous agents in biological products including e.g. vaccines, recombinant proteins, viral vectors used for gene therapy, and cell-based preparations for cell therapy
- ★ Outline of the different steps of the HTS workflow, the design of the method, analysis approaches

- ★ Recommendations on controls used in routine test (mandatory and optional controls)
- ★ Guidance for HTS method validation, including recommendations for selection of the spiking material for validation (e. g. WHO standard) and evaluation of the relevant performance characteristics for HTS
- ★ Built-in flexibility to account for the diversity of technical approaches and workflows
- ★ facilitate and promote the integration of the non-animal based methods for adventitious virus testing (also in relation to 5.2.14)

Texts in public consultation

https://pharmeuropa.edqm.eu/home



Pharmeuropa 37.4:

- 2.4.24. Identification and control of residual solvents

Pharmeuropa 37.3:

- 3.2.1. Glass containers for pharmaceutical use

Pharmeuropa 37.2:

- 2.2.22. Atomic emission spectrometry
- 2.2.23. Atomic absorption spectrometry
- 2.2.57. Inductively coupled plasma-atomic emission spectrometry
- 2.2.58. Inductively coupled plasma-mass spectrometry
- 5.1.6. Alternative methods for control of microbiological quality

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Some updates in the pipeline

- 2.1.7. Balances for analytical purposes (adopted November 2025, Issue 13.1)
  - *Definitions of multi-interval and multiple range balances introduced.*
  - *Clarifications of technical terms relating to equipment performance made.*
  - *Section on minimum weight expanded*
- 2.2.62. Evaporative light scattering detection (prepared for adoption)
  - Technique already present in 14 individual monographs
  - General chapter needed to cover common aspect and to aid introduction in newly elaborated monographs
- 2.6.41. High-throughput sequencing for the detection of viral extraneous agents (Issue 12.2)

Recent major additions on the work program

NON EXHAUSTIVE

- Mass spectrometry, 2.2.43
- Water: micro-determination, 2.5.32
- Optical rotation, 2.2.7
- Heavy metals, 2.4.8
- Charged aerosol detection, 2.2.69
- Nitrites in excipients, 2.5.48

European Pharmacopoeia

A new era

All-digital
12th Edition

Now available

All digital 12th Edition launched in July 2025

https://pheur-online.edqm.eu/home/

More user-friendly platform with content organised in a more intuitive way

Direct access to all versions of texts in one place

Simplified publication process for earlier availability

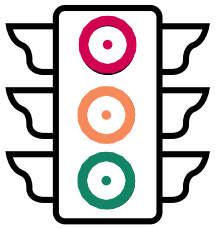
Simplified licensing model

https://www.edqm.eu/en/webinar-european-pharmacopoeia-online-july

Main changes

Before	After
1 edition and 8 supplements – 3 years e.g. 11.0, 11.1,..., 11.7, 11.8	1 edition composed of 3 issues per year e.g. 12.1, 12.2 and 12.3
Each online supplement/edition is provided as an updated cumulative version	Each issue contains new and updated texts only
Printed + Online version	Online version only No publication of paper version of the Ph. Eur. in its current format
Subscription : includes 3 supplements Maximum duration validity 18 months.	365 day licensing model: access to all the content for 1 year
Access to a supplement and then to the version of a specific text in this supplement	Easier access to text and all previous and future versions (each version is linked to an issue - starting from 11.0)
Archives : PDFs	Archives are available online (from 11.0) / and previous editions/supplements (as of 10.8 will remain accessible in PDFs)

How to navigate between text versions



- No longer in force (for example, superseded)
- Not yet in force (published BUT implementation date not yet reached)
- In force **Default**

Help Store EN Elisabeth Poirier

Title/text No. only

Highlights T EN

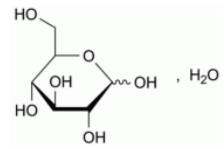
See the information section on general monographs.

Knowledge database Go to RS store

04/2023:0178

GLUCOSE MONOHYDRATE(1) (SEE NOTE)

Glucosum monohydricum



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Information

Text number **0178**

Text type: **Individual monograph**

In force
Effective from 01/04/2023 to 30/06/2025
Issue 11.1

New version from 01/07/2025

Change issue 11.1

11.8 Not yet in force
11.1 In force
9.1 No longer in force
Older Go to PDF archives

Information

Text number **0178**

Text type: **Individual monograph**

No longer in force
Effective from 01/01/2016 to 31/03/2023
Issue 8.6
Correction: 30/11/2016
Issue 9.1

New version from 01/07/2025

Version in force effective from 01/04/2023 to 30/06/2025

Change issue 9.1

Information

Text number **0178**

Text type: **Individual monograph**

Not yet in force
Effective from 01/07/2025
Issue 11.8

Version in force effective from 01/04/2023 to 30/06/2025

Change issue 11.8

Update on EDQM strategies

Removal of animal biological safety tests

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Update on strategies

Removal of animal biological safety tests

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Deletion of animal biological safety tests

Present since Ph. Eur. 1st Edition

WORK IN PROGRESS

Pyrogens (2.6.8)

Histamine (2.6.10) & **Depressor substances (2.6.11)**

2017 — Start — **2021** — Start — **2023**

Abnormal toxicity (2.6.9)

Test deleted from 49 Ph. Eur. monographs; chapter suppressed in Suppl. 9.6

Replacement of RPT by suitable control strategies in 59 Ph. Eur. texts;
Elaboration of general chapter *Pyrogenicity (5.1.13)*;
Revision general monographs (2034 and 0520)

Ph. Eur. 11.8

GOAL

Suppression of *(2.6.8)* in issue 12.1

Removal of references to *(2.6.10)* and *(2.6.11)* and their vestiges (sentences referring to control of substances lowering blood pressure in Production section) from 14 Ph. Eur. monographs;

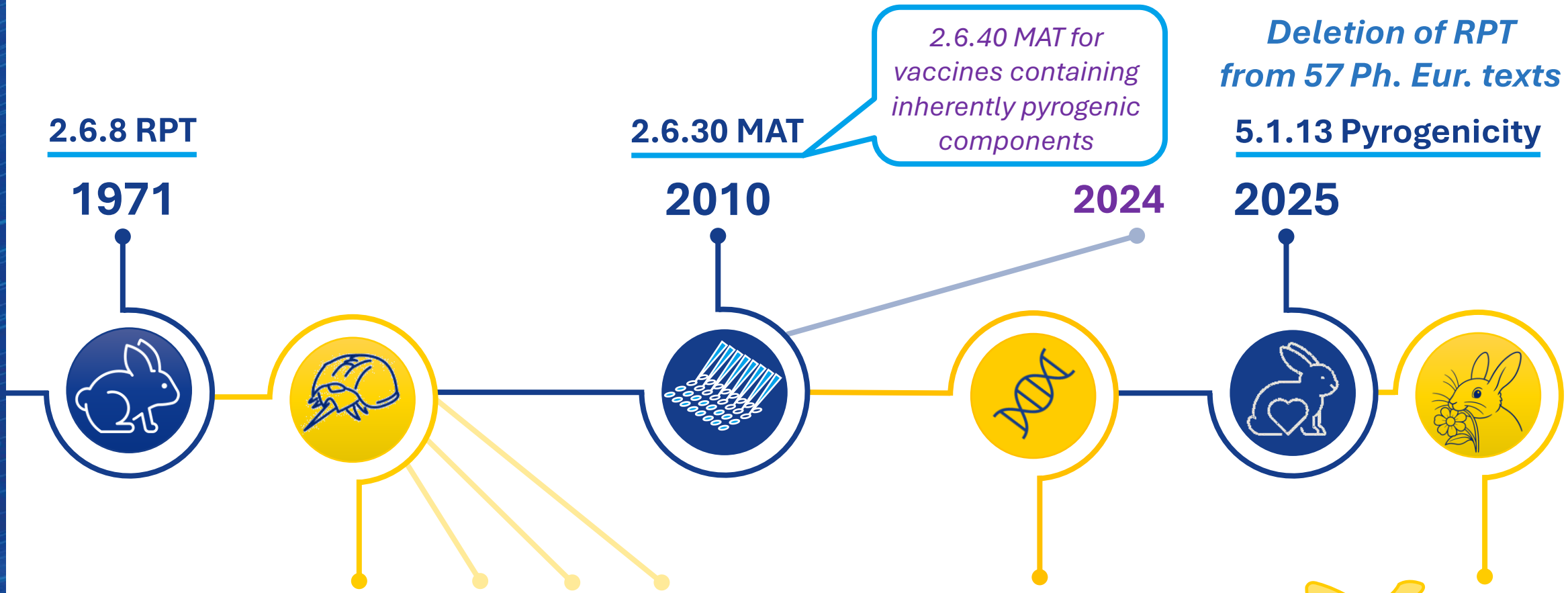
ISSUE 12.1

GOAL

Suppression of *(2.6.10)* and *(2.6.11)*

Elaboration of general chapter *Histamine in active substances (2.5.47)*

Ph. Eur. Pyrogenicity strategy over the years



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Suppression of Rabbit Pyrogen Test: Major Milestone! … But

https://www.edqm.eu/en/-/ph.-eur.-bids-adieu-to-rabbit-pyrogen-test-in-its-monographs

This concerns 57 texts

Non animal pyrogenicity approaches instead (BET, MAT)

- ★ As a result, the use of the RPT will **no longer** be required in any text of the Ph. Eur.
- ★ Implementation date : **1 July 2025**
- ★ The chapter itself will be removed from the Ph. Eur. on 1 January 2026
- ★ A major achievement for animal welfare and the advancement of modern in vitro approaches!

*"Great ! and what about **Horseshoe crabs**?"*

"we have to save them next"

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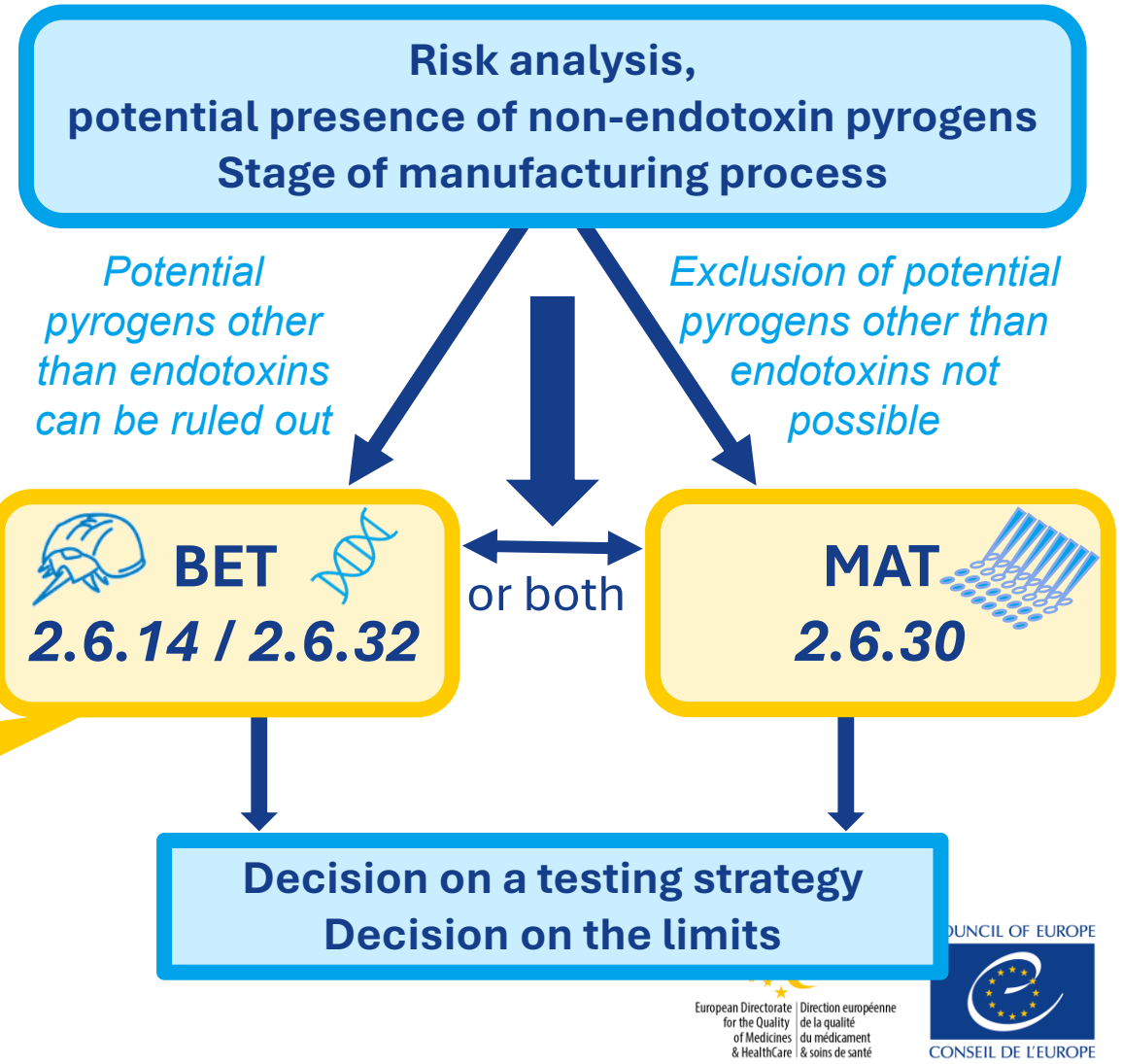
2.6.32 BET using rFC

- Currently referenced in 12 Ph. Eur texts, incl.
  - 5.1.13 Pyrogenicity
  - 5.1.10 Guidelines for using the test for BET
  - 0008 Water, purified
  - 0169 Water for injections
  - 0520 Parenteral preparations
  - 2034 Substance for pharmaceutical use
  - …

What about the 500 other occurrences of chapter 2.6.14?

No preference given between 2.6.14 and 2.6.32

5.1.13 Pyrogenicity



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BET: inclusion of rFC as new method G in 2.6.14

- At its March 2025 Session, the Ph. Eur. Commission decided to **revise chapter 2.6.14** *Bacterial Endotoxins* **to include** the test using recombinant factor C (**rFC**) as the 7th BET method (i.e. as new method G)

2.6.14. BACTERIAL ENDOTOXINS(1)

The following 6 methods ▸◊using the amoebocyte lysate and the method using recombinant factor C◊◂ are described in the present chapter:

Method A.	Gel-clot method: limit test
Method B.	Gel-clot method: quantitative test
Method C.	Turbidimetric kinetic method
Method D.	Chromogenic kinetic method
Method E.	Chromogenic end-point method
Method F.	Turbidimetric end-point method
▸◊Method G.◂	▸Fluorimetric end-point method using recombinant factor C◊◂

- Th... revision will give the possibility to use rFC in all... Ph. Eur. texts referring to chapter 2.6.14 (~500 texts) and will give full recognition of the **equivalence of rFC with** all the **LAL** methods

2.6.32. TEST FOR BACTERIAL ENDOTOXINS USING RECOMBINANT FACTOR C

- In addition, chapter 5.1.13 will be revised to reflect the changes to chapter 2.6.14 and highlight that considerations regarding **sustainability** should be made when choosing a BET method

- The revised chapters 2.6.14 & 5.1.13 have been released for **public consultation in Pharmeuropa 37.2** (commenting period from 1st April to end of June 2025)

5.1.13. PYROGENICITY

CHOICE OF THE TEST

Bacterial endotoxins from gram-negative bacteria are the most common and most active exogenous pyrogens. The tests for bacterial endotoxins described in general ▸~~chapters~~◂ ▸chapter◂ *2.6.14* ▸~~and 2.6.32~~◂ are thus the analytical methods most widely used to address the pyrogenicity of parenterally administered medicinal products and their components. ▸These methods use amoebocyte lysate from the horseshoe crab (gel-clot, turbidimetric or chromogenic techniques) or recombinant factor C based on the gene sequence of the horseshoe crab (fluorimetric technique). Using the test for bacterial endotoxins◂ ▸~~This approach~~◂ is only appropriate if the presence of non-endotoxin pyrogenic substances can be ruled out.

▸Considerations regarding sustainability should be made when choosing a method (A-G) for the test for bacterial endotoxins in general chapter *2.6.14.* Bacterial endotoxins.◂

Recombinant cascade reagent (rCR)

- Kits still recent
- Few peer-reviewed litterature
- Few user's data
- No medicinal product approved using this reagent in Europe

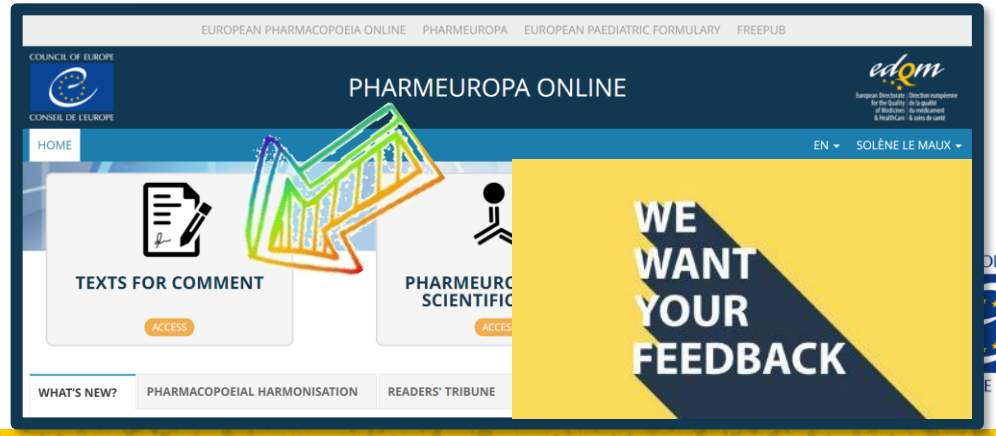
→ Alternative method

On-going revision of general chapter
5.1.10 Guidelines for using the BET

★ Better integration of rFC
★ Introduction of a reference to recombinant cascade reagents (rCR)

Draft will be published in Pharmeuropa for public consultation

https://pharmeuropa.edqm.eu/home



- When mature…
- Addition of new METHOD H in *2.6.14* *will for sure be considered by Ph. Eur. Commission*

Bringing it on the international scene…

- **Chapter 2.6.14. harmonised under PDG and ICH Q6A: Bacterial Endotoxin Test (Q-06)**
- **Ph. Eur. initiated to bring these discussions on the international stage with PDG**
- **PDG committed to follow the same direction at a later stage – see Press release from March 2025 meeting, published on the EDQM website on 19 May 2025**

https://www.edqm.eu/en/-/pharmacopoeial-discussion-group-achievements-14

"The PDG held productive discussions on aligning innovative approaches to the test for Bacterial Endotoxins using recombinant reagents. Through continuous and open dialogue, the PDG reached a major achievement by approving a unified position among the four member pharmacopoeias regarding the goal to include methods using recombinant reagents in the harmonised chapter."

Rapid Microbiological Methods

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Exploring a certification system for rapid microbiological methods

FEEDBACK collection

Hearings

Surveys

Brainstorming

How could EDQM better support or accelerate the implementation of alternative microbiological methods?

Points of view

- Suppliers
- Manufacturers/users
- Regulators

Proposal
to support or accelerate the implementation of RMM by capitalising on already validated and implemented methods

- ★ Main reasons to delay RMM implementation?
- ★ Implementation challenges?
- ★ RMM currently used?
- ★ Potential concepts?
- ★ etc.

Background

Rapid Microbiological Methods (RMM)

- Opportunities for replacement of alternative to conventional microbiological methods
- Faster (e.g. important for products with a short shelf-life)
- Possibility of earlier corrective action

Ph. Eur.

- Cannot provide detailed methods as they are equipment related
- Is committed to facilitate the use of RMM
- A milestone was the publication in 2006 of a new general chapter *5.1.6. Alternative methods for control of microbiological quality*

Stakeholders FEEDBACK

- Chapter *5.1.6* facilitates the use of these methods as alternative
- Implementing rapid microbiological methods still appears to be difficult and too labour-intensive
- Users are eager for the EDQM to play a bigger role in the facilitation of the use of these methods
- A system of certification rapid microbiological methods has been suggested by stakeholders

5.1.6. Alternative methods for control of microbiological quality

***Objective**: Facilitate the implementation and use of alternative microbiological methods*

General principles of alternative microbiological methods

Basic principles of methods

- No recommendation of one method over another
- Not an exclusive or exhaustive list
- Other methods may be applicable

Update of the list of methods included in the chapter
Update of the methods descriptions

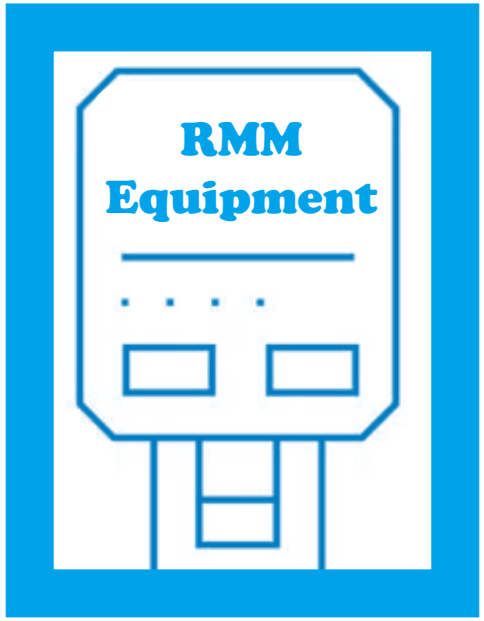
Implementation of alternative microbiological methods

- **Method selection**
- **Equipment qualification**
- **Primary validation**
- **Product-specific validation**
- **Comparability**
- **Application to routine use**

Update and clarification, incl.:

- Additional information to **optimise the implementation strategy** by capitalising on suitable tests previously performed and by evaluating different implementation activities simultaneously;
- **Clarification of the responsibilities of suppliers and users**, in particular for the primary validation and the comparability

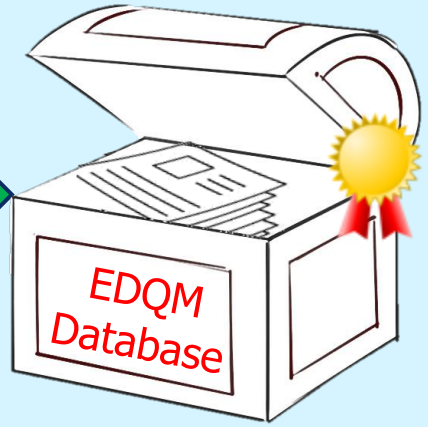
A recent initiative: Exploring a certification system for the validation and comparability of RMM



RMM supplier / user

RMM user (e.g. new use)

EDQM premises

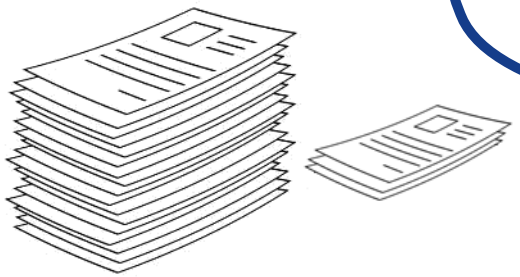


Review by board of experts

Ph. Eur. 5.1.6

Experts' opinion

- Suitability of the RMM according to 5.1.6
- Comparability to Ph. Eur. method



Validation/Comparability studies

Approved application

Competent authorities

Product approval review

RMM: rapid microbiological methods

Participation of Ph. Eur. in Global Harmonisation Efforts

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The Pharmacopeial Discussion Group (PDG)

- **Began as an informal group in 1989**; participants include USP, Ph. Eur., IPC, and JP
  - ★ IPC joined as member in 2023
  - ★ WHO joined as observer in 2001
- Focuses on selected official, broad-impact General Chapters and excipient monographs
- Eliminates/minimises need to perform multiple tests and procedures and to comply with multiple acceptance criteria for the same article
- Detailed process, with specific stages and terminology
- One face-to-face meeting a year, with a video conference in the interim

Ph. Eur. (EDQM)

IPC

JP (MHLW /PMDA)

USP

Candidate Participant

PDG Mission

To harmonize pharmacopeial standards while maintaining a constant level of science with the shared goal of protecting public health.

PDG Work Program: General Chapters

General Methods Relevant to Q6A:

Q-01 Dissolution*3
Q-02 Disintegration*3
Q-03/04 Uniformity of Content/Mass
Q-05a Tests for Specified Microorganism
Q-05b Microbial Enumeration
Q-05c Limits for Non-sterile Products
Q-06 Bacterial Endotoxin
Q-07 Color (Instrumental Method)
Q-08 Extractable Volume*3
Q-09 Particulate Contamination*3
Q-10 Residue on Ignition
Q-11 Sterility Test

General Chapters:

G-01 Analytical Sieving*3
G-02 Bulk Density and Tapped Density
G-03 Conductivity
G-04 Gas Pycnometric Density of Solids
G-05 Powder Flow
G-06 Tablet Friability
G-07 Elemental Impurities*2
G-09 Optical Microscopy*3
G-10 Powder Fineness
G-11 Specific Surface Area
G-13 Laser Diffraction Measurement of Particle Size*3

General Chapters:

G-14 X-Ray Powder Diffraction
G-15 Water-solid Interaction
G-16 Thermal Analysis*3
G-20 Chromatography*1
G-21 Dynamic Light Scattering*1

Methods for Biotechnology Products:

B-01 Amino Acid Determination
B-02 Capillary Electrophoresis*3
B-03 Isoelectric Focusing
B-05 Peptide Mapping
B-06 Polyacrylamide Gel Electrophoresis

*1 : Signed-Off in 2021-2023
*2 : Recent Sign Off in 2024!
*3 : Under revision

All 31 general chapters have now been harmonized!

PDG Work Program: Excipients

E-01 Alcohols
E-02 Dehydrated Alcohol
E-03 Benzyl Alcohol
E-04 Calcium Disodium Edetate*3
E-05 Calcium Phosphate Dibasic
E-06 Calcium Phosphate Dibasic Anhydrous
E-07 Carmellose Calcium
E-08 Carmellose Sodium*2
E-09 Croscarmellose Sodium*3
E-10 Microcrystalline Cellulose
E-11 Cellulose, Powdered
E-13 Cellulose Acetate Phthalate
E-14 Citric Acid, Anhydrous
E-15 Citric Acid, Monohydrate
E-16 Crospovidone
E-17 Ethylcellulose
E-18 Hydroxyethylcellulose*3
E-19 Hydroxypropylcellulose
E-20 Hydroxypropylcellulose, Low Substituted
E-21 Hypromellose
E-22 Hypromellose Phthalate
E-23 Lactose, Anhydrous*3
E-24 Lactose, Monohydrate*3
E-25 Magnesium Stearate
E-26 Methylcellulose
E-27 Methyl Paraben
E-28 Petrolatum*1
E-29 Petrolatum, White*1
E-30 Polyethylene Glycol*2
E-31 Polysorbate 80*3
E-32 Povidone*3
E-36 Silicon Dioxide*2
E-37 Silicon Dioxide, Colloidal*2
E-38 Sodium Chloride
E-39 Sodium Starch Glycolate
E-40 Starch, Corn*3
E-41 Starch, Potato
E-42 Starch, Rice
E-43 Starch, Wheat
E-44 Stearic Acid
E-45 Sucrose*3
E-46 Talc
E-48 Ethyl Paraben
E-49 Propyl Paraben
E-50 Butyl Paraben
E-51 Glycerin*2
E-52 Carmellose
E-54 Copovidone*3
E-55 Gelatin
E-56 Sucrose
E-58 Mannitol
E-59 Propylene Glycol*2
E-60 Sodium Laurylsulfate
E-61 Starch, Pregelatinized*2
E-62 Sterile Water for Injection*2
E-64 Isomalt
E-65 Isostearyl Alcohol*2
E-66 Myristyl Myristate*2
E-68 Polysorbate 65*2
E-69 Calcium Silicate*2
E-70 Polysorbate 20*2
E-71 Purified Water*2

*1 : Signed-Off in 2021-2023
*2 : Under discussion towards first harmonization
*3 : Under revision

48 of the 62 excipient monographs have now been harmonized

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PDG expansion

2025

The Korean Pharmacopoeia has been selected for admission as a **Candidate Participant**

https://www.edqm.eu/en/-/pharmacopeial-discussion-group-announces-outcome-of-2025-expansion-round

Framework for Next Stage of PDG Expansion

Candidate Participant

Evaluation (include resources)

(Full) Member

Observing 1 year

Actively participate At least 1 year

- **Observe** PDG activities and all meetings (including technical meetings and subteam meetings)
- Comments or feedback allowed but not required
- Start implementing PDG harmonized texts
- Gain understanding of PDG's way of working from passive participation

- **Active participation** in PDG activities and all meetings (including technical meetings and subteam meetings
- Required to submit comments and feedback
- Continue implementing PDG harmonized texts
- Actively integrate into harmonization work

- **Full participation**
- Same status as existing members

Excipient Strategy

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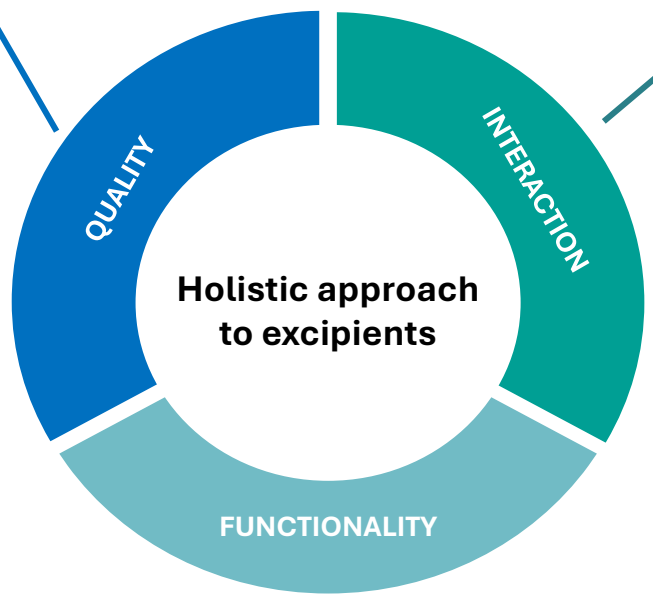
Ph. Eur. Strategy for excipients

Presence of mutagenic impurities, solvents, elemental impurities?

Role of excipients in formation of nitrosamines in medicinal products (e.g. residual nitrite)



Interdependencies:

Different routes of administration

- Creation of a **new Excipients Strategy Working Party (EXS WP)** approved at Ph. Eur. Commission in 2022
- European members from various areas of activities: Academia, Regulatory authorities, Manufacturers: Laboratory, Regulatory Affairs department, etc.
- ***Mission:*** Identify and discuss best possible approach(es) to address the quality and the standard setting process of excipients for pharmaceutical use in the Ph. Eur. in view of **making concrete recommendations to the Ph. Eur. Commission.**
- ***Upcoming:*** outreach to stakeholders and refinement of recommendations in several steps

General stakeholder consultation expected in 2026

EDQM initiatives in medicine shortages

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EDQM Initiatives in Medicine Shortages - Overview

Access to active substances

Certification (CEP)

Accelerated certification procedure for alternative production of active substances subject to shortage

European Pharmacopeia

Elaboration of monographs based on shortages criticality (Union List & other national lists upon request)

Availability of plasma-derived medicines

CD-P-TS committee

Recommendations regarding plasma supply continuity and anti-D immunoglobulins supply chain

Testing of unauthorised medicines

OMCL Network

Shelf-life extension, stockpiled medicines, testing of unauthorized medicines prior to decision to import

Compounding - pharmacy preparations

Methodological Guide

Identification/selection of medicines that may be subject to shortage and can be prepared by hospital/community pharmacies.

European Shortages Form

a. Monographs describing standardised unlicensed preparations

b. Technical recommendations

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EDSForm - new texts & platform

★ New platform: https://edsform.edqm.eu/

- Launched with first 3 texts for public consultation in the first issue of **Pharmeuropa EDSForm**
- Public consultation: 1 October - 31 December 2025

★ New texts

- Amoxicillin 125/250/500 mg, capsules -> *First draft monograph*
- Introduction to the European Drug Shortages Formulary
- General principles of the European Drug Shortages Formulary

} *2 General texts*

★ Comments are essential to shape texts!

★ April/ May 2026 - publication of the first 3 text – official launch of the Formulary

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EDSForm - work programme

- ★ **Paracetamol, oral liquid (F1001)**
- ★ Amoxicillin, oral solid (F1005)
- ★ Furosemide, solution for injection (F1002)
- ★ **Methotrexate, concentrated solution for injection (F1006)**
- ★ Metronidazole, oral solid (F1003)
- ★ **New** Quetiapine, oral solid (F1008) -> Added in March 2025
- ★ Rifampicin, oral liquid (F1007)
- ★ **Sulfamethoxazole and trimethoprim, oral liquid (F1004)**

Bold: *expected next items to be finalised for public consultation*

EDSForm - Technical recommendations

- ★ 2 New technical recommendations
  - Sulfamethoxazole-trimethoprim, paediatric formulations (August 2025)
  - Clarithromycin: paediatric formulations (July 2025)
- ★ Published technical recommendations on a dedicated webpage
- ★ Technical recommendations will continue to be drafted in case of need

Ph. Eur.: How to help reduce the risk of shortages ?

	UNION LIST	Ph. Eur.
AIM	Avoid potential shortages	Access to good quality medicine
Products	Chemicals/Fermentation, Vaccines, Proteins/mAbs, Blood	Chemicals/Fermentation, Vaccines, Proteins/mAbs, Blood
Scope	EU/EEA MS	Ph. Eur. MS

Monographs and CEPs as enablers

Ensuring global recognition

Ph. Eur. coverage goes beyond only EU/EEA

Union List vs Ph. Eur.

85%

of the listed MPs have the corresponding substance monograph published in Ph. Eur. or are on the work programme
Few MPs are currently covered

Groups of Experts started to work on new elaborations as of 2025

Other national lists:
- Swiss list of « vital medicines » : 42 additional items (50% chemical APIs, 40% mAbs)
- UK working list: based on MHRA prioritisation list, assessment ongoing

EDQM initiatives on sustainability

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Environmental sustainability (« external »)

What CEP holders can do:

- Avoid and reduce use of hazardous materials for production and in analytical testing
- Reduce amounts of solvents (including water) in processes and in analytical testing
- Use green(er) technologies to produce substances (enzymatic processes, flow chemistry, etc.)
- Share their greener procedures with the Ph. Eur.
- Etc.

What the EDQM can do:

- Update Ph. Eur. monographs and reference standards to incorporate even more sustainable approaches
  - ➔ Already ongoing on certain aspects: REACH, mercury, use of solvents, 3Rs
  - ➔ **Integrate such aspects for method selection during revisions**

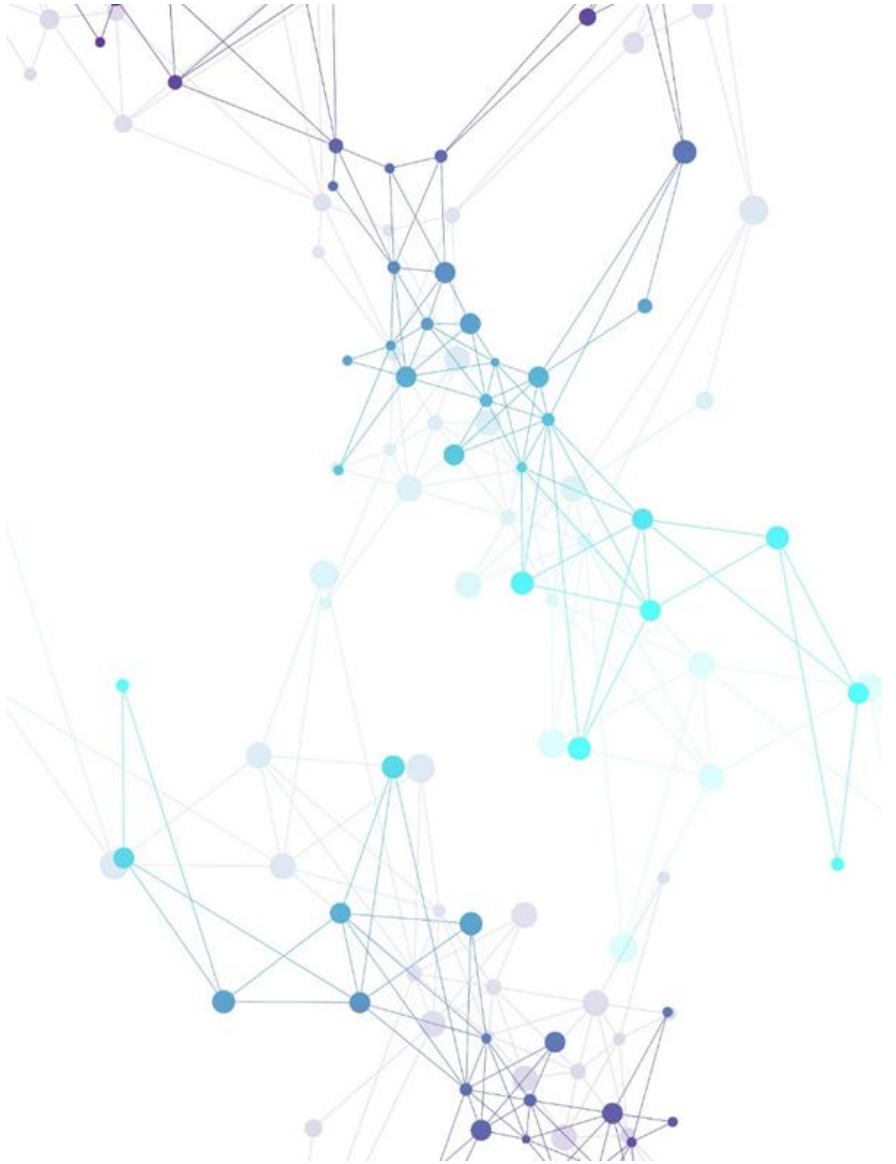
⇒ **Need for a defined and clear framework and for a coordinated action**

“Environmental Sustainability” working party

- Advise the Commission on the **best possible approaches to addressing environmental sustainability in the Ph. Eur**.
- Identify the current state of affairs in relation to the activities already being undertaken today to address environmental sustainability in the Ph. Eur.
- **Scan the environment** to identify relevant legislation and guidance impacting the Ph. Eur. in the field of environmental sustainability as well as technological/scientific developments in the field, monitor their developments and assess their impact on the Ph. Eur.
- **Draft the Ph. Eur. strategy on ‘environmental sustainability’.**
- Co-operate with and consult other Ph. Eur. groups of experts and working parties, where relevant and advise them on environmental sustainability principles/aspects to be incorporated in their work.
- Cooperate with the OMCL working group on environmental sustainability.
- Profile for experts
  - People responsible for environmental sustainability in e.g. control laboratories (whether private or public) or in the pharmaceutical or chemical industry or in academia.
  - Representatives of relevant European agencies (such as the European Commission (e.g. DG Research & Innovation), EEA, ECHA) with experience/knowledge in environmental sustainability
  - Representative of the OMCL working group on environmental sustainability

Concluding remarks

Help us on this journey !



https://www.edqm.eu/en/european-pharmacopoeia

The European Pharmacopoeia

- Background & Mission
- Membership & Observership
- The Ph. Eur. Commission
- Groups of experts and working parties
- European Pharmacopoeia 11th Edition

Focus

- Biotherapeutics
- Alternatives to animal testing (3Rs)

How to participate in the work of the Ph. Eur.

- Join the Network!
- Submitting drafts and requests for revision
- Comment on drafts (Pharmeuropa)

The Ph. Eur. work programme

- Elaborations & Revisions
- Where to find: the Knowledge database
- The Ph. Eur. work programme

Pharmacopoeial Harmonisation

- International harmonisation
- Harmonisation status for Excipient monographs (PDG)
- Harmonisation status for General Texts (PDG)

Ph. Eur. reference standards

- Ph. Eur. reference standards
- Biological standardisation programme (BSP)

Find information on

- Standard terms Database

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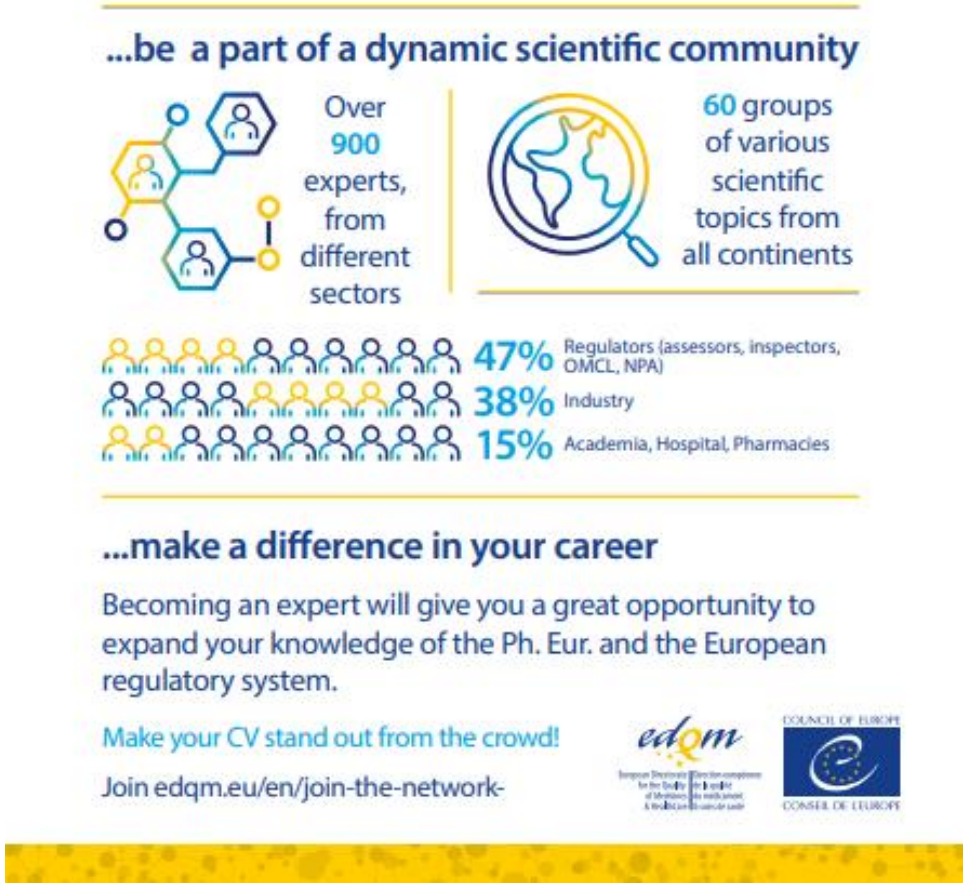
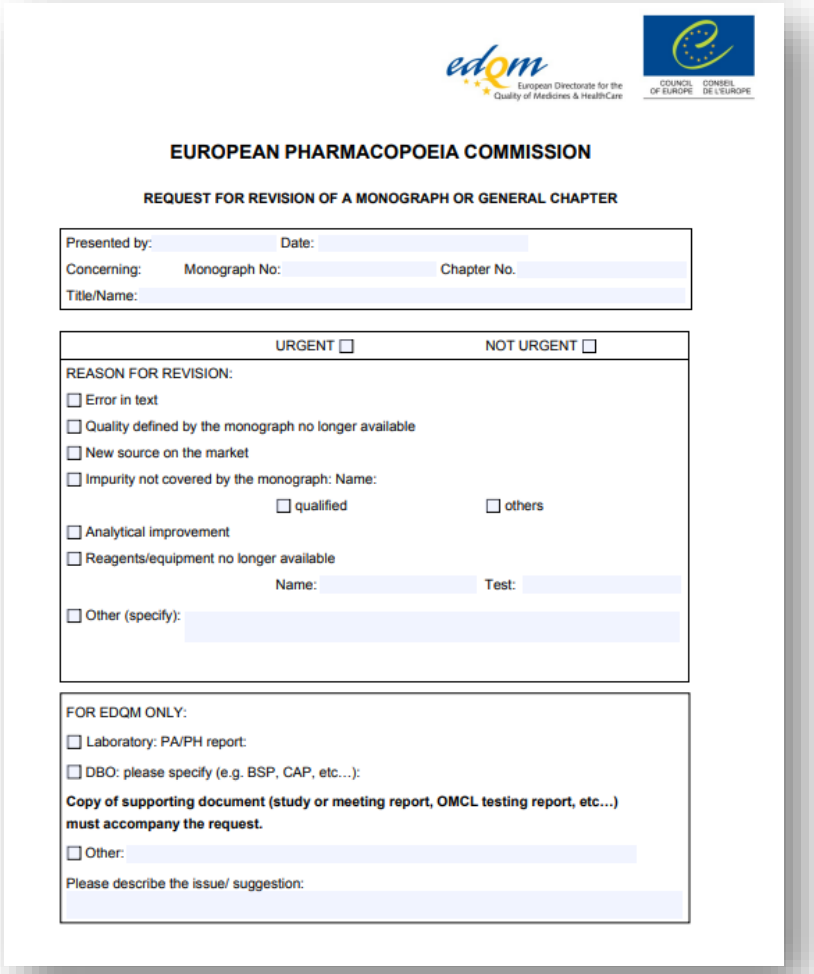
Join as an expert

https://www.edqm.eu/en/join-the-network-



Shape the documentary standards

https://www.edqm.eu/en/submitting-drafts-and-requests-for-revision



EUROPEAN PHARMACOPOEIA COMMISSION

REQUEST FOR REVISION OF A MONOGRAPH OR GENERAL CHAPTER

Presented by: Date:

Concerning: Monograph No: Chapter No.

Title/Name:

URGENT ☐ NOT URGENT ☐

REASON FOR REVISION:

☐ Error in text

☐ Quality defined by the monograph no longer available

☐ New source on the market

☐ Impurity not covered by the monograph: Name:

☐ qualified ☐ others

☐ Analytical improvement

☐ Reagents/equipment no longer available

Name: Test:

☐ Other (specify):

FOR EDQM ONLY:

☐ Laboratory: PA/PH report:

☐ DBO: please specify (e.g. BSP, CAP, etc…):

Copy of supporting document (study or meeting report, OMCL testing report, etc…) must accompany the request.

☐ Other:

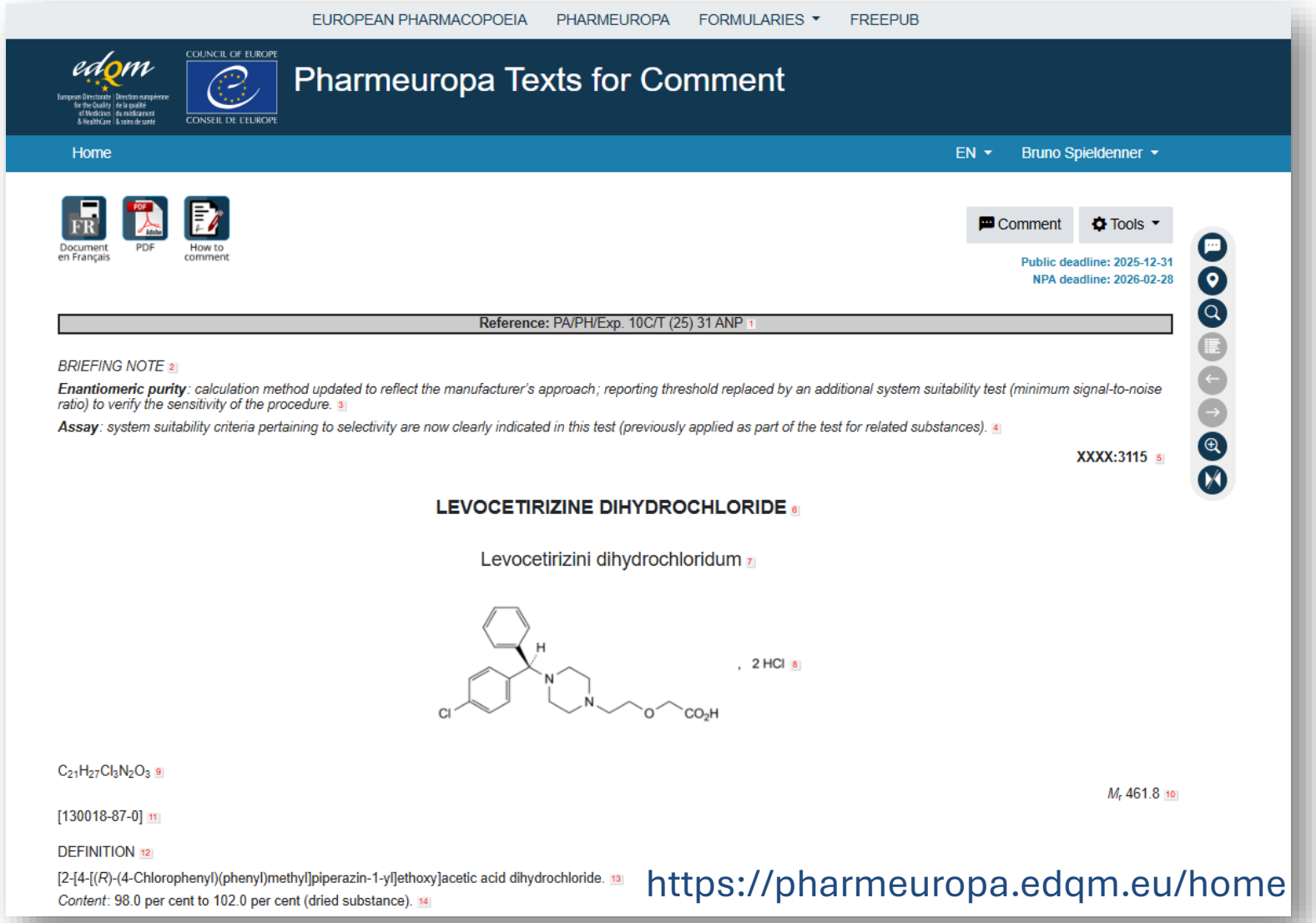
Please describe the issue/ suggestion:

For manufacturers and other interested parties from Member States of the Ph. Eur. Convention: via the national pharmacopoeia authority.

For others (manufacturers and other interested parties from non-Member States of the Ph. Eur. Convention or multinational interested parties, for international organisations and for industry associations or other associations): via EDQM HelpDesk

How to participate .... last but not least ... make your view count

MAKE SURE YOUR PRODUCT IS COVERED AND COMMENT IN PHARMEUROPA



EUROPEAN PHARMACOPOEIA PHARMEUROPA FORMULARIES FREEPUB

Pharmeuropa Texts for Comment

Home EN Bruno Spieldenner

Document en Français PDF How to comment

Comment Tools

Public deadline: 2025-12-31
NPA deadline: 2026-02-28

Reference: PA/PH/Exp. 10C/T (25) 31 ANP

BRIEFING NOTE

***Enantiomeric purity**: calculation method updated to reflect the manufacturer's approach; reporting threshold replaced by an additional system suitability test (minimum signal-to-noise ratio) to verify the sensitivity of the procedure.*

***Assay**: system suitability criteria pertaining to selectivity are now clearly indicated in this test (previously applied as part of the test for related substances).*

XXXX:3115

LEVOCETIRIZINE DIHYDROCHLORIDE

Levocetirizini dihydrochloridum

, 2 HCl

$C_{21}H_{27}Cl_3N_2O_3$

*M*r 461.8

[130018-87-0]

DEFINITION

[2-[4-[(*R*)-(4-Chlorophenyl)(phenyl)methyl]piperazin-1-yl]ethoxy]acetic acid dihydrochloride.

Content: 98.0 per cent to 102.0 per cent (dried substance).

https://pharmeuropa.edqm.eu/home

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Thank you for your attention

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