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

edqm

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

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Ph. Eur. General Notices

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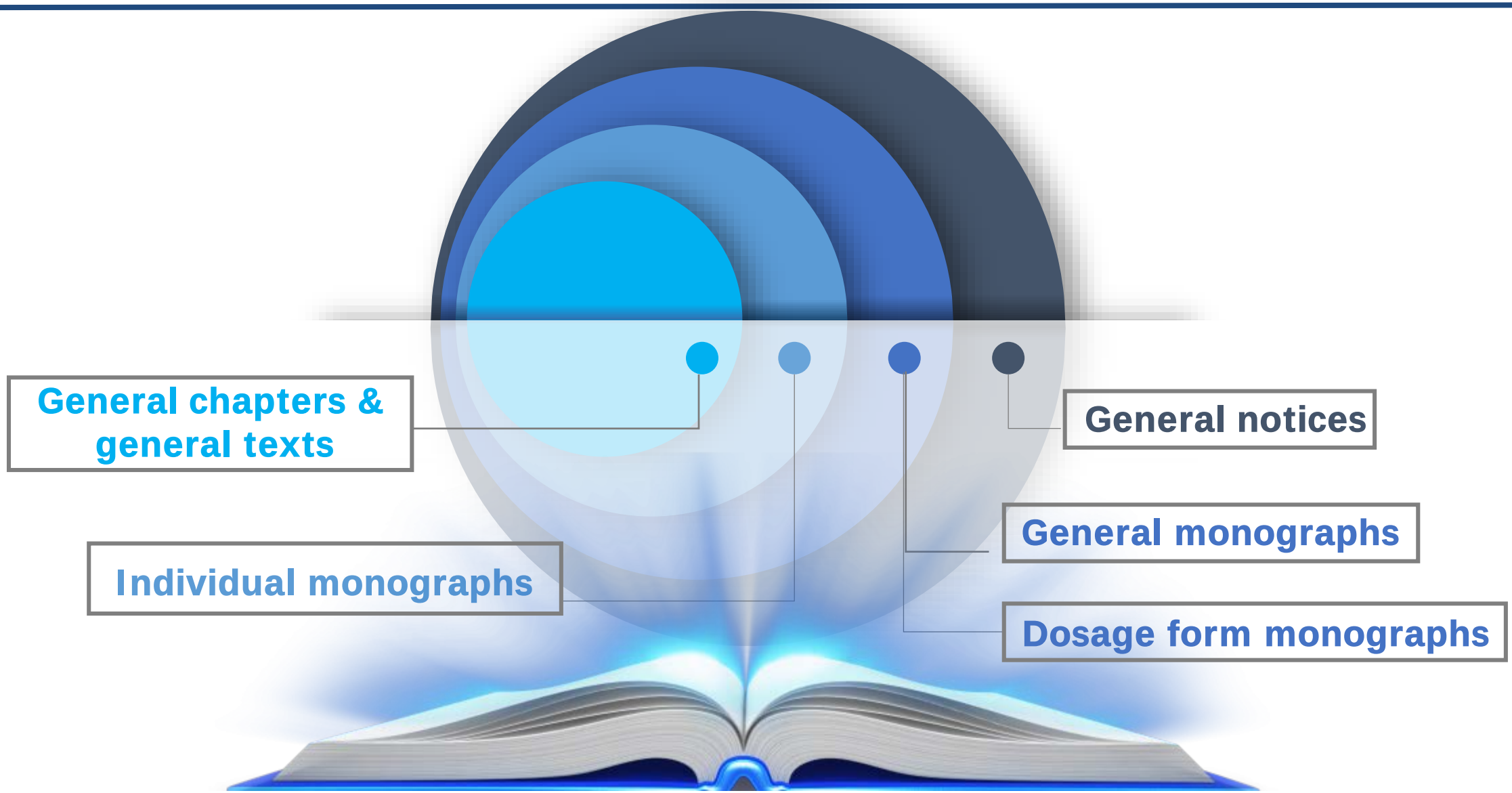
Ph. Eur.: Content and structure

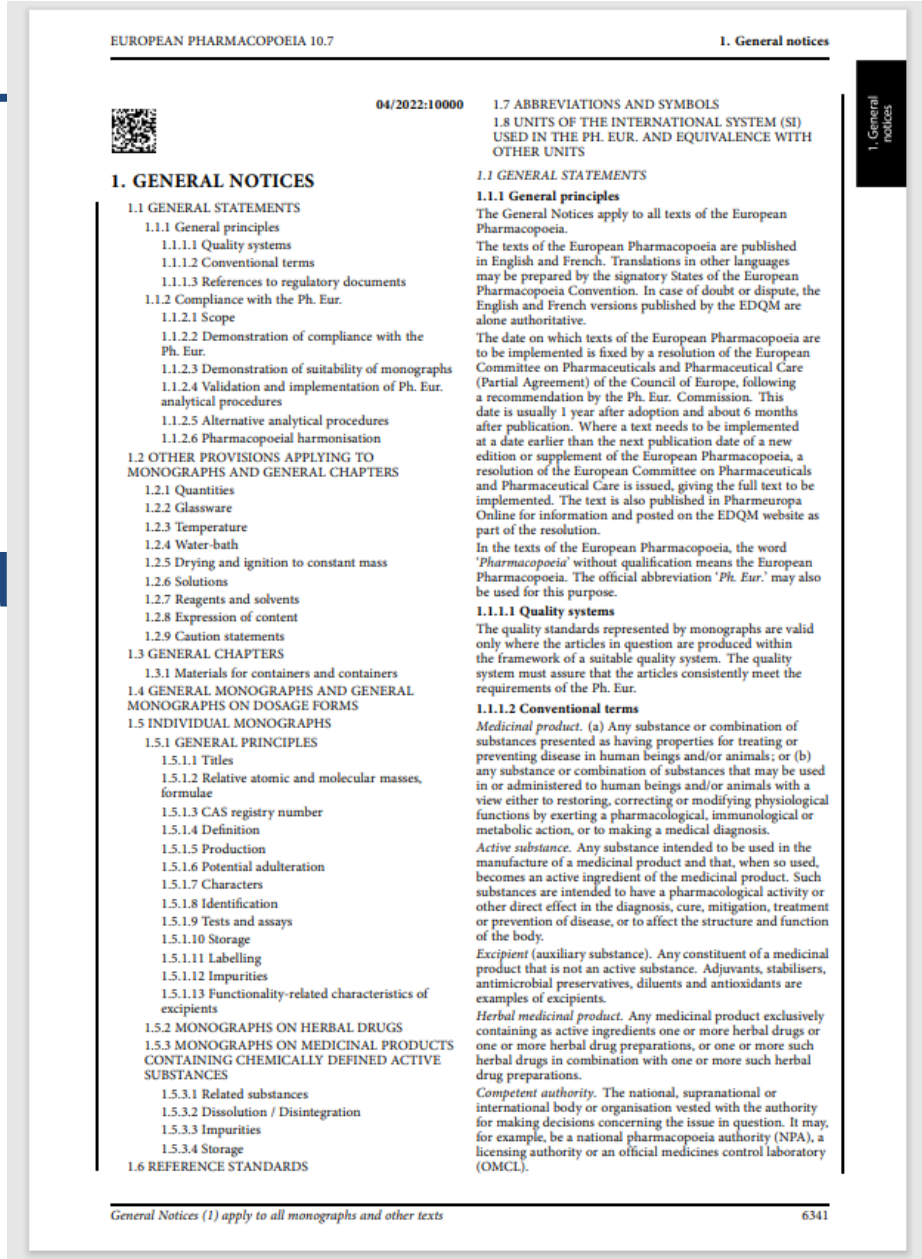


General Notices

At the very beginning of the Ph. Eur.

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

Essential reading before starting to use monographs and other texts



EUROPEAN PHARMACOPOEIA 10.7 — 1. General notices

04/2022:10000

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1.1 GENERAL STATEMENTS

1.1.1 General principles

The General Notices apply to all texts of the European Pharmacopoeia.

The texts of the European Pharmacopoeia are published in English and French. Translations in other languages may be prepared by the signatory States of the European Pharmacopoeia Convention. In case of doubt or dispute, the English and French versions published by the EDQM are alone authoritative.

The date on which texts of the European Pharmacopoeia are to be implemented is fixed by a resolution of the European Committee on Pharmaceuticals and Pharmaceutical Care (Partial Agreement) of the Council of Europe, following a recommendation by the Ph. Eur. Commission. This date is usually 1 year after adoption and about 6 months after publication. Where a text needs to be implemented at a date earlier than the next publication date of a new edition or supplement of the European Pharmacopoeia, a resolution of the European Committee on Pharmaceuticals and Pharmaceutical Care is issued, giving the full text to be implemented. The text is also published in Pharmeuropa Online for information and posted on the EDQM website as part of the resolution.

In the texts of the European Pharmacopoeia, the word '*Pharmacopoeia*' without qualification means the European Pharmacopoeia. The official abbreviation '*Ph. Eur.*' may also be used for this purpose.

1.1.1.1 Quality systems

The quality standards represented by monographs are valid only where the articles in question are produced within the framework of a suitable quality system. The quality system must assure that the articles consistently meet the requirements of the Ph. Eur.

1.1.1.2 Conventional terms

Medicinal product. (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings and/or animals; or (b) any substance or combination of substances that may be used in or administered to human beings and/or animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Active substance. Any substance intended to be used in the manufacture of a medicinal product and that, when so used, becomes an active ingredient of the medicinal product. Such substances are intended to have a pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure and function of the body.

Excipient (auxiliary substance). Any constituent of a medicinal product that is not an active substance. Adjuvants, stabilisers, antimicrobial preservatives, diluents and antioxidants are examples of excipients.

Herbal medicinal product. Any medicinal product exclusively containing as active ingredients one or more herbal drugs or one or more herbal drug preparations, or one or more such herbal drugs in combination with one or more such herbal drug preparations.

Competent authority. The national, supranational or international body or organisation vested with the authority for making decisions concerning the issue in question. It may, for example, be a national pharmacopoeia authority (NPA), a licensing authority or an official medicines control laboratory (OMCL).

General Notices (1) apply to all monographs and other texts — 6341

General chapters and general texts

General chapters

- avoid repeating standard procedures or requirements in each monograph
- become mandatory when referred to in a monograph
- provide standard
- g
- g

ation or calibration

General chapters also become mandatory when referred to in another general chapter that is itself referred to in a monograph, unless otherwise stated.

General texts

- often published for information and guidance
- become mandatory when referred to in a monograph
- aspects that cannot be treated in each individual monograph
- specific to certain topics (e.g. Microbiology, Chemometrics)
- reproduce principles of regulatory guidelines (e.g. 5.20. Elemental impurities → introduction and scope of ICH Q3D GL)

General chapters 3. Materials for containers and containers

- 3.1. Materials used for the manufacture of containers

  'The specifications for each of these materials depend on the formulation and are therefore applicable only for materials whose formulation is covered by the preamble to the specification. The use of materials with different formulations, and the corresponding tests and limits applied to them, are subject to approval by the competent authority.'

- 3.2. Containers

  '... the publication of a specification does not exclude the use, in justified circumstances, of containers that comply with other specifications, subject to approval by the competent authority'.

- 3.3. Containers for human blood and blood components and materials used for their manufacture ... (since 01.2020)

General monographs & Dosage form monographs

General 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)

- Ex.: Vegetable fatty oils (2098), Allergen products (1063), Vaccines for vet. use (0062)

Dosage form monographs

- Mandatory for all medicinal products within scope of their definition

- Referred to in monographs on medicinal products containing chemical APIs

Ex.: Capsules (0016), Tablets (0478), Parenteral preparations (0520), Eye preparations (1163) ...

General monographs & Dosage form monographs

01/2021:2034

SUBSTANCES FOR PHARMACEUTICAL USE

Corpora ad usum pharmaceuticum

DEFINITION

Substances for pharmaceutical use are any organic or inorganic substances that are used as active substances or excipients for the production of medicinal products for human or veterinary use. They may be obtained from natural sources or produced by extraction from raw materials, fermentation or synthesis.

This general monograph does not apply to herbal drugs, herbal drugs for homoeopathic preparations, herbal drug preparations, herbal drug extracts, or mother tinctures for homoeopathic preparations, which are the subject of separate general monographs (Herbal drugs (1433), Herbal drugs for homoeopathic preparations (2045), Herbal drug preparations (1434), Herbal drug extracts (0765), Mother tinctures for homoeopathic preparations (2029)). It does not apply to raw materials for homoeopathic preparations, except where there is an individual monograph for the substance in the non-homoeopathic part of the Pharmacopoeia.

This monograph does not apply to chemical precursors for radiopharmaceutical preparations which are the subject of a separate monograph (Chemical precursors for radiopharmaceutical preparations (2902)).

Where a substance for pharmaceutical use not described in an individual monograph of the Pharmacopoeia is used in a medicinal product prepared for the special needs of individual patients, the need for compliance with the present general monograph is decided in the light of a risk assessment that takes account of the available quality of the substance and its intended use.

- Complementary with individual monographs
- Not overruling each other
- Exceptions clearly indicated either in general monograph or in individual one

General monographs & Dosage form monographs

OMEPRAZ

Omeprazo

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)

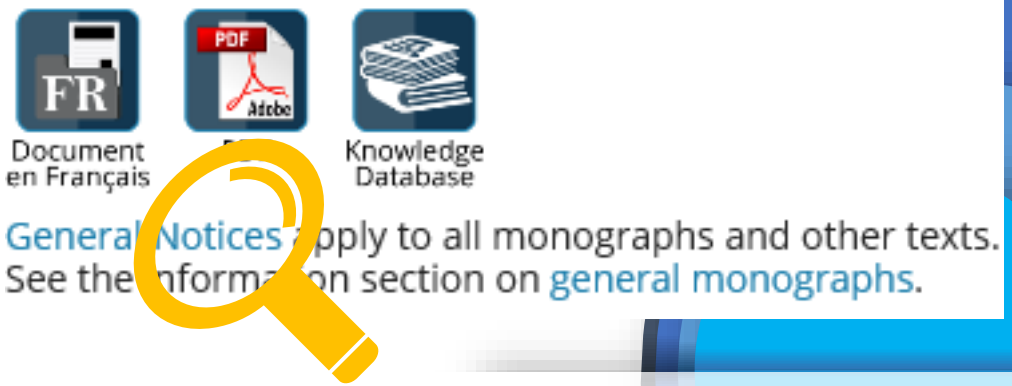
Essential oils (2098)

Herbal drug extracts (0765)

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)

General Notices



- General notices

General Notices – answer to a lot of questions!

Such as:

- What does compliance mean?
- What is mandatory?
- What about waiving of tests?
- What about alternative procedures?
- Why two series of identification tests sometimes?
- Human and/or veterinary use?

and many more ...

OF NOTE: SECTION NOW NUMBERED FOR BETTER REFERENCING

Conventional terms: meanings

‘competent authority’. The national, supranational or international body / organisation vested with the authority for **making decisions concerning the issue in question**. May be a national pharmacopoeia authority (NPA), a licensing authority or an official medicines control laboratory (OMCL).

‘unless otherwise justified and authorised’. Means that the requirements must be met, **unless the competent authority authorises a modification** (e.g. of an analytical procedure or limit) or an **exemption** where **justified** by the manufacturer in a particular case.

‘should’. Statements are informative or advisory.

Other defined terms

‘Freshly prepared’: the solution is prepared each time the test/assay is to be carried out and is used within 24 h.

‘Immediately before use’: the stability of the corresponding solution(s) has been found critical during the elaboration of the text.
The time between preparation and use must be minimised.

Alignment of terms

REVISED

‘Method’, ‘test method’ => ‘analytical procedure’ [ICH Q2(R1)]

‘Pharmaceutical preparations’, ‘finished products, ‘medicinal products’ => ‘medicinal products’

Scope (1/2)

- The *scope of a monograph* is stated in the section DEFINITION

> Fatty oil obtained from the ripe seeds of *Sesame indicum* L. by expression of extraction. It is then refined ...

- *Human/veterinary use*
  - Unless otherwise stated, monographs cover **human and veterinary** use.
  - Where a substance is used in both human and veterinary products, the same quality specification is applied.
  - When the monograph title bears "for veterinary use" the substance is intended for veterinary products only e.g. *Levamisole for veterinary use*

- *Grades*

Certain articles (substances, materials) exist as different grades. Unless otherwise stated, requirements apply to all grades (see FRC section)

Scope (2/2)

NEW

~~Period of validity~~

- *Shelf life:* medicinal products must comply with monograph requirements until end of shelf life
  - ➢Distinct shelf life and/or specification for broached or opened containers may be decided by a competent authority;
  - ➢Monographs on medicinal products provide shelf life specifications that may differ from release specifications.

~~Period of use~~

- *Re-test period:* the subject of any other monograph must comply thoughout its re-test period
  - ➢Exception: substances known to be labile, biotech/bio substances and certain antibiotics, where a shelf life is established rather than a re-test period;

Demonstration of compliance with the Ph. Eur.

"*Unless otherwise indicated in the General Notices or in the monographs, statements in monographs constitute mandatory requirements.*"

Compliance

= satisfaction to all **mandatory** parts of a **monograph**

MANDATORY	INFORMATIVE
Definition Production Identification Tests Assay	Characters Storage *Functionality-related characteristics*

Demonstration of compliance with the Ph. Eur.

… and flexibility

The way(s) to compliance - Flexibility

(1) An article is of Ph. Eur. quality if it complies with all of the requirements stated in the monograph. This does not im cribed in a monograph when assessing compl may obtain assurance that an article is of Ph. Eu ol strategy and data derived, for example, from validation studies of the manufacturing process.

In certain monogra hat the analytical procedu e replaced by a suitable, validated proce e' procedure), subject to approval by the competent authority.

(2) An en e releas - time r ded by the need to comply with the Ph. Eur.

(3) Reduction of animal testing: the Ph. Eur. is committed to phasing out the use of animals for test purposes, in accordance with the 3Rs (Replacement, Reduction, Refinement) set out in the European Convention for the Pr Scientific Purposes. In demonstrating compl y consider establishing additional syste the competent authority, the choice of tests performed to assess compliance with the Ph. Eur. when animal tests are prescribed is established in such a way that animal usage is kept to a minimum.

(1) WAIVING OF TESTS

NEW

EXAMPLE PROCEDURE

(2) PROCESS ANALYTICAL TECHNOLOGY

(3) SUPPORTING THE 3Rs

Flexibility #1: Waiving of tests

Compliance ≠ Performance of test

prerequisite

not a prerequisite

Tests may be omitted based on:

- **Design and control strategy**
- **Process knowledge** : validation studies of the manufacturing process or other suitable justification

Additional flexibility: Example procedure

In certain monographs, identified by the statement

'*The following procedure is given as an example*'

✓ the analytical procedure has been validated for the intended purpose;

A

Implement & use the example procedure

OR

B

Replacement by another suitable **validated** procedure

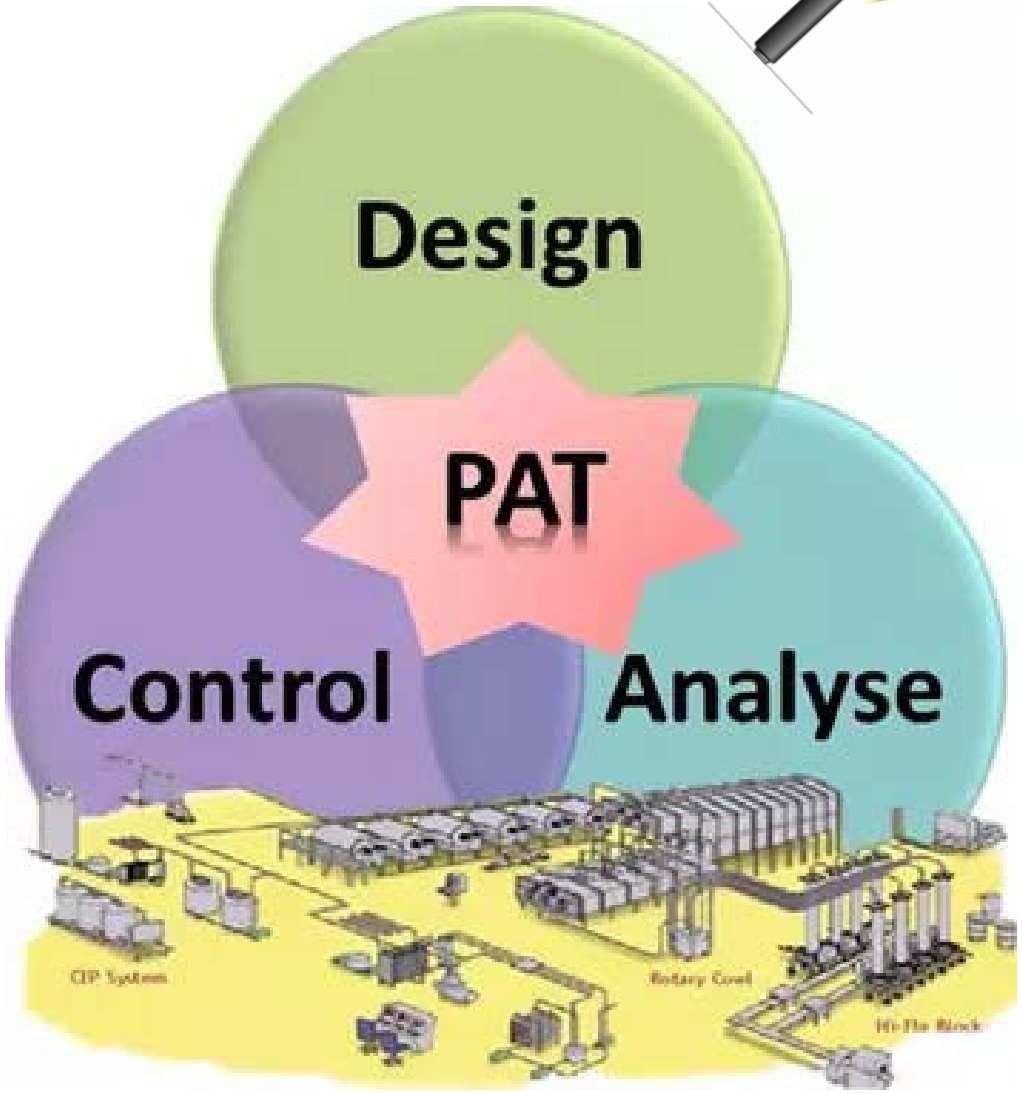
No need to demonstrate equivalence to the procedure in the monograph

subject to approval by the competent authority.

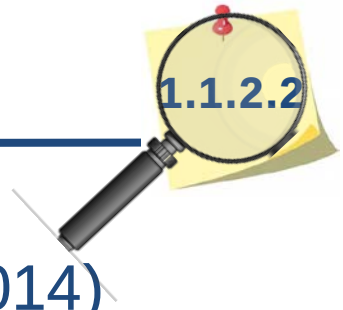
Flexibility #2: PAT

1.1.2.2

"An **enhanced approach to quality control** could utilise process analytical technology (**PAT**) and/or **real-time release testing** (including parametric release) strategies as **alternatives to end-product testing alone**. Real-time release testing in circumstances deemed **appropriate by the competent authority** is thus **not precluded by the need to comply with the Pharmacopoeia**."



Flexibility #3: supporting the 3Rs



- **Consistency of production** to aid the demonstration of compliance (in General Notices since Supplement 8.2 – implemented 1st January 2014)
- Under strict application of a manufacturing **quality system** (e.g. GMP rules and guidelines).
- Constitution of a **product profile** that can replace current release tests based on *in vivo* methods.
- Promotes **minimal use of animals**.
- Reference to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes of the Council of Europe (1986)

Demonstration of suitability of monographs

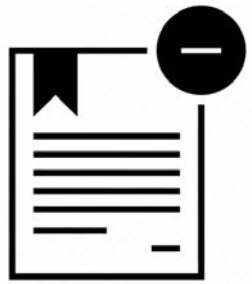
1.1.2.3

NEW*

*In line with EU directive 2001/83/EC, as amended

Manufacturer to evaluate the **suitability of the monograph** for QC of their article. Choice of analytical procedures may be influenced by:

- the manufacturing process and/or
- the composition of the medicinal product.



When a competent authority considers a specification described in a monograph **insufficient** to ensure quality of the article, it may **request more-appropriate specifications** from the **manufacturer** in line with national or regional regulations.

Demonstration of suitability of monographs (cont.)

In such cases, the competent authority informs the Ph. Eur. Commission through either

- the national pharmacopoeia authority or
- the Secretariat of the Ph. Eur. Commission (@EDQM).

Details of the alleged insufficiency and the additional specifications : provided by the **manufacturer** to the national pharmacopoeia authority or the EDQM (Helpdesk)

➔ the decision to revise the monograph in question will be taken by the Ph. Eur. Commission.

Important concepts: validation and implementation

VALIDATION

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**.

IMPLEMENTATION

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.

COMING SOON: NEW CHAPTER 5.26 (PH. EUR. 11th EDITION)

Flexibility: 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."

- ✓ Users' responsibility to demonstrate comparability to the satisfaction of the *competent authority*
  - ➔ Assessors (through *NCA or EMA)* during assessment of marketing authorisation applications

NB: during assessment of a CEP, the EDQM evaluates a proposed alternative procedure

- ✓ Compliance required, but alternative procedures may be used: same pass/fail decision
- ✓ The pharmacopoeial procedure remains the reference procedure

IN PUBLIC CONSULTATION (PHARMEUROPA 34.2): NEW CHAPTER 5.27
"COMPARABILITY OF ALTERNATIVE ANALYTICAL PROCEDURES"

Other provisions in the General Notices

Applying to general chapters and monographs:

- **Quantities** (masses and volumes)
- Glassware (class A)
- Temperature / water bath
- Definition of ‘Drying and ignition to constant mass’
- Solutions (timing of preparation)
- Reagents and solvents:
  - Chapter 4.
  - Default grade = analytical grade
  - *Water R* = Purified water (0008) (except BET and microbial contamination)

Quantities in the Ph. Eur.

REVISED

- **NEW**: Ref to *2.1.7. Balances for analytical purposes*, applicable to all texts. Definition of '*minimum weight*'
- **THE 10 PER CENT-RULE**:
  - this tolerance is allowed as covered by the original validation
  - **ONLY** when the amount of sample actually weighed enters into the calculation of the final result, e.g. quantification of impurities or content determination
  - take into account the number of significant figures given in text to defined needed accuracy (see below)
  - use the exact weighed amount for calculation of result
- **NUMBER OF SIGNIFICANT FIGURES FOR MASSES**:
  - intended use of a quantity affects the needed accuracy for weighing ➔ expressed by number of significant figures
  - the indication of a balance must match the target mass value given in the text
  - weighing is done within ± 5 subunits after the last figure of the stated mass value (for example, 50.0 mg is to be interpreted as 49.9**5** mg to 50.0**4** mg or 49.9**50** mg to 50.0**49** mg, depending on the readability of the balance).
  - *FOR EXAMPLE*: CRS for peak ID (i.e. qualitative purposes) is given as 5 mg, while for an *impurity CRS*, used as external standard (quantitative or limit test), given as 5**.0** mg

Individual monographs

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)

EXAMPLES

Active substances or excipients

Paracetamol (0049)
Rosuvastatin calcium (2631)
Calcium carbonate (0014)
Etanercept (2895)

Medicinal products

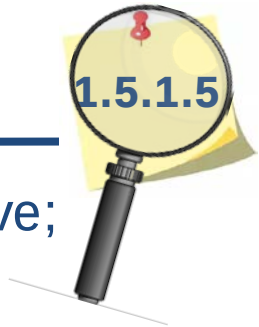
Deferiprone tablets (2986)
Lacosamide infusion (2991)
Cyanocobalamin (58Co) capsules (1505)

GENERAL PRINCIPLES in 1.5.1

Info on sections of individual monographs:

Production
Characters
Identification
Tests
Assay
...

General principles - Production section



- Draw attention to particular aspects of the manufacturing process - not necessarily exhaustive;
- mandatory requirements for manufacturers, unless otherwise stated (source materials, manufacturing process and its validation and control ...);
- requirements cannot necessarily be verified on a sample of the final article by an independent analyst.

Examples:

Paroxetine hydrochloride (2283)

Impurity G: maximum 1 ppm, determined by a suitable validated method.

Chitosan hydrochloride (1774)

The animals from which chitosan hydrochloride is derived must fulfil the requirements for the health of animals suitable for human consumption to the satisfaction of the competent authority. It must have been shown to what extent the method of production allows inactivation or removal of any contamination by viruses or other infectious agents.

Carbon dioxide (0375)

Tests for Carbon monoxide (GC), Nitrogen monoxide and dioxide (GC), Total sulfur, Water, Assay (IR)

Absence of a Production section does not imply that attention to above features not required

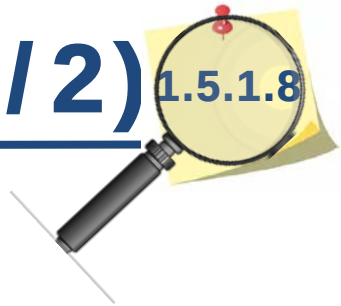
General principles - Characters section

NEW

11th Ed.

- As of 11th Ed., '**ethanol' and 'alcohol' without qualification**: sentence deleted and terms replaced in monographs by 'anhydrous ethanol' and 'ethanol (96 per cent)'.
- **Hygroscopicity, crystallinity, solubility**: transfer of information to chapter *5.11 Characters section in monographs*
- **Polymorphism**: paragraph copied from II. Introduction

General principles - Identification section (1/2)



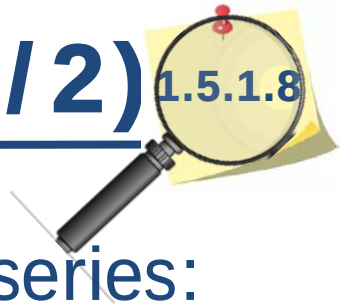
‘The tests given in the Identification section are

- not designed to give a full confirmation of the chemical structure or composition of the article;
- intended to give confirmation, with an acceptable degree of assurance, that the article conforms to the description on the label.’

If the monograph lists, for example, identification tests A, B and C, all three tests must be carried out and must satisfy the requirements.

NEW

General principles - Identification section (2/2)



In some monographs, Identification section is subdivided in two series:

First identification The test(s) may be used **in all circumstances**.

Second identification The test(s) may be used **in pharmacies only**

CONDITIONS: Article fully traceable to a monograph compliant batch, subject to national regulation

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In case of statement: '*Carry out either tests A, B or tests C, D*'.

⚠ **≠** First identification, Second identification series

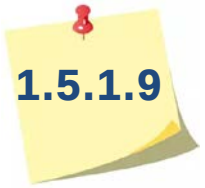
These **two (or more) sets** of identification tests are equivalent and may be used independently, at user's discretion.

General principles - Tests and assays

- Scope:
  - Requirements not designed to take all possible impurities into account;
  - do not presume, for example, that an impurity that is not detectable by prescribed tests is tolerated if common sense and good pharmaceutical practice require that it be absent.
- Limits:
  - Take account of normal analytical errors, of acceptable variations in manufacture/preparation and of deterioration to an acceptable extent;
  - no further tolerances applied to prescribed limits.
  - in determining compliance: first rounded, then compared with numerical limit.

Miscellaneous

NEW



Chiral substances: enantiomeric purity by chromatographic procedure (favoured technique) or specific optical rotation

Functionality-related characteristics (excipients):

- ≠ requirements but guidance
- decision to control a F-R characteristic remains with manufacturer of medicinal product
- analytical procedures, limits and tolerances determined on a bilateral basis (contract) between user and supplier of the excipient

Monographs on Herbal drugs: paragraphs gathered under a new sub-section.

Individual monographs on medicinal products

1.5.3

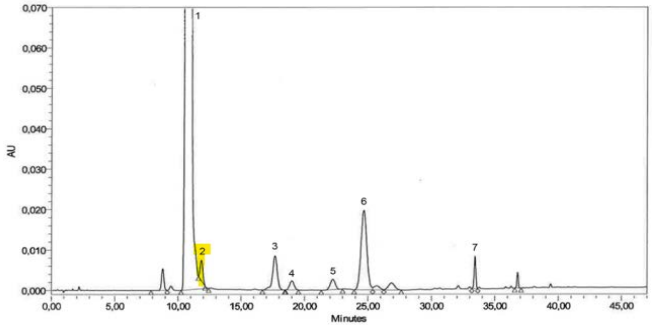
NEW

… containing chemically defined active substances

ICH Q3B

Related substances:

- Only control of *degradation products* arising during manufacture and shelf life;
- Need to *identify impurities of synthesis* in chromatogram when > reporting threshold to disregard them;



- Additional controls might be required to monitor *degradation products other* than those controlled by monograph (due to different excipients, container or manufacturing process).

Individual monographs on medicinal products

… containing chemically defined active substances (1.5.3)

Dissolution:

ICH Q6A

A suitable product-specific t[illegible]o be proposed (in MAA) by applicant for routine quality control to confirm batch-to-batch consistency

When test included in monograph, manufacturers may either

- select this test as ***product-specific dissolution test*** or
- develop an in-house test as ***product-specific dissolution test***

Demonstration of the suitability of the dissolution test selected to be made by the applicant to the satisfaction of the competent authority

Justification for not selecting monograph test normally not requested in MAA.

Individual monographs on medicinal products

… containing chemically defined active substances

Dissolution (cont.)

However, when tested, the medicinal product *has to comply with the monograph dissolution test*, unless otherwise justified by the applicant.

If the product does not comply but is approvable by a CA, the CA shall bring this to the attention of Ph. Eur. Commission for review.

Disintegration

For rapidly dissolving medicinal products containing a highly soluble active substance, disintegration may be substituted for dissolution, if justified by the applicant and authorised by CAs.

ICH Q6A

Individual monographs on medicinal products

… containing chemically defined active substances

Impurities

- Those listed in the monograph on API keep their name (A, B, C …);
- Imp. specific to medicinal product designated FP-.. (FP-A, FP-B, …).

Storage

- Statements constitute recommendations only
- Other conditions possible subject to approval by CAs

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