

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



General concepts in the Ph. Eur.: theory and rationale

2019 Training Session
"The European Pharmacopoeia"
Mrs Cathie Vielle
EDQM, Head of European Pharmacopoeia Department

10 – 11 September 2019, Iselin, New Jersey, USA

Where do you start ... when using the Ph. Eur.?



Sample of e.g. Omeprazole
to be tested



OMEPRAZOLE
Omeprazolium

Cc1cc2c(nc(=O)n2C(=O)Nc3ccc(OC)c3)c(C)c1

CHARACTERS
Appearance: white or almost white powder.
Solubility: very slightly soluble in water; soluble in methylene chloride, sparingly soluble in ethanol (36 per cent) and in methanol. It dissolves in dilute solutions of alkali hydroxides.
It shows polymorphism (5.9).

IDENTIFICATION
Infrared absorption spectrophotometry (2.2.26).
Comparison: omeprazole CRS.
If the spectra obtained in the solid state show differences, dissolve the substance to be examined and the reference substance separately in methanol R₁, evaporate to dryness and record new spectra using the residues.

TESTS
Solution S. Dissolve 0.50 g in methylene chloride R and dilute to 25 mL with the same solvent.
Assessment of solution. Evaluation R in chapter 2.9.7.15.

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Where do you start ... when using the Ph. Eur.?

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Draft monographs for public enquiry

Preliminary drafts of new and revised monographs proposed for inclusion in the European Pharmacopoeia can be found in [Pharmeuropa Online](#).

Publication calendar

Each new edition or supplement of the European Pharmacopoeia is usually published 6 months before its implementation date. All publications schedules, correction dates and implementation dates are available in the [10th Edition publication schedule](#).

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User manual

Key to monographs

How to access

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KEY TO MONOGRAPHS (ONLINE VERSION)

Document en Français PDF Knowledge Database General Monographs General Notices

CH₃N₃O₅

[2232-64-8]

DEFINITION
Ethyl 3-methyl-2-thioxo-2,3-dihydro-1H-imidazole-1-carboxylate.
Content: 98.0 per cent to 102.0 per cent (dried substance).

CHARACTERS
Appearance: white or yellowish-white, crystalline powder.
Solubility: slightly soluble in water, soluble in acetone and in ethanol (96 per cent).

IDENTIFICATION
First identification: B.
Second identification: A, C, D.
A. Melting point (2.2.14): 122 °C to 125 °C.
B. Infrared absorption spectrophotometry (2.2.24).
Comparison: carbimazole CRS.
C. Thin-layer chromatography (2.2.27).
Test solution: Dissolve 10 mg of the substance to be examined in methylene chloride R and dilute to 10.0 mL.
Reference solution: Dissolve 10 mg of carbimazole CRS in methylene chloride R and dilute to 10.0 mL with R.
Plate: TLC silica gel F₂₅₄ plate R.
Mobile phase: acetone R, methylene chloride R (20:80 V/V).
Application: 10 µL.
Development: over 3/4 of the plate.
Drying: in air for 30 min.

CARBIMAZOLE (CODE: ACTY)
Carbamazolum
CC1=CN(C(=O)OCC)C=S1

CH₃N₃O₅

[2232-64-8]

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Reference solution: Dissolve 10 mg of carbimazole CRS in methylene chloride R and dilute to 10.0 mL with the same solvent.
Plate: TLC silica gel F₂₅₄ plate R.
Mobile phase: acetone R, methylene chloride R (20:80 V/V).
Application: 10 µL.
Development: over 3/4 of the plate.
Drying: in air for 30 min.
Detection: examine in ultraviolet light at 254 nm.
Results: the principal spot in the chromatogram obtained with the test solution is similar in position and size to the principal spot in the chromatogram obtained with the reference solution.
D. Dissolve about 10 mg in a mixture of 0.5 mL of dilute hydrochloric acid R and 50 mL of water R. Add 1 mL of potassium iodobismuthate solution R. A red precipitate is formed.

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Where do I find the Key to Monographs?

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About the European Pharmacopoeia
This menu page provides information on the European Pharmacopoeia and its editions. It also provides information on the paper versions, in view of the linguistic environment, and refers to the PDF version.

Key to Monographs

Carbamazole
Version date of the test
Test reference number
Modification to be taken into account as soon as possible and not later than the end of the month following the month of publication of Ph. Eur. 10.0 (see section IV, Contents of the 10th Edition)
Link to further information on the test (e.g. Knowledge database) for smartphones/tablets with camera and barcode reader app
CAS number
Chemical name in accordance with IUPAC, nomenclature rules
For the meaning of black and white diamonds see chapter 5.8, Pharmaceutical harmonisation
Application of the first and second identification is defined in the General Notices (chapter 1)
Reference standard available from the EDQM (see <http://www.edqm.eu>)
Reagent described in chapter 4
Further information on certain reagents available in the Knowledge database (<http://knowledge.edqm.eu>)
Vertical line in the margin indicating where the test has been modified
Horizontal line in the margin indicating where part of the test has been deleted
Reference to a general chapter

en using the Ph. Eur.?

Draft monographs for public enquiry
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Where do you start ... when using the Ph. Eur?



Sample of e.g. Omeprazole
to be tested



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Where do you start ... when using the Ph. Eur?



Sample of e.g. Omeprazole
to be tested



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07/2014:10000
corrected 10.0**1. GENERAL NOTICES****1.1. GENERAL STATEMENTS**

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

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

In the texts of the European Pharmacopoeia, the word 'Pharmacopoeia' without qualification denotes the European Pharmacopoeia. The official abbreviation Ph. Eur. may be used to indicate the European Pharmacopoeia.

The use of the title or the subtitle of a monograph implies that the article complies with the requirements of the relevant monograph. Such references to monographs in the texts of the Pharmacopoeia are shown using the monograph title and reference number in italics.

A preparation must comply throughout its period of validity, a defined period of validity and/or specifications for opened or unopened containers may be decided by the competent authority. The subject of any other monograph must comply throughout its period of use. The period of validity that is assigned to any given article and the time from which that period is to be calculated are decided by the competent authority in light of experimental results of stability studies.

Unless otherwise indicated in the General Notices or in the monographs, statements in monographs constitute mandatory requirements. General chapters become mandatory when referred to in a monograph, unless such reference is made in a way that indicates that it is not the intention to make the text referred to mandatory but rather to cite it for information. The active substances, excipients, pharmaceutical preparations and other articles described in the monographs are intended for human and veterinary use (unless explicitly restricted to one of these uses).

Quality systems. The quality standards represented by monographs are valid only when the articles in question are produced within the framework of a suitable quality system. The quality system must ensure that the articles consistently meet the requirements of the Pharmacopoeia.

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

Demonstration of compliance with the Pharmacopoeia

(1) An article is not of Pharmacopoeia quality unless it complies with all the requirements stated in the monograph. This does not imply that performance of all the tests in a monograph is necessarily a prerequisite for a manufacturer in assessing compliance with the Pharmacopoeia before release of a product. The manufacturer may obtain assurance that a product is of Pharmacopoeia quality on the basis of its design, together with its control strategy and data derived, for example, from validation studies of the manufacturing process.

(2) An enhanced approach to quality control could utilize 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.

(3) Reduction of animal testing. The European Pharmacopoeia is dedicated 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 Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes. In demonstrating compliance with the Pharmacopoeia as indicated above (1), manufacturers may consider establishing additional systems to monitor consistency of production. With the agreement of the competent authority, the choice of tests performed to assess compliance with the Pharmacopoeia when animal tests are prescribed is established in such a way that animal usage is minimised as much as possible.

Grade of materials. Certain materials that are the subject of a pharmaceutical monograph may exist in different grades suitable for different purposes. Unless otherwise indicated in the monograph, the requirements apply to all grades of the material. In some monographs, particularly those on excipients, a list of functionality related characteristics that are relevant to the use of the substance may be appended to the monograph for information. Test methods for determination of one or more of these characteristics may be given, also for information.

General monographs. Substances and preparations that are the subject of an individual monograph are also required to comply with relevant, applicable general monographs. Cross-references to applicable general monographs are not normally given in individual monographs.

General monographs apply to all substances and preparations within the scope of the definition section of the general monograph, except where a preamble limits the application, for example to substances and preparations that are the subject of a monograph of the Pharmacopoeia.

General monographs on dosage forms apply to all preparations of the type defined. The requirements are not necessarily comprehensive for a given specific preparation and requirements additional to those prescribed in the general monograph may be imposed by the competent authority.

General monographs and individual monographs are complementary. If the provisions of a general monograph do not apply to a particular product, this is expressly stated in the individual monograph.

Validation of pharmaceutical methods. The test methods given in monographs and general chapters have been validated in accordance with accepted scientific practice and current recommendations on analytical validation. Unless otherwise stated in the monograph or general chapter, validation of the test methods by the analyst is not required.

Implementation of pharmaceutical methods. When implementing a pharmaceutical method, the user must assess whether and to what extent the suitability of the method under the actual conditions of use needs to be demonstrated according to relevant monographs, general chapters and quality systems.

Conventional terms. The term 'competent authority' means 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, a licensing authority or an official laboratory.

The expression 'unless otherwise justified and authorised' means that the requirements have to be met, unless the



General Notices apply to all monographs and other texts. See the information section on **general monographs**.

IMPORTANT NOTICE

GENERAL MONOGRAPHS

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 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. Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question. 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 (2002)
Dosage forms monographs
(published in the *Dosage Forms* section or the *Homoeopathic Preparations* section, as appropriate)
Essential oils (2098)
Herbal drug extracts (0745)
Herbal drug preparations (1434)
Herbal drugs (1433)
Herbal drugs for homoeopathic preparations (2045)
(published in the *Homoeopathic Preparations* section)
Herbal teas (1435)
Herbal teas, instant (2420)
Homoeopathic preparations (1070)
(published in the *Homoeopathic Preparations* section)
Immunogens for human use, animal (0094)
Immunogens for veterinary use (0030)
Live biotechnological products for human use (3053)
Methods of preparation of homoeopathic stocks and potentisation (2371)
(published in the *Homoeopathic Preparations* section)
Monoclonal antibodies for human use (2031)
Mother tinctures for homoeopathic preparations (2026)
(published in the *Homoeopathic Preparations* section)
Pharmaceutical preparations (2416)
Products of fermentation (1406)
Products with risk of transmitting agents of animal spongiform encephalopathies (1483)
Radiopharmaceutical preparations (0125)
Recombinant DNA technology, products of (0794)
Substances for pharmaceutical use (2034)
Vaccines for human use (0153)
Vaccines for veterinary use (0062)
Vegetable fatty oils (1579)

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

3

Knowledge database



General Notices apply to all monographs and other texts. See the information section on **general monographs**.

Search Database online | Knowledge Database

Detailed view of Omprazole

Str. Use	00942
Monograph Number	00942
English Name	Omprazole
French Name	Ompérazole
Latin Name	Ompirazonum
Pharmacopoeia	20.3
Published in English Supplement	7.7
Published in French Supplement	7.7
Chromatogram	Available
Additional information	Not available
History	Your history
Interchangeability (ICH Q4B)	NO
Chapter 5.6	NO
Pharmaceutical Information	
Availability	
Ref. No.	00150200
Ref. Name	Omprazole
Batch No.	5
Unit Quantity	50 mg
Product Code	75
Ref. No.	00331000
Ref. Name	Omprazole
Batch No.	3
Unit Quantity	15 mg
Product Code	75
Ref. No.	13231552
Ref. Name	Omprazole
Batch No.	2
Unit Quantity	10 mg
Product Code	75

Substance	Substance	Certificate Holder	Certificate Number	Issue Date	Status	End date	Type
001	Omprazole	Novartis (UK) Ltd	001-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
002	Omprazole	Novartis (UK) Ltd	002-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
003	Omprazole	Novartis (UK) Ltd	003-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
004	Omprazole	Novartis (UK) Ltd	004-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
005	Omprazole	Novartis (UK) Ltd	005-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
006	Omprazole	Novartis (UK) Ltd	006-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
007	Omprazole	Novartis (UK) Ltd	007-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
008	Omprazole	Novartis (UK) Ltd	008-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
009	Omprazole	Novartis (UK) Ltd	009-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
010	Omprazole	Novartis (UK) Ltd	010-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
011	Omprazole	Novartis (UK) Ltd	011-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
012	Omprazole	Novartis (UK) Ltd	012-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
013	Omprazole	Novartis (UK) Ltd	013-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
014	Omprazole	Novartis (UK) Ltd	014-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
015	Omprazole	Novartis (UK) Ltd	015-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
016	Omprazole	Novartis (UK) Ltd	016-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
017	Omprazole	Novartis (UK) Ltd	017-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
018	Omprazole	Novartis (UK) Ltd	018-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
019	Omprazole	Novartis (UK) Ltd	019-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
020	Omprazole	Novartis (UK) Ltd	020-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
021	Omprazole	Novartis (UK) Ltd	021-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
022	Omprazole	Novartis (UK) Ltd	022-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
023	Omprazole	Novartis (UK) Ltd	023-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
024	Omprazole	Novartis (UK) Ltd	024-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
025	Omprazole	Novartis (UK) Ltd	025-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
026	Omprazole	Novartis (UK) Ltd	026-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
027	Omprazole	Novartis (UK) Ltd	027-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
028	Omprazole	Novartis (UK) Ltd	028-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
029	Omprazole	Novartis (UK) Ltd	029-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
030	Omprazole	Novartis (UK) Ltd	030-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
031	Omprazole	Novartis (UK) Ltd	031-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
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039	Omprazole	Novartis (UK) Ltd	039-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
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041	Omprazole	Novartis (UK) Ltd	041-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
042	Omprazole	Novartis (UK) Ltd	042-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
043	Omprazole	Novartis (UK) Ltd	043-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
044	Omprazole	Novartis (UK) Ltd	044-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
045	Omprazole	Novartis (UK) Ltd	045-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
046	Omprazole	Novartis (UK) Ltd	046-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
047	Omprazole	Novartis (UK) Ltd	047-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
048	Omprazole	Novartis (UK) Ltd	048-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
049	Omprazole	Novartis (UK) Ltd	049-001	2013-01-16	Rev. 05	2013-01-16	Chemistry
050	Omprazole	Novartis (UK) Ltd	050-001	2013-01-16	Rev. 05	2013-01-16	Chemistry

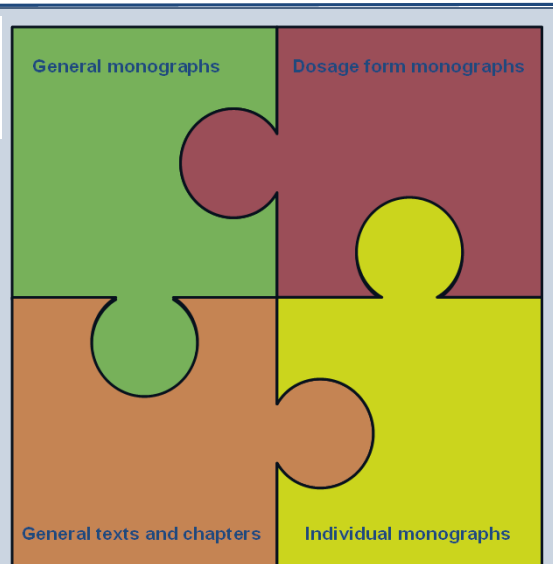
The structure of the Ph. Eur.



General Notices apply to all monographs and other texts. See the information section on general monographs.

Table of contents

- ☐ European Pharmacopoeia 10.0
- ▼ ☐ European Pharmacopoeia 10.0
 - ☐ 00 Introduction
 - ☐ 01 General notices
 - ☐ 02 Methods of analysis



General Notices

At the very beginning of the Ph. Eur. (page 3)

- address general issues
- aim at providing basic information to the user
- apply to **all** texts
- include rules to understand texts, conventional expressions

Essential reading before starting to use monographs and chapters



General Notices – answer to a lot of questions!

- Such as:
 - What about alternative methods?
 - What about waiving of tests?
 - What does compliance mean?
 - What is mandatory?
 - What to do when implementing a method?
 - Why two identification tests ... sometimes?
 - Human and/or veterinary use?

And many more

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, a licensing authority or an official control laboratory.

'unless otherwise justified and authorised' means that the requirements have to be met, unless the competent authority authorises a modification or an exemption where justified in a particular case.

Etc...

Flexibility in the Ph. Eur. **Alternative methods**



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Alternative methods

- Ph. Eur. tests = reference methods, alone authoritative in cases of doubt or dispute.
- Compliance required, but alternative methods may be used: **same pass/fail decision**
- Users' responsibility to demonstrate their suitability. Approval of *competent authority* needed in any case

The EDQM does not decide if acceptable or not!

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Alternative methods

Example:

- You may replace an existing HPLC method (impurities or assay) by an alternative one, provided the alternative method is cross-validated against the official one and leads to the same pass/fail decision.
- ✗ Not possible to replace a selective HPLC assay by a volumetric titration [since the same pass/fail cannot be obtained].

Flexibility in the Ph. Eur. **Waiving of tests**

Compliance \neq **Performance**

↓
prerequisite

↓
not prerequisite



- In some cases, some tests may be omitted based on validation data or other suitable justification
- Tests for process-specific impurities may be omitted if it is demonstrated that they will not occur with the particular process used e.g. boron in salbutamol

Waiving of tests

*"(1) An article is not of Pharmacopoeia quality unless it complies with all the requirements stated in the monograph. **This does not imply that performance** of all the tests in a monograph is necessarily a prerequisite for a manufacturer in assessing compliance with the Pharmacopoeia before release of a product. **The manufacturer may obtain assurance that a product is of Pharmacopoeia quality** on the basis of its design, together with its control strategy and data derived, for example, from validation studies of the manufacturing process."*

Flexibility in the Ph. Eur. **PAT**

*"(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."*

What does compliance mean?

- All **mandatory** parts of a **monograph**
(*"Unless otherwise indicated in the General Notices or in the monographs, statements in monographs constitute mandatory requirements."* Characters section, second identification test and storage section – not mandatory)
- Compliance **throughout period of validity** for preparations.
- A distinct period of validity and/or specifications for opened or broached containers may be decided by licensing authority for each preparation
- Compliance **until end of shelf-life** for all other items: API, excipients, ...

What to do when implementing a method?

- **Validation of pharmacopoeial methods.** The test methods given in monographs and general chapters have been validated in accordance with accepted scientific practice and current recommendations on analytical validation. **Unless otherwise stated in the monograph or general chapter, validation of the test methods by the analyst is not required.**
- **Implementation of pharmacopoeial methods.** When implementing a pharmacopoeial method, the user must assess whether and to what extent the **suitability** of the method under the actual conditions of use needs **to be demonstrated** according to relevant monographs, general chapters and quality systems.
- **# Demonstration of suitability:** Each MAA still to provide to the competent authority demonstration that **tests in the monograph are appropriate** for the quality control of their product.

Reference to regulatory documents

- *"These references are provided for information for users for the Pharmacopoeia. Inclusion of such a reference does not modify the status of the documents referred to, which may be mandatory or for guidance."*

Human and 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 only for veterinary products e.g. *Levamisole for veterinary use*

Section 1.4 Monographs

DEFINITION

Statements under the heading Definition constitute an official definition of the substance, preparation or other article that is the subject of the monograph.

CHARACTERS

The statements under the heading Characters are not to be interpreted in a strict sense and are not requirements.

TESTS AND ASSAYS

Scope. The requirements are not framed to take account of all possible impurities. It is not to be presumed, for example, that an impurity that is not detectable by means of the prescribed tests is tolerated if common sense and good pharmaceutical practice require that it be absent. See also below under Impurities.

IDENTIFICATION

Scope. The tests given in the Identification section are not designed to give a full confirmation of the chemical structure or composition of the product; they are intended to give confirmation, with an acceptable degree of assurance, that the article conforms to the description on the label.

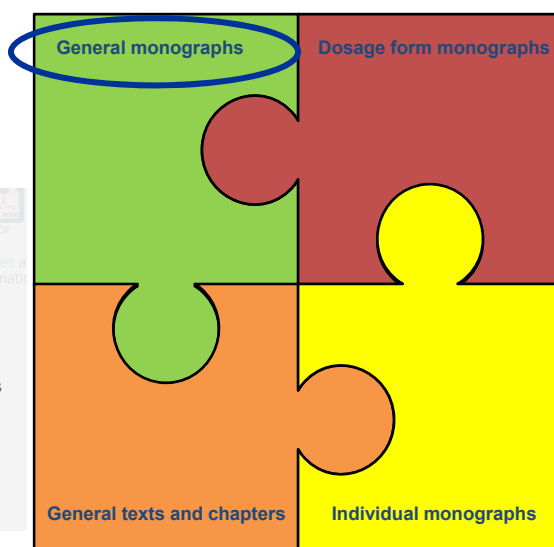
First and second identifications. Certain monographs have subdivisions entitled 'First identification' and 'Second identification'. The test or tests that constitute the 'First identification' may be used in all circumstances. The test or tests that constitute the 'Second identification' may be used in pharmacies provided it can be demonstrated that the substance or preparation is fully traceable to a batch certified to comply with all the other requirements of the monograph.

Certain monographs give two or more sets of tests for the purpose of the first identification, which are equivalent and may be used independently. One or more of these sets usually contain a cross-reference to a test prescribed in the Tests section of the monograph. It may be used to simplify the work of the analyst carrying out the identification and the prescribed tests. For example, one identification set cross-refers to a test for enantiomeric purity while the other set gives a test for specific optical rotation: the intended purpose of the two is the same, that is, verification that the correct enantiomer is present.


The structure of the Ph. Eur.

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Document
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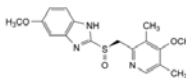


Knowledge
Database

General Notices apply to all monographs and other texts.
See the information section on [general monographs](#).

OMEPRAZOLE

Omeprazole



and enantiomers

$C_{17}H_{19}N_2O_5S$

[73590-58-6]

DEFINITION

5-Methoxy-2-[(S)-[4-methoxy-3,5-dimethylpyridin-2-yl)methyl]sulfinyl]-1H-benzimidazole.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white powder.

IMPORTANT NOTICE

GENERAL MONOGRAPHS

The European Pharmacopoeia contains a number of general monographs covering classes of products. These general monographs are requirements that are applicable to all products in the given, but not in every case, in any particular country. They are intended to be used in conjunction with the specific monographs for individual products. When an indication on 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. Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question. The general monographs listed below are published in the General Monographs section under various headings. This list is updated where necessary and reprinted in each supplement.

Astringent products (190)

Chemical preservatives for ophthalmic/ocular preparations (190S)

Orange Fumes Monographs

(published in the Orange Fumes section in the Monographs Preparations section, as appropriate)

Essential oils (204)

Herbal drug extracts (175)

Herbal drug preparations (180)

Herbal drugs (141)

Herbal drugs for homeopathic preparations (204S)

(published in the Homeopathic Preparations section)

Herbal teas (142)

Herbal teas, instant (202)

Homeopathic preparations (204)

(published in the Homeopathic Preparations section)

Infusions for babies and, animal (198)

Insulin preparations (see 198)

Low molecular products for babies and (192)

Mixtures of preparations of homeopathic, animal and pharmaceutical (207)

(published in the Homeopathic Preparations section)

Mineralised waters for babies and (201)

Mixture vaccines for homeopathic preparations (202S)

(published in the Homeopathic Preparations section)

Pharmaceutical preparations (204S)

Products of biotechnology (140)

Products with risk of transmitting agents of animal zoonoses: microspores (140S)

Ophthalmic/ocular preparations (192)

Resuscitators (204) including products of (204S)

Substances for pharmaceutical use (204)

Vaccines for babies and (201)

Vaccines for veterinary use (202S)

Vaginal sets (175)

General monographs

IMPORTANT NOTICE
GENERAL MONOGRAPHS

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 scope of a general monograph is given it is a premise, it is applicable to all products in the class defined, irrespective of whether there is an individual monograph for the product in the Pharmacopoeia.

Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question. The general monographs listed below are published in the General Monographs section (unless otherwise stated).

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 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.

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

General monographs. Substances and preparations that are the subject of an individual monograph are also required to comply with relevant, applicable general monographs. Cross-references to applicable general monographs are not normally given in individual monographs.

General monographs apply to all substances and preparations within the scope of the Definition section of the general monograph, except where a preamble limits the application, for example to substances and preparations that are the subject of a monograph of the Pharmacopoeia.

General monographs on dosage forms apply to all preparations of the type defined. The requirements are not necessarily comprehensive for a given specific preparation and requirements additional to those prescribed in the general monograph may be imposed by the competent authority.

General monographs and individual monographs are complementary. If the provisions of a general monograph do not apply to a particular product, this is expressly stated in the individual monograph.

- Radiopharmaceutical preparations (10125)
- Recombinant DNA technology, products of (10784)
- Substances for pharmaceutical use (3034)
- Vaccines for human use (1033)
- Vaccines for veterinary use (1062)
- Vasoactive drugs only (1076)

General monographs

Two types:

- General monographs on **classes of substances**

e.g. Products of fermentation, Allergen products, Herbal drugs, Essential oils, Monoclonal antibodies for human use, etc.

- General monographs on **dosage forms**

e.g. capsules, tablets, parenteral preparations, eye preparations, etc.

General monographs

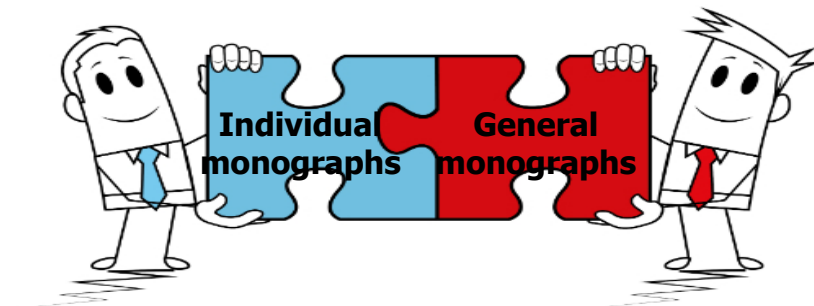
- Deal with aspects that cannot be treated in each individual monograph
- “*General monographs apply to all substances and preparations within the scope of the Definition section of the general monograph, except where a preamble limits the application, for example to substances and preparations that are the subject of a monograph of the pharmacopoeia.*”

General monographs

- No cross-reference in individual monographs: *"Whenever a monograph is used, it is essential to ascertain whether there is a general monograph applicable to the product in question."*

CHECK WHICH GENERAL MONOGRAPH APPLIES!

General vs. individual monographs



- Complementary
- One not overruling the other
- Exceptions are clearly indicated either in the general monograph or in the individual one

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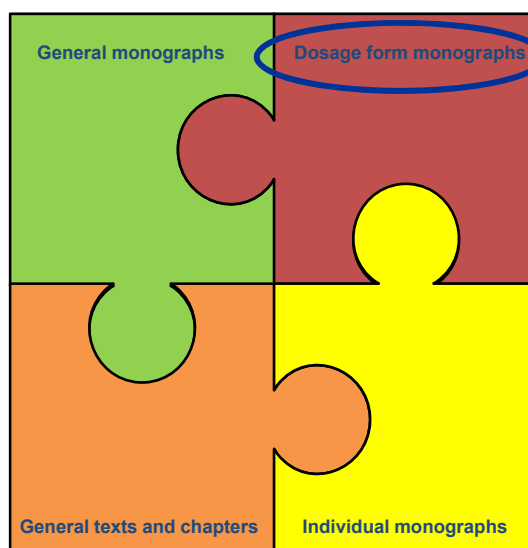


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<input type="checkbox"/>	12 Herbal drugs and herbal drug preparations
<input type="checkbox"/>	13 Homeopathic preparations

Section 7 Dosage forms

- 1st text published in there:

This glossary provides definitions and/or explanations of terms that may be found in, or used in association with, the general monographs on dosage forms and the corresponding chapters on Pharmaceutical technical procedures (2.9), but that are not defined within them. Where relevant, reference is made to other equivalent terms that may be found in other publications or contexts.

This glossary is published for information.



072017:1562

GLOSSARY

Glossa

This glossary provides definitions and/or explanations of terms that may be found in, or used in association with, the general monographs on dosage forms and the corresponding chapters on Pharmaceutical technical procedures (2.9), but that are not defined within them. Where relevant, reference is made to other equivalent terms that may be found in other publications or contexts.

This glossary is published for information.

Active substance
Equivalent terms: active ingredient, drug substance, medicinal substance, active pharmaceutical ingredient.

Basis
Basis is an alternative term for 'vehicle' in a semi-solid or moulded solid preparation. The basis may be single-phase or multiphase.

Conventional release dosage form
A conventional release dosage form is a preparation showing a release of the active substance(s) that is not deliberately modified by a special formulation design and/or manufacturing method. In the case of a solid dosage form, the dissolution profile of the active substance depends essentially on its intrinsic properties. Equivalent term: immediate-release dosage form.

Delayed release dosage form
A delayed release dosage form is a modified release dosage form, usually administered orally, where the onset of release of the active substance(s) is adjusted to take place after a specific time or at a specific location in the gastrointestinal tract. Delayed release is achieved by a special formulation design and/or manufacturing method. Delayed release dosage forms include gastro-resistant preparations as defined in the general monographs on solid oral dosage forms.

Dispersion
From a Ph. Eur. perspective, a dispersion is a system consisting of 2 or more phases.

– **Colloidal dispersion**
A colloidal dispersion is a system in which particles of colloidal size (a nominal diameter between approximately 1 µm and 1 µm) of any nature (solid, liquid or gas, including suspensions and microemulsions) are dispersed in a continuous phase of a different composition and/or state. The size of nominal diameter is intended to convey that not all particles are spherical. Dispersions of particles below 1 µm are considered less likely to undergo sedimentation because of the effect of Brownian motion.

– **Suspension**
A suspension is a dispersed system comprising solid particles of a nominal diameter greater than approximately 1 µm, dispersed in a liquid or semi-solid continuous phase. If the solid particles are of a nominal diameter lower than approximately 1 µm, the system is a colloidal suspension.

– **Emulsion**
An emulsion is a dispersed system consisting of a mixture of at least 2 liquids that are not miscible with each other. One of the liquids is dispersed in the other as droplets of a

diameter greater than approximately 1 µm. If the droplets are of a nominal diameter lower than approximately 1 µm, the system is a colloidal emulsion.

Large-volume parenteral

A large-volume parenteral is an infusion or injection supplied in a container with a nominal content of more than 100 ml.

Modified-release dosage form

A modified-release dosage form is a preparation where the onset, rate and/or place of release of the active substance(s) is different from that of a conventional release dosage form administered by the same route. This deliberate modification is achieved by a special formulation design and/or manufacturing method. Modified release dosage forms include prolonged-release, delayed-release and pulsatile-release dosage forms.

Prolonged-release dosage form

A prolonged-release dosage form is a modified-release dosage form showing a slower release of the active substance(s) than that of a conventional release dosage form administered by the same route. Prolonged-release is achieved by a special formulation design and/or manufacturing method. Equivalent term: extended-release dosage form.

Pulsatile-release dosage form

A pulsatile-release dosage form is a modified-release dosage form showing a sequential, intermittent release of the active substance(s). Pulsatile release is achieved by a special formulation design and/or manufacturing method.

Small-volume parenteral

A small-volume parenteral is an infusion or injection supplied in a container with a nominal content of 100 ml or less.

Solution

A solution is a homogeneous mixture forming a single phase containing one or more dissolved substances, i.e. substances in a molecular or ionic state dispersed in a solvent or in miscible solvents. The dissolved substances can be solids, liquids or gases.

Spherulite

Spherulites are considered to be spherical or approximately spherical granules with a usually increased mechanical resistance compared to conventional Granules (0499). They possess a smooth, uniform surface, with a typical size range of 200 µm to 2.5 mm. Spherulites may be prepared by any suitable method.

Standard Terms

Standard Terms are approved terms for describing certain aspects of a medicinal product, namely the dosage form and route or method of administration, and certain important packaging items such as the container, closure and administration device. They are established by the European Pharmacopoeia Commission, which started working on the basis of Standard Terms in response to a request made by the EU Commission for use in the marketing authorisation application (MAA) summary of product characteristics (SPC), labelling, and electronic communications. Standard Terms have the double purpose of bringing uniformity to the product name/preparator and distinguishing medicinal products having the same trade name, and are published in a specific Standard Terms database.

Vehicle

A vehicle is the carrier, composed of one or more excipients, in which the active substance(s) are contained, usually when referring to a liquid or semi-solid preparation.

- Classified by **pharmaceutical form/route of administration** e.g. Tablets, Preparations for inhalation ...
- Applied during **licensing**
- **Framework** specification: extra tests and acceptance criteria are proposed by manufacturer and approved by competent authority

Capules		Implementation date:	04/2018 (5.4)	Text number:	0016	
Chewing gums, medicated		Implementation date:	01/2018 (3.3)	Text number:	1229	
Ear preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	04/2011 (7.1)	Text number:	0652
Eye preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.5)	Text number:	1163
Foams, medicated		Implementation date:	01/2008 (5.4)	Text number:	1105	
Granules		Implementation date:	01/2019 (3.4)	Text number:	0499	
Intramammary preparations for veterinary use	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.4)	Text number:	0945
Intracranial delivery systems		Implementation date:	01/2018 (3.3)	Text number:	1228	
Intrauterine preparations for veterinary use	Correction date:	6.3 (06/2004)	Implementation date:	01/2008 (5.4)	Text number:	1806
Liquid preparations for cutaneous application	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.5)	Text number:	0927
Liquid preparations for oral use		Implementation date:	01/2018 (3.3)	Text number:	0675	
Nasal preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.4)	Text number:	0676
Oromucosal preparations		Implementation date:	01/2018 (3.3)	Text number:	1807	
Parenteral preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	04/2015 (4.4)	Text number:	0320
Patches, transdermal		Implementation date:	01/2008 (5.4)	Text number:	1011	
Powders for cutaneous application		Implementation date:	01/2017 (4.7)	Text number:	1166	
Powders, oral		Implementation date:	01/2020 (16.5)	Text number:	1165	
Premixes for medicated feeding stuffs for veterinary use		Implementation date:	01/2014 (3.4)	Text number:	1037	
Preparations for inhalation		Implementation date:	04/2018 (3.4)	Text number:	0671	
Preparations for irrigation		Implementation date:	01/2008 (5.4)	Text number:	1118	
Pressurised pharmaceutical preparations		Implementation date:	01/2019 (3.4)	Text number:	0323	
Rectal preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.4)	Text number:	1145
Semi-solid preparations for cutaneous application	Correction date:	10.0 (31/08/2016)	Implementation date:	04/2019 (4.7)	Text number:	0132
Sticks		Implementation date:	01/2019 (3.4)	Text number:	1154	
Tablets		Implementation date:	01/2018 (3.3)	Text number:	0478	
Tampons, medicated		Implementation date:	01/2017 (5.8)	Text number:	1155	
Vaginal preparations	Correction date:	10.0 (31/08/2016)	Implementation date:	01/2008 (5.4)	Text number:	1164
Veterinary liquid preparations for cutaneous application		Implementation date:	01/2018 (3.3)	Text number:	1808	
Veterinary semi-solid preparations for oral use		Implementation date:	04/2014 (4.1)	Text number:	2338	

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for the Quality
of Medicines
in Europe

— Apply to all categories of tablets of oral use

[illegible]

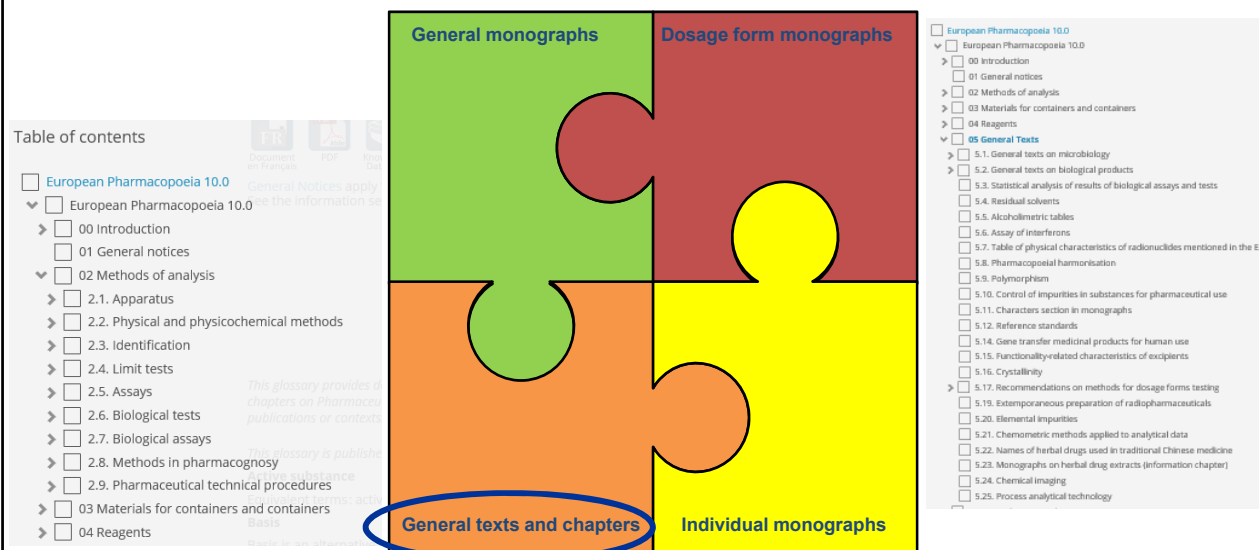
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See the information section on general monographs (cover page)

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

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Why general chapters?

Analytical methods:

- Editorial convenience: avoid repeating standard methods in each monograph
- Provide standard methods that can be used when there is no monograph
- Give general requirements for equipment, equipment qualification or calibration

General chapters

- Not mandatory "*per se*"
- When referred to in a monograph, they become part of the standard
- Can be used for substances not covered by monographs → may need validation
- Some general chapters are not referred to in any monograph (2.4.30 EG and DEG in ethoxylated substances): useful guidance, can be referred to in applications

General texts

- Are often published for information and guidance.
- Aspects that cannot be treated in each individual monograph ≠ standard methods
- Become mandatory when referred to in a monograph

Examples

- **5.10. Control of impurities in substances for pharmaceutical use** referred to in general monograph *Substances for pharmaceutical use (2034)* → chapter 5.10 applies to all APIs (whether or not an individual monograph exists in the Ph. Eur.)

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.

PRODUCTION

Substances for pharmaceutical use are manufactured by procedures that are designed to ensure a consistent quality and comply with the requirements of the individual monograph or approved specification.

The manufacture of active substances must take place under conditions of good manufacturing practice.

The provisions of general chapter 5.10 apply to the control of impurities in substances for pharmaceutical use.

Examples

- **5.10. Control of impurities in substances for pharmaceutical use** referred to in general monograph *Substances for pharmaceutical use (2034)* → chapter 5.10 applies to all APIs (whether or not an individual monograph exists in the Ph. Eur.)
- **5.4 Residual solvents** referred to in general monograph *2034* → chapter 5.4 applies to APIs and excipients covered by *2034*

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.

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.

Examples

- **5.10. Control of impurities in substances for pharmaceutical use** referred to in general monograph *Substances for pharmaceutical use (2034)* → chapter 5.10 applies to all APIs (whether or not an individual monograph exists in the Ph. Eur.)
- **5.4 Residual solvents** referred to in general monograph *2034* → chapter 5.4 applies to APIs and excipients covered by *2034*
- **5.20 Elemental impurities** reproduces the essentials of ICH Q3D guideline, is referred to in general monographs *2619 Pharmaceutical preparations* and *2034 Substances for pharmaceutical use* for ex.

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.* **2619**

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. **2034**



The structure of the Ph. Eur.

Product specific

Active substances:

- *Paracetamol* (0049)
- *Rosuvastatin calcium* (2631)
- *Sitagliptin phosphate monohydrate* (2778)

Finished products:

- *Sitagliptin tablets* (2927)

- Specifications for individual product
- Based on approved specifications backed up by batch data
- Analytical procedures and acceptance criteria to demonstrate that the substance or product meets required quality standards

General texts and chapters

Individual monographs

- > ☐ 08 Vaccines
- > ☐ 09 Immunosera
- > ☐ 10 Radiopharmaceutical preparations and starting materials for radiopharm.
- > ☐ 11 Sutures
- > ☐ 12 Herbal drugs and herbal drug preparations
- > ☐ 13 Homoeopathic preparations
- > ☐ 14 Monographs A-C
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