Monographs set forth an article's nonproprietary name, definition, specification and may include other requirements such as packaging and storage. The specification consists of tests, procedures and acceptance criteria that define the identity, strength, quality and purity of the monographed material. Pharmacopoeial monographs provide an important tool for assuring of the safety and efficacy of marketed medicinal ingredients and products through testing of their quality. Thus, a medicinal product may be tested at any point in the time when it is legally marketed with a pharmacopoeial monograph to assure its compliance with the monograph.

Pharmacopoeial monographs may cover the medicinal product itself, its ingredients and associated materials. Pharmacopoeial monographs may include additional information related to allied components, such as process (e.g. a preparation monograph to guide compounding practitioners).

Pharmacopoeial monographs allow manufacturers, compounding professionals, purchasers, governmental bodies and others independent of sellers and buyers to test the quality of the ingredients and associated materials of a medicine and the medicine itself in its packaging.

Pharmacopoeial standards allow independent testing and are a critical part of the "safety net" of standards that help ensure the quality, safety and efficacy of medicines. They are closely allied with good manufacturing practice standards, which are process standards.

Pharmacopoeial monographs generally cover chemical and biological medicines and their ingredients approved by national regulatory authorities or otherwise legally marketed within a national or regional sphere of control. Some pharmacopoeias also include standards for herbal medicines and nutritional ingredients and products.

Pharmacopoeial monograph procedures often call for reference standards, which are developed and made available for distribution by the pharmacopoeia (see section 4 on Reference Standards).

General principles

(a) Pharmacopoeial standards should be available for marketed medicines and their ingredients and associated materials.

(b) Public pharmacopoeial standards are science-based and data-driven and based on sound measurement and allied sciences.

(c) Pharmacopoeias respect the intellectual property of considerations of donors and recognize the importance of maintaining the confidentiality of proprietary third-party information. A pharmacopoeia's core mission is to create public standards to help ensure the quality of medicines. Pharmacopoeias hope to work collaboratively with manufacturers and regulators in the development of public standards.

General chapters

General chapters may contain the following:

(i) Descriptions of tests and procedures for application through individual monographs;

(ii) Information for the interpretation of the compendial requirements and explanations of terms, definitions, and symbols (if any);

(iii) Descriptions of general pharmaceutical storage, dispensing and packaging practices;

(iv) General guidance to manufacturers of official substances or official products;

(v) Descriptions and specifications of conditions and practices for pharmaceutical compounding.

When a general chapter is referenced in a monograph, acceptance criteria specified in the general chapter should be followed unless otherwise specified in the monograph. Some general chapters may serve as introductory overviews of a test or of analytical techniques. They may reference other general chapters that contain techniques, details of the procedures and, at times, acceptance criteria. At times, general chapters may be grouped by topic for ease of use, given that they speak to a broad category of monographs, e.g. chemical drug substances.

Adoption of pharmacopoeial standards

(a) Text in a pharmacopoeial monograph or general chapter is approved by an expert body of the pharmacopoeia, following publicly available rules and procedures, including applicable conflict of interest and confidentiality rules.

(b) Reference materials cited in a monograph and/or their compendial uses also are approved by a pharmacopoeial expert body.

(c) At times, pharmacopoeial experts may elect not to set a standard for a particular medicinal product.

Open and transparent process

(a) Pharmacopoeias ensure openness and transparency throughout the development of pharmacopoeial standards, which includes:

(i) Development, revision and, in the absence of a public health emergency or other urgent need for expedited action, public notice with adequate time for review and comment from impacted stakeholders;

(ii) Rapid correction of errors published in compendial text, when necessary;

(iv) Timely and appropriate revision and/or withdrawal of compendial standards, when necessary.

Continuous revision

(a) Pharmacopoeial standards are in a continuous revision process to ensure that they are based on current scientific knowledge. Pharmacopoeias can prioritize monograph updating based on factors such as prevalence of use, toxicological data, evolving scientific techniques and technologies, requests from a regulatory authority or other stakeholder and emergent public health issues.

Harmonization

Pharmacopoeias should harmonize standards wherever possible, through monographs and general chapters. Harmonization may occur through several processes including: revision of a standard between two pharmacopoeias (bilateral harmonization); development of a new standard through coordinated consideration of a single submission (prospective harmonization); revision or creation of standards through a coordinating body (PDG and ICH) or others.

Legal recognition

Pharmacopoeial monographs may acquire legal status and then become subject to enforcement depending on applicable national or regional requirements.

Conformance with a pharmacopoeial monograph

A pharmacopoeial medicinal product is considered to be in conformance with a monograph when: (1) the name and identity conform to those provided in the pharmacopoeial monograph; (2) the article complies with all relevant procedures in the pharmacopoeia; and (3) is analyzed using the reference standard(s) specified in the

pharmacopoeial monograph.

Acceptance criteria

Acceptance criteria are numerical limits, ranges, or other suitable measures for acceptance of the results of analytical science to allow determination of pass/fail criteria. Acceptance criteria indicated in a pharmacopoeial monograph may allow for analytical error, for unavoidable variations in manufacturing processes and for deviations to an extent considered acceptable under practical storage conditions. They provide standards with which substances or products must comply throughout their shelf life.

3.2 Technical guidance

3.2 Technical guidance

3.2.1 Monographs for pharmaceutical substances, including active pharmaceutical ingredients and excipients [*as received from* Ph.Eur., BP, Russian Pharmacopoeia, USP]

Prior to the preparation of any monograph, it is essential to gather as much information as possible on the substance in question.

In particular it is necessary to ascertain:

- whether the substance is of natural, synthetic or semi-synthetic origin;
- whether the substance is a mixture or a single entity;
- the method(s) of preparation of the substance;
- whether there are differences in physical form, for example, crystallinity since the properties of the substance may vary in accordance with this parameter;

- whether a single chemical isomer (e.g. enantiomer) as well as mixtures of isomers (e.g. racemate) are available;
- whether different hydrates are available;
- whether different entities (acid, base, salt, etc.) are available.

Substances that are to be described in a monograph may be members of a group of very similar substances (family). This holds true especially for excipients such as macrogols. A master monograph is to be drafted clearly stating the attributes common to all members of the family and that can be used to identify single members of the family (family monograph).

3.2.1.1 Monograph title

The International Nonproprietary Name (INN) established by WHO should be considered for use wherever it is available, while recognizing that individual pharmacopoeias may apply their own nomenclature policies. Where the INN is used, it is supplemented as appropriate by the name of the anion or cation and by "hydrate", "dihydrate", "hydrated" (for ill-defined degrees of hydration) or "anhydrous" (where a hydrated form is also known to exist). Anions and cations are indicated as "mono-", "di-", "tri-", etc., as appropriate. Where a substance is used in approved medicinal products for veterinary use only, "for veterinary use" is included in the title.

3.2.1.2 Definition

- Graphic formula. The recommendations of WHO on the drawing of structures are normally followed.
- Empirical formula and relative molecular mass. The latter is calculated based on the figures of the International Table of Relative Atomic Masses.
- CAS (Chemical Abstracts Service) number.

- Chemical name. The chemical names are based on the rules of the International Union of Pure and Applied Chemistry (IUPAC). In addition, non-IUPAC names may also be indicated.

This implies investigating in particular:

- the possible existence of isomers so as to be able to specify which isomer is used or, otherwise, to state that the product is a mixture of isomers;
- in the case of an optical isomer, the absolute configuration is given by the *R/S* system at the asymmetrical centre(s) or any other appropriate system (e.g. for carbohydrates and amino acids);
- ascertaining the state of hydration or solvation so as to distinguish clearly between the well-defined hydrates and solvates and the products that contain variable quantities of solvent(s). As regards the former, water or solvent content ranges are specified but for the latter only a maximum content is given. When a substance exists both in a water-free or solvent-free form and in the form of (a) hydrate(s) or (a) solvate(s) with different water or solvent contents, and if all these forms are used, they are normally treated as individual substances requiring separate monographs.

Some chemical substances, particularly those obtained from raw materials of natural origin and substances produced by fermentation, may not be easily separated from certain related substances (for instance, quinine salts). These may be treated as:

- a chemical product when obtained in a very pure state and when they can be assayed by a physicochemical method;
- a substance accompanied by a certain proportion of related substances, giving an exact definition of the main component only (e.g. neomycin);
- a mixture of several components, sometimes difficult to define, where an overall description may suffice (e.g. nystatin).

Where applicable, the origin of the substance is specified (name and strain of the organism from which the substance is derived). Where applicable, the monograph indicates that the substance is semi-synthetic and derived from a fermentation product.

3.2.1.2.1 Combinations

In therapeutics, more or less well-defined chemical combinations (for instance, theophylline-ethylenediamine) or even mixtures are sometimes used. In such cases, it is necessary to specify precisely each component of the combination or mixture, with its chemical structure and the proportion in which it is present.

3.2.1.3 Content

Assay limits are specified between which the content falls. The content may be also defined in a one-sided manner. The assay limits take account of the precision of the method as well as the acceptable purity of the substance. Assay limits are normally expressed with reference to the dried or anhydrous/solvent-free substance.

For a non-specific assay (for example, titrimetry) the assay limits are usually 99.0-101.0 % (unless otherwise justified). For a specific assay using a separation technique (for example, liquid or gas chromatography), the upper assay limit is normally 102.0 %; the lower assay limit will take any necessary account of the impurities present and may therefore be lower than 98.0 %.

In setting these limits for the active ingredient content, account is taken of:

- the method of preparation, which determines the degree of purity that may be reasonably required;
- the reproducibility and accuracy of the analytical method;
- where a separation technique is employed both for the test for related substances and the assay, content limits are set taking into account the maximum permitted amount of impurities and the analytical error;

- the evaluation of the tolerable degree of deterioration during storage (since the limits are intended to apply throughout the shelf life of the substance and not just at the time of testing);
- a sufficient number of experimental results obtained on several batches (at least 3), if possible, of different origins and ages.

In cases where the water content is high (e.g. in the case of disodium phosphate dodecahydrate), limits of content may be expressed with reference to the hydrated substance, taking into account the molecular mass of the hydrated form (only for well-defined and stable hydrates) or with reference to the substance "as is" in combination with determination of water content/loss on drying.

When the substance to be examined contains a relatively large proportion (a few %) of impurities, which are determined at the same time as the active ingredient, an appropriate wording is to be used (for instance, in the case of quinine salts: "x % of total alkaloid salts, expressed as quinine salts").

Exceptionally reference is made to only a part of the molecule or to an element (for example, assay of magnesium oxide in light magnesium carbonate or assay of magnesium in magnesium stearate).

In the case of antibiotics determined by microbiological assay, the activity is expressed in International Units, where these exist, and only a minimum value is given.
See also section Assay.

3.2.1.4 Characters

The statements under the heading Characters are not to be interpreted in a strict sense and are not regarded as analytical requirements. Caution statements may be included here.

The principal items that may be referred to under this heading are the following.

3.2.1.4.1 Appearance

This description will normally embrace colour and physical form.

3.2.1.4.2 Taste

The taste is not to be taken into consideration for safety reasons.

3.2.1.4.3 Odour

In general, no reference is made to odour – with the exception of substances having specific odour (methyl salicylate, camphor, menthol, etc.). In particular no reference to odour is made for those materials that would constitute a hazard if inhaled. Mention of odour in other cases is justified. Odour may also serve as a sign of the substance good quality, because the appearance of foreign odour may speak of the substance degradation (e.g. acetic acid in acetylsalicylic acid, cacao butter, etc.).

3.2.1.4.4 Solubility

All solubilities are quoted in general terms. A method recommended for the estimation of solubility is given in a general chapter/method. Solvents quoted usually include water, an alcohol and a lipophilic solvent.

In special cases the solubility of different samples of a material may vary rather considerably even though their composition is still within the limits set by the monograph. The solubilities in the solvents thereby affected are then given to cover more than one solubility class, e.g. "sparingly soluble to soluble in ...".

3.2.1.4.5 Stability factors

Evidence of instability due to exposure to air, light and for moisture is to be given, e.g. physostigmine sulfate turns red when exposed to air and light.

3.2.1.4.6 Hygroscopicity

Some substances are hygroscopic (they deliquesce, dampen or dissolve). In such cases, this is indicated for information of the analyst as an alert for precautions to be taken in

handling the substance. A method recommended for the determination of the tendency of a substance to take up atmospheric water is given in a general chapter/method.

Where a substance is described under Characters as hygroscopic or deliquescent, storage in an airtight container is indicated.

3.2.1.4.7 Solid-state properties

Solid-state properties include crystallinity, polymorphism, density of solids, particle size of solids and specific surface area of solids. A method recommended for the determination of crystallinity is given in a general chapter/method.

Solid-state properties of excipients that are relevant for functionality may be dealt with in the Tests section.

When polymorphism is known to exist in the substance, this information is given as a separate statement ("it shows polymorphism"). This statement is intended to alert users to the need to evaluate this phenomenon during the development of a dosage form.

Two cases are to be distinguished when polymorphism is known to exist:

- usually, the monograph does not exclude any of the possible crystalline forms;
- exceptionally, if the substance is only used in solid dosage forms and one form has been shown to be preferred from the point of view of bioavailability or to have a better safety/efficacy profile, then the monograph may be limited to that form. The techniques required to identify the form are included in the monograph, typically in the Identification section.

3.2.1.4.8 Other characteristics

Other physical characteristics that may be useful as information may be stated under the heading Characters. This will usually apply to a melting point that is insufficiently precise to allow a range to be quoted ("about X°C"). When decomposition may occur, this is stated ("about X°C (with decomposition)")..

3.2.1.5 Identification

3.2.1.5.1 General

The purpose of the Identification section of a monograph is to provide a means for confirming that the substance in question is indeed the article named in the monograph. The physical and/or chemical tests and reactions, when taken together, that enter into the Identification section ensure, as far as possible, specificity. The specificity of the identification should be such that active substances and excipients exhibiting similar structures are distinguished. When an identification series is being investigated, it is desirable that other similar substances, whether or not they are the subject of monographs of the Pharmacopoeia, are examined at the same time to ensure that a particular combination of tests within a series will successfully distinguish one similar substance from another. They are not to be too sensitive, i.e. false reactions caused by the presence of tolerated impurities are to be avoided.

Some of the purity tests in a monograph may also be suitable for identification purposes, possibly in a modified form. A system of cross-reference to the TESTS section(s) can be exploited. This is particularly relevant in cases where distinction between closely related materials depends on properties that are also parameters in purity or composition control, e.g. water content of different hydrates, optical rotation of different isomers, enantiomeric purity, viscosity of chain-length homologues of a polymer.

In the case of a family monograph, identification of the type of substances may be supplemented by non-specific but discriminating tests to identify individual members of the family.

Examples are given below of some methods of identification and they are followed by detailed guidelines concerning some of them.

3.2.1.5.2 Methods requiring complex instrumentation

- Spectrophotometric analysis, such as recording of infrared or nuclear magnetic resonance spectra.

- Chromatographic examination by means of gas chromatography (GC) or liquid chromatography (LC).

3.2.1.5.3 Other methods

- Determination of physical constants such as melting point, freezing point, boiling point, specific optical rotation, angle of rotation, ultraviolet spectrum, specific absorbance, relative density, refractive index and viscosity.
- Chemical reactions such as colour or precipitation reactions (including formation of derivatives or degradation products, which may subsequently be subjected to physical examination) and determination of chemical values (saponification, ester, hydroxyl and iodine values).
- Chromatographic examination by thin-layer chromatography (TLC).

3.2.1.5.4 Infrared absorption spectrophotometry

This is generally considered to be a satisfactory single method for verification of the identity of non-ionized organic substances other than salts of organic acids or bases. This method always necessitates the use of a reference substance or a reference spectrum. Reference substances are preferred to reference spectra.

Organic salts of organic substances and some inorganic salts of organic substances (e.g. phosphates and sulfates) can readily be distinguished from each other.

The method of sample preparation (disk, halide salt plate, mull, etc.) might not be specified unless this has been found to be necessary during the development of the monograph to obtain a satisfactory spectrum.

In certain cases, there is a need to supplement the infrared spectrum with other tests where the spectrum alone is insufficient for confirmation of identity, as follows.

3.2.1.5.4.1 Salts of organic acids or bases

Ions are usually identified using one of the commonly applied identification reactions described in a general method.

3.2.1.5.4.2 Chemically related substances

When substances closely related to the substance under examination exhibit variations in the spectra that are considered insufficient for unambiguous identification, the infrared spectra are accompanied by another simple test, e.g. melting point or thin-layer chromatography.

3.2.1.5.4.3 Polymorphism

Where a monograph mentions polymorphism, a method for recrystallization is described unless it is the intention to limit the scope of the monograph to the crystalline form represented by the chemical reference substance. In the latter case the monograph indicates that the spectrum is recorded "without recrystallization".

Exceptionally, when the monograph describes a specific crystalline form or forms and when the IR spectrum is not characteristic, an additional test is introduced.

3.2.1.5.4.4 Optical isomers

To identify a particular isomer or a racemate, a test for optical rotation is given in the IDENTIFICATION section or a cross-reference is made to a test for enantiomeric purity or optical rotation in the TESTS section.

3.2.1.5.5 Ultraviolet and visible absorption spectrophotometry

This method is usually non-specific for identification purposes, unlike infrared spectrophotometry, unless the absorption curve exhibits several maxima and minima, unusually strong or weak regions of absorption, etc. Reference substances are generally not used. The UV spectrum of a substance can, therefore, seldom stand on its own as an identification criterion.

The concentration of the solution to be examined is such that the absorbance preferably lies above 0.5, measured in a 1 cm cell.

The range of wavelengths to be explored is stated; generally it does not extend towards the region where end-absorption and solvent interference may be expected.

Care is taken in the choice of solvents and solvent purity prescribed for ultraviolet spectrophotometry in order to avoid the presence of impurities, which may influence the absorbance of the substances to be examined.

In certain cases of identification by means of absorption spectra in the UV-visible range, the resolution of the instrument can be expected to constitute a critical factor in observing the required spectral features (e.g. benzenoid-type spectra showing a fine structure). In certain cases the minimum resolution required is indicated in the monograph.

3.2.1.5.6 Melting temperature, freezing temperature and boiling temperature

These physical constants are of value in identification only if they are well defined and their determination is not accompanied by destruction to a degree that renders them extremely dependent on the actual mode of operation. The possible existence of polymorphism is also be taken into account.

Neither the melting point alone nor the addition of a chemical reaction is sufficient to confirm identity of a substance. However, the addition of another identification test such as TLC will often suffice.

3.2.1.5.7 Optical rotation

When an enantiomer is described in a monograph, a test for optical rotation is given in the IDENTIFICATION section or a cross-reference is made to the TESTS section which contains either a test for enantiomeric purity or a test for optical rotation.. When both the racemate (or the racemic mixture) and the enantiomer are available then, in the monograph of the racemate, the verification of the angle of rotation will be given in the TESTS section and will be referred to in the IDENTIFICATION section. When only the

racemate is available the verification of the angle of rotation will be given in the TESTS section, provided the specific optical rotation of the chiral form is known and is of sufficient magnitude to provide a meaningful test for racemic character.

3.2.1.5.8 Thin-layer chromatography (TLC and HP-TLC)

This identification method requires the use of reference substances. Selectivity may be improved by combining thin-layer chromatography with chemical reactions in situ, i.e. by employing appropriate spray reagents. In the latter case, the same or a similar reaction is not to be repeated on a test-tube scale.

During development and validation, separation of the substance from structurally similar substances is demonstrated.

3.2.1.5.9 Gas chromatography and liquid chromatography

Gas and liquid chromatography are used for identification only when applied elsewhere in the monograph (in a test or the assay). These methods are used if there is no suitable alternative and should not be used as a sole identification test.

3.2.1.5.10 Chemical reactions

Commonly applied identification reactions of a chemical nature are described in a general method and are to be used whenever appropriate. Each chemical reaction is to be chosen to demonstrate the presence of a different part of the molecule to be identified.
Identification criteria that call for the recognition of an odour or a taste are to be avoided.
To differentiate substances within a group (family) which differ by:

- the extent of condensation;
- the length of the hydrocarbon chain (e.g. fatty acids),

it is necessary to cross-reference to the appropriate purity test(s) where values are determined (e.g. iodine value, saponification value, etc.).

3.2.1.6 Other tests

3.2.1.6.1 General

The Tests section is principally directed at limiting impurities in chemical substances. While it is an essential function of the monograph to ensure adequate purity in the interests of public health, it is not the aim of the pharmacopoeia to impose excessive requirements that restrict unnecessarily the ability of manufacturers to produce compliant products.

In the interests of transparency, information is included wherever possible on: the impurities controlled by a test; the approximate equivalent (percentage, ppm, etc.) of the prescribed limit in terms of the defined impurities or class of impurities.

Certain tests may apply to special grades (parenteral, dialysis solutions, etc.) or a test may have a special limit for a particular use: the particular application of a test/limit is indicated within the test.

3.2.1.6.2 Titles

Wherever possible, the title includes the impurity or class of impurities limited by the test. Non-specific tests carry a more general title appropriately chosen from the standard terminology of the pharmacopoeia or a similar designation.

3.2.1.6.3 Solutions

The solvent used and the concentration chosen depend on the solubility of the substance to be examined and the purpose for which the test is intended. The quantity of solution prepared is sufficient to carry out each of the tests for which it has been prepared. Depending on the particular tests, the concentration of a solution is defined with varying precision.

3.2.1.6.4 Appearance of solution

This test makes it possible to ascertain the general purity of a substance by the detection of impurities insoluble in the solvent selected, or of coloured impurities.

The "Appearance of solution" test is normally prescribed for substances intended for preparations for parenteral use. Apart from this, it is to be applied only if it yields useful information concerning the general purity/stability of the substance which is not obtained by other tests of the monograph.

It can comprise the verification of the clarity/degree of opalescence of the solution and/or the verification of the degree of its coloration. Corresponding methods are described in general methods.

The solvent employed is usually water but other solvents may be preferred depending on the solubility of the substance to be examined.

When an organic solvent is used to prepare the solution, it may be necessary to ensure that the solvent also complies with the test, especially where there is a very stringent requirement.

The more concentrated the solution the stricter the test. For very pure substances or those used in high doses, the concentration chosen is 50 to 100 g/L, whereas for less pure substances or substances administered in small doses the concentration is 10 to 20 g/L.

3.2.1.6.4.1 Clarity and degree of opalescence

This test is mainly performed on colourless substances or those that give only slightly coloured solutions in order to permit valid comparison with reference suspensions.

3.2.1.6.4.2 Degree of coloration

The test applies to essentially colourless substances that contain, or may degrade to form, coloured impurities that can be controlled by limiting the colour of solution of the substance.

An appropriate reference solution is given for comparison. When the shade of colour varies according to the samples, 2 or more reference solutions of the same degree of

colour may be mentioned, or even only the degree of coloration without specifying the actual colour.

For material intended for parenteral use and for highly coloured solutions, it is often preferable to apply a limit of absorbance measured with a spectrophotometer at a suitable wavelength (usually between 400 and 450 nm). The concentration of the solution and the limit of absorbance are stated. The conditions and limit are based on knowledge of the absorbance curve in the range defined and on results obtained with appropriate samples, including stored and degraded samples, as necessary.

3.2.1.6.5 pH and acidity or alkalinity

This test allows the limitation of acidic or alkaline impurities stemming from the method of preparation or purification or arising from degradation (e.g. from inappropriate storage) of the substance. The test may also be used to verify the stoichiometric composition of certain salts.

Two types of test for protolytic impurities are used:

- pH measurement or
- Acidity or alkalinity test (a semi-quantitative titration experiment using indicators or electrometric methods to define the limits).

pH measurement is included if the material has buffering properties, otherwise a titrimetric procedure is recommended. If, the addition of standard acid/or base results in decomposition or precipitation of the substance to be examined, it may be necessary to prescribe a pH test regardless of the buffering properties.

3.2.1.6.6 Optical rotation

The optical rotation test, though sometimes useful for identification purposes, is mainly used as a purity test:

- either to assess the general purity of an optically active substance (a liquid or a solid in solution), by calculating the specific optical rotation;

- or to limit the presence of optically active impurities in any optically inactive substance (racemate or racemic mixtures), provided that the specific optical rotation at 589.3 nm is sufficient to ensure adequate sensitivity. In this case the range normally given should be − 0.10° to + 0.10° (covering the substances that are not true racemates). In this case the angle of rotation of the liquid or of a solution of the solid, is measured under defined conditions.

It is usually more appropriate to control these impurities by chiral separation methods since the specific optical rotation is often insufficient to limit the presence of the unwanted enantiomer in the presence of the active enantiomer.

The test is not suitable for highly coloured or opalescent solutions (in the latter case a filtration can sometimes make the determination possible).

The concentration of the solution: is chosen to be high enough to give a reliable reading of the angle of rotation. The degree of hydration or organic solvation of the substance is taken into account in calculating the result.

3.2.1.6.7 Absorption spectrophotometry (ultraviolet and visible)

The absorption of electromagnetic radiation may be used in purity tests as a limit test for certain impurities. The typical case is that of impurities that absorb in a region where the substance to be examined is transparent. This test may be performed by direct measurement on a solution, or after carrying out a chemical reaction that forms, with the impurity, a substance that absorbs at a wavelength where the substance to be examined is transparent.

For measurements in the ultraviolet, it is advisable not to measure below 230 nm.