Technical Guide for the Elaboration of Monographs
欧洲药典质量标准的起草技术指南

I. INTRODUCTION 绪论

I.1 PURPOSE OF THE GUIDE 本指南的目的

This document is a guide for the authors of monographs and also a means of communicating the principles for the elaboration and revision of monographs to the users of the European Pharmacopoeia (Ph. Eur.), especially industry, licensing authorities and official medicines control laboratories. Since the principles applied and guidance given for the elaboration and revision of monographs should be the same as those applied by licensing authorities, this Technical guide may also serve as a guideline in the elaboration of specifications intended for inclusion in marketing authorisation applications.
本文件为欧洲药典各论起草的指南，同时也是与欧洲药典的用户，特别是药品生产企业、药品注册管理机构以及官方药品检验机构（简称：OMCL）沟通各论起草和修订原则的一种途径。由于各论的起草和修订的原则及指南应与药品注册管理机构执行的原则一致，因此本技术指南也可以作为拟上市许可申请用质量标准起草的指导原则。

It is necessary to bear in mind that a monograph will be a mandatory standard and must be applicable in marketing authorisation procedures in all states parties to the Convention on the Elaboration of a European Pharmacopoeia (hereinafter the “European Pharmacopoeia Convention”)
需要注意的是各论为强制执行的标准，必须适用于所有欧洲药典编纂委员会成员国（以下简称欧洲药典委员会）的上市许可程序。

The term “elaboration” used hereinafter in this guide covers both “elaboration” and/or “revision”.
本指南下文中使用的术语“起草”包括“起草”和/或“修订”。

I.2 ANALYTICAL PROCEDURES 测定方法

The analytical procedures chosen for the identification tests, purity tests and assay(s) constituting the bulk of a pharmacopoeial monograph are preferably those already described and utilised in the Ph. Eur. In this context, the author of a monograph is referred not only to the General Chapters of the Ph. Eur. but also to published monographs on similar materials. The above considerations are intended to ensure a reasonable degree of harmonisation within the Ph. Eur. and only apply in cases where the procedures are found to be adequate for the specific purposes. However, due attention is also to be paid to the development of new procedures that offer significant improvements in terms of sensitivity, precision, accuracy or specificity/selectivity.
组成药典各论的鉴别试验、纯度检查和含量所选定的测定方法最好是那些在欧洲药典中收载或采用的方法。在这种情况下，各论的编写人员参考的不仅是欧洲药典通则，还包括已经颁布的类似药物的质量标准。上述考虑的目的是确保药典内容协调的合理性，并且只适用于测定方法足以满足特定目的的情况。然而还应当致力于建立能显著改善灵敏度、精密度、准确度和专属性（选择性）的新的测定方法。

Analytical procedures included in monographs are validated as described in part III (ANALYTICAL VALIDATION) and other relevant specific parts of this guide. Validation reports are provided to the EDQM but are not published or otherwise provided to users.
各论中的测定方法应当依据本指南第三部分（分析方法验证）及其他相关章节的要求进行分析方法验证。应向 EDMQ 提供保密的或者需要向用户提供的验证报告。

The analytical procedures included in a monograph are validated and further verified in two or more laboratories. One of these may be the supplier of the procedure who initially validated it.
各论中包括的分析方法应当经过验证并在两个及以上实验室进行进一步确认。实验室可包含最初验证该方法的实验室。

The laboratory reports on the validation and verification are to be provided to the EDQM to ensure future traceability.
（分析方法的）验证和确认的实验室报告应提供给 EDQM 以确保未来的可追溯性。

The instructions for any analytical procedure cover all factors that may influence the results and that are deemed essential for an experienced analyst working according to acknowledged laboratory practices to be able to perform the analysis without necessarily having any prior knowledge of the investigation in question. Variations in the description of similar analytical procedures are to be avoided
任何测定方法的说明应包括所有可能影响测定结果的因素，这些对于确保有经验的分析人员在不需要对研究有预先了解的情况下，按照公认的实验室规范进行分析工作是非常必要的。应避免对相似的测定方法描述的不一致。

If it is expected that an analytical procedure will be used generally or if it requires a lengthy description and is used more than once, it may be proposed for inclusion in the general chapters of the Ph. Eur., to be referred to in the individual monographs. The procedures are prescribed on the scale conventionally applied in the Ph. Eur. except in cases where for reasons of availability of the material to be analysed, or because of its toxicity or its cost, work on a small scale would be advantageous.
如果预期某一测定方法会被普遍使用，或该方法需要较长的文字描述并且会被多次使用，可以建议在欧洲药典的通则中收载该测定方法，在各论中注明参照该通则描述。应使用指定的样品量并按照药典方法进行分析，只有在供试品的数量有限、具有毒性作用或者价格原因等情况下，才可采取减少供试品用量的方法。

I.3 EQUIPMENT 设备

If the equipment utilised for an analytical procedure is not generally available in the states parties to the European Pharmacopoeia Convention, it must be possible to have it constructed according to its description in the Ph. Eur.
如果用于某一种分析程序所用设备在欧洲药典委员会的成员国中并不常用，必须按照欧洲药典中的要求进行设备制造。

I.4 QUANTITIES 数量

In prescribing the quantities (i.e. masses and volumes of substances, reagents and solvents to be taken for analysis), it is the practice of the Ph. Eur. to indicate, with the given number of significant figures, the exact target quantity value that is to be measured (see paragraph on Quantities in the *General Notices*). It is therefore necessary to take this aspect into consideration when drafting pharmacopoeial texts.
在规定数量（即用于分析的物质、试剂和溶剂的质量和体积）时，欧洲药典的惯例是用给定数量的有效数字表示要测量的目标值（见凡例中关于数量的内容）。因此，在起草药典文本时，有必要考虑这一方面。

Table 1, which provides estimations of relative uncertainty, is to be consulted as a guide for minimising errors in the preparation of analytical solutions.
表1提供了相对不确定度的估计值，可作为分析溶液制备误差最小化的指导。

In order to avoid either the use of extremely low amounts or unnecessarily large quantities of solvents, a dilution series will often have to be prescribed for the preparation of dilute solutions used particularly for spectrophotometric measurement. In this case, not all combinations of (usually two or three) dilution steps will contribute equally to the random error of the dilution procedure. If critical for the purpose, the optimal dilution is prescribed in consideration of the relative errors (capacity tolerance divided by nominal volume) associated with the various sizes of volumetric pipettes and volumetric flasks commonly used for these operations The standard formula for estimating relative dilution error is the square root of the sum of the squares of individual relative errors.
为了避免使用极少量或不必要地大量溶剂，在配制一系列稀释溶液时，特别是用于分光光度法测量的稀释溶液，通常需要规定稀释步骤。当然，并非所有的稀释过程(通常是2步或3步) 引入的随机误差都相同。如果稀释程序对于结果至关重

要，应考虑与操作中常用的移液管和容量瓶的相对误差（容量公差除以标称体积），制定最佳稀释方法。估计相对稀释误差的标准公式是单个相对误差平方和的平方根。

Tables giving the optimal number and nature of dilution steps needed to achieve a given dilution ratio, based upon given specifications for the capacity tolerances of volumetric glassware, are available in the literature. For guidance, see Table 2 (note that these factors do not include reading errors).

根据文献中玻璃仪器的容量公差限度标准,在给定的稀释比条件下，表2给出了最佳的稀释次数和稀释效果.相关指南详见表2（需要注意的是，这些因素当中不包括读数误差）。

Table1–Relative uncertainties in the preparation of analytical solutions

表 1--分析溶液制备中的相对不确定度

Concentration to be prepared 待配制溶液浓度	Preparation of solution 溶液的配制	Percentage relative uncertainty 百分比相对不确定度		
		Mass 称量	Volume 体积	Total 总不确定度
10g/1000ml	10g/1000mL	<0.01	0.05	0.05
	1g/100mL	0.02	0.12	0.12
	0.5g/50mL	0.04	0.17	0.17
	0.25g/25mL	0.08	0.23	0.24
	0.1g/10mL	0.02	0.50	0.54
1g/1000ml	1g/1000mL	0.02	0.05	0.05
	0.5g/500mL	0.04	0.07	0.08
	0.25g/25mL	0.08	0.23	0.24
	100mg/100mL	0.2	0.12	0.23
	50mg/50mL	0.4	0.17	0.43
	10mg/10mL	2.0	0.50	2.06
0.1g/1000ml	100mg/1000mL	0.2	0.05	0.21
	50mg/500mL	0.4	0.07	0.41
	25mg/250mL	0.8	0.08	0.80
	10mg/1000mL	2.0	0.12	2.0
	5mg/500mL	4.0	0.17	4.0
	1mg/100mL	20.0	0.50	20.0
0.01g/1000ml	10mg/1000mL	2.0	0.05	2.0
	5mg/500mL	4.0	0.07	4.0
	1mg/100mL	20.0	0.12	20.0

An uncertainty of 0.2mg for the weighing procedure has been assumed for the calculations of the percentage relative uncertainties.

对于百分比相对不确定度的计算，假设称重过程的不确定度为 0.2 毫克。

Table2–Relative errors for dilution with analytical glassware (pipettes P/flasks F)

表 2.分析玻璃器皿稀释的相对误差(移液管 P/容量瓶 F)

Concentration ratio	No. of steps	Step1		Step2		Relative error
		P	F	P	F	
1/2	1	25	50			0.16
1/2.5	1	20	50			0.18
1/5	1	20	100			0.17
1/10	1	25	250			0.13
1/12.5	1	20	250			0.16
1/30	1	15	500			0.20
1/50	1	20	1000			0.15
1/100	1	25	250	25	250	0.18
1/125	2	20	250	25	250	0.20
1/160	2	25	1000	25	100	0.19
1/200	2	25	500	25	100	0.18
1/250	2	20	250	25	500	0.20
1/400	2	25	250	25	1000	0.18
1/500	2	20	500	25	500	0.20
1/1000	2	20	1000	25	500	0.20

AdaptedfromR.B.LamandT.L.Isenhour,Minimizingrelativeerrorinpreparationofstandardsolutionsbyjudiciouschoiceofvolumetricgla

ssware,AnalyticalChemistry,1980,53,1158-1161
摘自 R.B.Lam 和 T.L. Isenhour，通过合理选择玻璃器皿来降低标准溶液制备中的相对误差，分析化学，1980，53,1158-1161

I.5 REAGENTS 试剂

When the quality of a reagent in one or more respects is critical for its intended use, it must be carefully defined by prescribing appropriate tests to demonstrate its suitability.
当试剂的一个或多个性质对其用途有决定作用时，必须明确该试剂的质量，必要时还可以规定适当的检测方法对试剂的适用性进行检测。

Typically, analytical grade reagents are employed, in which case it is sufficient to give the name of the reagent, the CAS number and its formula.
通常采用分析纯试剂时，给出试剂的名称\CAS 号和分子式即可。

Whenever possible, the reagent substances, reagent solutions, buffer solutions, volumetric solutions and standard solutions already described in Ph. Eur. general chapter 4. Reagents are to be employed.Sim ple solutions of reagents that are prepared for sing le use are to be described in the employed monograph itself.
如果在限度检查中所需的试剂\试液\滴定液和标准溶液已经在《欧洲药典》的通则 4<试剂和试液>中收载，就可以使用药典通则收载的试剂和试液。如果偶尔使用一次的简单试液或溶液，应在各论中给出配制方法。

The use of reagents that are acknowledged to be extremely toxic or otherwise hazardous (e.g.
carcinogenic) is to be avoided, especially in circumstances where their dangerous properties are difficult to control (e.g. when handled as fine powders or in spray reagents).
应当避免使用公认的剧毒试剂（例如，致癌物），尤其是在它们的危险特性难以控制的情况下（例如，被处理为细粉末或用在喷雾试剂）.

The use of those substances that are prohibited or restricted in one or more of the states parties to the European Pharmacopoeia Convention is also to be avoided (mercury containing reagents, substances regulated through REACH regulation annex XIV, etc.).In monographs where these reagents are still described, the group of experts (GoE) concerned should initiate a revision of the relevant test with the objective of avoiding such reagents where possible.
也应避免使用《欧洲药典公约》一个或多个缔约国禁止或限制使用的物质（含汞的试剂、REACH 法规附件 XIV 规定的物质等）。在对这些试剂仍有使用的各论中，有关专家组（GoE）应着手修订相关实验，目标是尽可能避免使用这些试剂。

I.6 COMMERCIAL NAMES 商品名称

Commercial names for chromatography columns/plates and solvents/titrants/conditions for water determinations are always given as footnotes in draft monographs. Commercial names may also be provided for other products (test kits, reagents that are available from a single supplier or types of filter, etc.), depending on the perceived usefulness for analysts. These commercial names are transferred to the EDQM Knowledge Database after the monograph is adopted and are not published in the Ph. Eur.
在起草的各论中应采用脚注的形式给出色谱柱/薄层板和用于测定水的溶剂/试剂/条件的商品名称。当试剂的商品名称有助于分析人员的工作时，也应以脚注的形式给出（例如检测试剂盒、某个供应商提供的试剂或过滤器类型等）。在药典正式收载该各论后，这些商品名称可在 EDQM 数据库中找到，在正式发行的药典中不出现商品名称。

I.7 REFERENCE STANDARDS 标准物质

The general policy for Ph. Eur. reference standards is provided for information purposes in general chapter 5.12. Reference standards. In addition to procuring candidates and establishing reference standards, the EDQM is responsible for storing and distributing reference standards. When candidate reference standards, notably impurity standards, are available only in limited quantities, the amount prescribed for the preparation of solutions is kept to a minimum. For the same reason, when a reference standard is introduced in a monograph or general chapter, consideration is to be given to its long-term sustainability. Before a monograph is published in Pharmeuropa, the required quantities of candidates should be supplied to the EDQM, who will advise on the best strategy for reference standards, while optimising the use of substances that are available in limited quantities (e.g. preparation of a spiked substance, use of a “dirty sample” or supply of the impurity alone). The EDQM aims to have the reference standards available at the date of publication of the monograph or, if this is not possible, by the time of implementation at the very latest. Having a sufficient amount of a suitable candidate reference available at the EDQM before the monograph is adopted is a pre-requisite for

achieving this goal.
关于 Ph. Eur.标准物质的政策和指导原则详见附录 5.12 “Reference standards”。除了标准物质候选材料的采购和建立质量标准外，EDQM 还负责标准物质的储存和分发。当候选标准物质的数量有限时，尤其是杂质标准品，用于制备溶液的最小称样量要保持最小。出于同样的原因，当在各论或总论中引入一个标准物质时，要考虑其长期的可持续性。在药典发布各论之前，应当向 EDQM 提供足够的标准物质候选材料，EDQM 将对标准物质的最佳策略提出建议，同时优化使用数量有限的物质（例如，制备加标物质、使用“脏样”或单独提供杂质）。EDQM 的目标是在各论出版之日提供标准物质，如果不可能，则最迟在实施之时提供。能够实现这一目标的前提条件是，在各论出版之前 EDQM 拥有足够数量的可用的候选标准物质。

For infrared (IR) identification, preference is given to chemical reference substances (CRS) over reference spectra, except in special cases (e.g. when it is difficult to procure). In exceptional cases, for monographs on narcotic/psychotropic substances, the relevant GoE may decide to describe both a CRS and a reference spectrum in the identification test.
对于红外（IR）鉴别，优先考虑化学标准物质（CRS），而不是标准光谱，除非在特殊情况下（例如，难以采购的标准物质）。在特殊情况下，对于麻醉/精神药物的各论，相关的专家组可以决定在鉴别测试中同时描述 CRS 和标准光谱。

Technical Guide for the Elaboration of Monographs

欧洲药典质量标准的起草技术指南

——第II章 Part 1

II. MONOGRAPH ON A SUBSTANCE FOR PHARMACEUTICAL USE[1]
药用物质的各论

Monographs are based on the specifications for substances used in medicinal products approved in member states. When a monograph is added to the work programme, enquiries are made by the EDQM to identify manufacturers of such substances and all data received is taken into account for preparation of the monograph. Stakeholders are invited to collaborate on the elaboration of the monograph when the topic is added to the work programme so that their approved specifications can be taken in account.
各论是基于各成员国批准的药品中使用物质的规格而制定的。当一个各论的起草被纳入到工作计划中后，EDQM 会进行查询以确定这些物质的制造商，并在起草各论时参考所有收到的数据。当专题被添加到工作计划中时，将邀请利益相关方合作起草各论，以便考虑到他们批准的规格。

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:
在起草任何各论之前，必不可少的是尽可能多地收集有关该物质的信息。特别是有必要确定如下问题：

- whether the substance is of natural, synthetic or semi-synthetic origin;
  该物质是否来源于天然产物、合成或是半合成；
- whether the substance is a mixture or a single entity;
  该物质是否为混合物或是单一物质；
- whether there are different crystalline forms, since the properties of the substance may vary in accordance with this parameter;
  该物质是否有不同的晶型，因为物质的性状会因晶型参数的不同而随之变化；
- whether both an enantiomer as well as the racemate or other mixtures of enantiomers are available;
  该物质是否有对映异构体、消旋体或者是其他对映异构体的混合物；
- whether substances with a different degree of hydration (defined or variable) are available;
  该物质是否具有不同水合程度的物质（确定的或可变的）
- whether the substance is available as a solvate (excluding hydrates);
  该物质是否可作为溶剂使用（不包括水合物）
- whether different entities (acid, base, salt, etc.) are available;
  该物质是否可以获得不同的化合物形式（酸、碱、盐等）；
- where appropriate, the method(s) of preparation.
  适当情况下的制备方法。

1. Where appropriate, the statements in this section apply to monographs on medicinal products, otherwise see other relevant technical guides such as the *Technical Guide for the elaboration of monographs on medicinal products containing chemically defined active substances*
   如适用，本节的声明适用于药品的各论，否则请参见其他相关的技术指南，如《含有化学定义活性物质的药品各论的起草技术指南》。

The Ph. Eur. and other relevant documents on the state of work must be consulted to see if monographs on similar substances exist or are being elaborated. If this is the case, it is important to ensure that similar monographs follow the same approach unless there are good reasons to deviate from it (e.g. developments in analytical techniques or different specifications).
必须查阅欧洲药典以及其他关于工作状态的相关文件，以了解是否存在或正在起草关于类似物质的各论。如果是这样，必须确保类似的各论遵循相同的方法，除非有充分的理由偏离它（例如分析技术

的发展或不同的规格）。

When a substance exists both in a water-free form and in the form of one or more hydrate with different water contents, and if all these forms are used, they are normally treated as individual substances requiring separate monographs. The same rule applies for other solvates.
如果一种物质既以无水形式存在，又以一种或多种含水量的水合物形式存在，并且如果所有形式都被使用，他们通常会被视为需要单独编写各论的独立物质。同样的规则也适用于其他溶剂。

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. In such cases, a master monograph (family 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.
将在各论中描述的物质可能是一组非常相似的物质（族）中的成员。对于辅料（例如聚乙二醇）来说更是如此。在这种情况下，应起草一份主各论（族各论），明确说明该族所有成员的共同属性，并可用于识别该族的单个成员。

Most active substances and excipients are subject to the provisions of the general monograph *Substances for pharmaceutical use (2034)*.
大多数活性物质和辅料都要遵守总论《药用物质》（2034）的规定。

II.1. TITLE 标题

The International Nonproprietary Name (INN) established by the World Health Organization (WHO) should be used wherever it is available, unless there are justifiable reasons for not doing so; it is supplemented as appropriate by the name of the anion or cation and by the degree of hydration. Anions and cations are indicated as “mono-, di-, tri-, etc.”, as appropriate.
如有世界卫生组织（WHO）制定的国际非专利名称（INN），就应该使用 INN 名称，除非有合理的理由不这样做；以阴离子或阳离子的名称和水合度进行适当的补充。阴离子和阳离子根据情况以“一价，二价，三价”等来表示离子的化合价。

The following rules apply for the degree of hydration.
下列规则适用于水合度：

- In the case of a well-defined hydrate, “hemi, mono-,1.5-, di-, tri-, etc. hydrate” is added to the title, whereas if the monograph covers more than one degree of hydration, the general term “hydrate” is used. In the latter case, a sentence is added to the DEFINTION section of the monograph (see chapter II.3). For monographs published prior to the 9th edition of the Ph. Eur., retrospective introduction of the degree of hydration in titles would only be made after careful consideration.
  如果是明确定义的水合物，则在标题中加入“半水合物、一水合物、1.5-水合物、二水合物、三水合物等”，而如果各论涵盖一种以上的水合物，则使用一般术语“水合物”。在后一种情况下，要在各论的“定义”部分增加一句话（见第 II.3 章）。对于在欧洲药典第 9 版之前出版的各论，只有在仔细考虑后才能在标题中回顾性引入水合度。

- Since the 9th edition of the Ph. Eur., monographs referring to “anhydrous” substances no longer specify this in their title, with the exception of a few monographs where this information has a recognised added value and/or is used in common scientific language (e.g. *Ethanol, anhydrous*).
  从第 9 版欧洲药典开始，提及“无水”物的各论将不再在其标题中说明，但少数各论除外，因为这些信息具有公认的附加值和/或在通用科学语言中使用（例如：乙醇，无水）。

- No mention is added to the title of monographs covering substances that can be either water-free or with a defined or variable degree of hydration. This supplementary information is provided in the DEFINITION section of the monographs (see part II.3).

对于涵盖不含水或具有特定或可变水合程度的物质，将不在各论标题中提及。这一信息将在各论的“定义”部分进行补充（见第 II.3 部分）。

Where a substance is used in member states in approved medicinal products for veterinary use only, “for veterinary use” is included in the title.
如果批准的药品中使用的物质在成员国中只用于兽药，则应在标题中包括“供兽药用”。

II.2. FORMULAE, MASSES AND CAS NUMBERS

结构式、质量和 CAS 编号

The chemical structure must be ascertained with the greatest possible care in order to establish the exact:
必须尽最大可能仔细地确定化合物的结构，以确保其准确性：

- graphic formula;
  结构式；
- empirical formula and relative molecular mass. The latter is calculated as follows: first, the relative atomic masses, or multiples thereof, are added together using all the figures of the International Table of Relative Atomic Masses; the total is then rounded off according to general rules and given to four significant figures if the molecular mass is below 600 or otherwise to three significant figures;
  经验公式和相对分子质量。后者的计算方法如下：首先，使用国际相对原子质量表的所有数字将相对原子质量或其倍数相加；然后根据一般规则对总数修约，如果分子质量低于 600，则为四位有效数字，否则为三位有效数字；
- the CAS number, included for information, wherever appropriate;
  CAS 编号，在适当的情况下，包括在信息中；
- chemical name (mentioned in the DEFINITION section of the monograph). This involves in particular:
  化学名称（在各论的“定义”部分被提到），这尤其涉及：
  - investigating the possible existence of isomers so as to be able to specify which isomer is used or, failing that, to state that the product is a mixture of isomers;
    调查可能存在的异构体，以便能够说明使用的是哪种异构体，如果不能说明，则说明产品是异构体的混合物；
  - in the case of a stereoisomer, it is not sufficient to take into account only the direction 190 of the optical rotation. The absolute configuration is given by the appropriate IUPAC nomenclature at the asymmetrical centre(s), e.g. R/S system or any other appropriate system, such as for carbohydrates and amino acids;
    在立体异构体的情况下，仅考虑旋光度的方向为 190 度是不够的。用适当的 IUPAC 命名法来命名该物质不对称中心的绝对构型，例如 R/S 系统或任何其他适当的系统，如碳水化合物和氨基酸；
  - ascertaining the state of hydration so as to distinguish clearly between the well defined hydrates (mono-, di-, tri-, etc. hydrate) and the products that contain variable quantities of water. In the latter case, the term “x-hydrate” is introduced in the chemical name.
    确定水合状态，以便明确区分定义明确的水合物（一水合物、二水合物、三水合物等）和不同含水量的产品。在后一种情况下，在化学名称中引入“x-水合物”一词。

II.3. DEFINITION 定义

If the substance contains a variable quantity of water, or refers to both water-free and hydrate form, a sentence is added to the DEFINITION section to explain the exact scope of the monograph.
如果物质有不同的含水量，或同时提及无水和水合物形式，则在“定义”部分增加一句话来解释各论的确切范围。

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:
一些化学物质，特别是那些从天然原料中获得的物质和通过发酵产生的物质可能不容易与某些相关物质（例如奎宁盐）分离。这些物质可被视为：

- a chemical product when obtained in a very pure state and when they can be assayed by a physico-chemical method;
  当获得的物质是很纯的状态且可以采用物理化学方法进行含量测定时的化学药品；
- a substance accompanied by a certain proportion of related substances, giving an exact definition of the main component only (e.g. neomycin);
  伴随一定比例的相关物质，仅给出主要成分的确切的定义（如新霉素）；
- a mixture of several components, sometimes difficult to define, where an overall description may suffice (e.g. nystatin).
  多种组分的混合物，有时难以定义，采用总体描述就足够了（如制霉菌素）。

Where applicable, the origin of the substance must be 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 [to clarify application of the general monograph *Substances for pharmaceutical use* (2034)].
如适用，必须详细说明该物质的来源（该物质来源的生物体的名称和种属）。如适用，各论中应指出该物质是半合成的，且来自于发酵产品的[阐明符合总论《药用物质》（2034）中规定的用途]。

II.3.1. Combinations 化合物

In medicinal products, more or less well-defined chemical combinations (e.g. theophylline-ethylenediamine) or even mixtures are sometimes used. In such cases, it is necessary to specify precisely each component of the combination or mixture precisely, with its chemical structure and the proportion in which it is present.
在药品中，会使用明确定义程度不同的化合物组合（例如，茶碱-乙二胺）或者（有时候）甚至是混合物。在这种情况下，有必要精确的说明化合物或是混合物的各个组分，包括化学结构式和组分间的比例。以及每个组分的化学结构和组分间的比例。

II.3.2. Content 含量

The substance described by a monograph is never a wholly pure substance but contains a limited proportion of impurities. The content is therefore an important part of the definition.
各论中所描述的物质从来不是完全纯的物质，而是含有有限比例的杂质。因此，含量是定义项的一个重要部分。

The content of the active substance must be within specified assay limits. These limits are established taking into account the following:
活性物质的含量必须在规定的检测限度内。这些限度的确定应考虑以下因素：

- the manufacturing process, which determines the degree of purity that may be reasonably achieved;
  制备工艺，它决定了物质的可合理得到的纯度；
- the reproducibility and accuracy of the analytical method;
  分析方法的重现性和准确性；
- current batch data of at least 10 production batches at release;
  当前至少 10 个生产批次放行批数据；
- the evaluation of stability data;
  稳定性数据的评价；
- a sufficient number of experimental results obtained on several batches (at least three), if possible, of

different origins and ages
足够数量的实验结果，如果可能的话，从几批（至少三批）不同来源和不同生产时间的产品上获得。

For a non-specific assay by titrimetry, the limits are set according to the table provided in part III.3.7 (i.e. usually 99.0-101.0 %). Some monographs still include an assay by UV-Vis spectrophotometry, for which wider limits are generally set.
对于通过滴定法进行的非特异性检测，其限度是根据第 III.3.7 部分提供的表格确定的（即通常为 99.0-101.0 %）。一些各论仍包括通过 UV-Vis 分光光度法进行的测定，该方法通常为其设定更宽的限度。

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 based on the available batch/stability data and approved specifications. It may therefore be lower than 98.0 %.
对于使用分离技术（例如，液相或气相色谱）的特定检测，检测上限通常为 102.0 %；检测下限将根据现有的批次/稳定性数据和批准的规格，对存在的杂质进行必要的考虑。因此它可能低于 98.0 %。

When the substance to be examined contains only impurities that do not interfere with the assay, or when it contains only a very low proportion of impurities interfering with the assay, the results of the assay can be used directly. It will then be stated that: "*[the substance] contains not less than x per cent and not more than the equivalent of y per cent* (at least 100.5 %, but often a little more) of *[chemical definition of the pure product]*". The content of the substance is usually expressed with reference to the anhydrous or dried substance. According to the general monograph *Substances for pharmaceutical use (2034)*. the content of residual solvent is taken into account for calculation of the assay content of the substance, therefore no reference is made in the DEFINITION section of the individual monograph.
当待检物质只含有不干扰含量测定的杂质，或者只含有极低比例的干扰含量测定的杂质时，可以直接使用检测的结果。然后将将说明“该物质]”含有不少于 x%且不超过 y%（至少 100.5%，但往往多一点）的“[化学定义上的纯产品]”。物质的含量通常是以无水物或以干燥品来表示。根据总论《药用物质》（2034），在计算物质的含量时考虑到了残留溶剂的含量，因此在各论的“定义”部分没有提及。

In cases where the water content is high (e.g. disodium phosphate dodecahydrate), content limits may be expressed with reference to the hydrate form of the substance, taking into account the molecular mass of the hydrate form (only for well-defined hydrates) or with reference to the substance on the anhydrous/dried basis in combination with determination of water content/loss on drying.
在水含量较高的情况下（如十二水合磷酸氢二钠），含量限度可参考该物质的水合物形式来表示，考虑到水合物形式的分子量（仅适用于定义明确的水合物），或参考无水物/干燥品形式（结合了水分含量/干燥失重的测定）。

When the substance to be examined contains a relatively large proportion (a few %) of impurities that are determined at the same time as the active substance, appropriate wording is to be used (for instance, in the case of quinine salts: "*x per cent of total alkaloid salts, expressed as quinine salts*").
当待检物质含有相对较高比例（百分之几）的杂质，并与活性物质同时被测定时，应采用适当的措辞（例如，就奎宁盐来说：“以奎宁盐计总生物碱盐的 x%，”）。

In exceptional cases, reference is made to only a part of the molecule or to an element (e.g. assay of magnesium oxide in light magnesium carbonate or assay of magnesium in magnesium stearate).
在特殊情况下，含量只以部分分子或元素计（例如，轻质碳酸镁中的氧化镁的测定或硬脂酸镁中的镁的测定）。

In the case of antibiotics determined by microbiological assays, the active substance content is expressed in International Units, where these exist, and only a minimum value is given.

对于通过微生物法测定抗生素含量，如果有国际单位，则以国际单位表示活性物质含量，并且只给出最小值。

See also under part II.8.
详见 II.8 部分。

II.4. PRODUCTION 产品

Statements in the PRODUCTION section draw attention to particular aspects of the manufacturing process, but these are not necessarily exhaustive. They constitute mandatory requirements for manufacturers, unless otherwise stated. See the *General Notices* for further information.
“产品”部分的说明请注意生产工艺的特定方面，但这些说明不一定是详尽的。它们构成了对制造商的强制性要求，除非另有说明。更多信息请参见《凡例》。

II.5. CHARACTERS 性状

As defined in the General Notices, statements in the CHARACTERS section of a monograph are not to be interpreted in a strict sense and are not regarded as requirements. The principal items that may be referred to under this section are outlined below.
正如凡例中所定义的，各论中的“性状”部分的陈述不是严格意义上的解释，也不视为必备的要求。本节中可能提到的主要项目概述如下：

II.5.1. Appearance 外观

This description will typically cover colour and physical form. The term “white” is not used without qualification since, if viewed against a standard white material, very few pharmaceutical materials will appear truly white. Of course, it is not intended that such a comparison be made, but experience has shown that some users of the Ph. Eur. may insist on it as part of a purchasing contract. The term “white or almost white” is used instead. Where positive colours are to be described, this is done in terms of primary colours or combinations of primary colours.
这种描述通常包括颜色和物理形态。术语“白色”的使用是基于一定条件的，因为如果与标准的白色材料相比，很少有药物看起来为真正的白色。当然，我们并不打算进行这样的比较，但经验表明，某些欧洲药典的用户可能会坚持将颜色的对比作为采购合同的一部分。因此，取而代之的是术语“白色或类白色”。如果要描述正色，则用三原色或三原色的组合来描述。

II.5.2. Taste 味道

The taste is not to be taken into consideration.
无需考虑味道。

II.5.3. Odour 气味

In general, no reference is made to odour, especially for materials that would constitute a hazard if inhaled. Mention of odour in other cases must be justified.
一般来说，不对气味的描述进行规定，特别是对于吸入后引起毒害作用的物质。其他情况下，对气味的描述必须合理。

II.5.4. Solubility 溶解度

For solid materials, all solubilities are quoted in the general terms defined in the general chapter *5.11*

Characters section in monographs, which also includes a procedure recommended for the estimation of solubility. For liquid materials, it is stated whether they are miscible or not. Solvents quoted are normally confined to water, an alcohol and a lipophilic solvent (e.g. water, ethanol(96 per cent) or anhydrous ethanol, heptane). Solubilities in chloroform and ether are not mentioned and the use of hexane is discouraged. In exceptional cases, the solubility of different samples of a material may vary considerably, despite their composition still being within the limits set by the monograph. More than one solubility class is therefore given to cover the solubilities in the solvents affected (e.g. *"sparingly soluble to soluble in..."*). In some cases, it may be useful to specify solubility in alkalis or acids and, especially for materials that are very insoluble in the above-mentioned solvents, a special solvent may be indicated (e.g. dimethylformamide or dimethyl sulfoxide). It is not necessary to specify the solubility in every solvent that is used in performing the tests of the monograph itself. The solubilities or miscibilities in other solvents with which the material is often combined in practice (e.g. fatty oils) may also be mentioned.
对于固体物质，所有的溶解度都以通则 5.11“各论中的性状”部分所定义的术语来引用，它还包括推荐用于估计溶解度的程序。对于液体物质，会说明它们是否可混溶。所引用的溶剂通常仅限于水、乙醇和亲脂性溶剂（如水、乙醇（96%）或无水乙醇、庚烷）。不对在氯仿和乙醚中的溶解度进行描述，不建议使用正己烷。在特殊情况下，同一物质的不同样品的溶解度可能会有很大的不同，尽管它们的组分仍然在各论规定的限度内。因此，会给出一个以上的溶解度等级，以涵盖受溶剂影响的溶解度（例如，“略溶至溶解...”）。在某些情况下，注明该物质在碱或酸中的溶解度可能是有用的，特别是对于在上述溶剂中很难溶解的物质，可能需要注明一种特殊的溶剂（如二甲基甲酰胺或二甲基亚砜）。没有必要说明在执行各论检测时所用到的每一种溶剂的溶解度。也可提及在实际中经常与该物质结合的其他溶剂（如脂肪油）中的溶解度和混溶度。

II.5.5. Stability factors 稳定性因素

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). Any such statement in the CHARACTERS section is given separately from the description of a pharmacopoeial material.
应提供因暴露于空气、光照和水气中的不稳定性的证据（例如，硫酸毒扁豆碱暴露于空气和光照中会变红）。任何在“性状”部分这样的表述，要与药物的表述分开给出。

II.5.6. Hygroscopicity 吸湿性

A pragmatic method recommended for the determination of the tendency of a substance to take up atmospheric water (rather than a true determination of hygroscopicity) is given in general chapter *5.11. Characters section in monographs*. Some substances are hygroscopic or deliquescent, which results in difficulties for the analyst during weighing procedures. In such cases, this is indicated using the terminology defined in general chapter *5.11.*, and serves as an alert to the analyst should take necessary precautions when handling the substance. When a substance is hygroscopic, a STORAGE section is added ("*in an airtight container*").
在通则 5.11 章节“各论中的性状”，推荐了一种实用的方法来测定物质吸收大气中水分的趋势（而不是真正的吸湿性测定）。有些物质具有吸湿性或潮解性，给分析人员在称量过程中带来了困难。在这种情况下，将使用通则 5.11 章中定义的术语进行说明，并提醒分析员在处理该物质时应采取的预防措施。当某种物质具有吸湿性时，要增加“储存”部分的说明（“在密闭容器中”）。

II.5.7. Solid-state properties 固态特性

Solid-state properties include crystallinity, polymorphism, density of solids, particle size of solids and specific surface area of solids. Solid-state properties, particularly polymorphism and pseudopolymorphism, may have an effect on the bioavailability of the substance and for the production of the medicinal product. General chapter *5.9. Polymorphism* should be consulted.
固态特性包括结晶度、多晶型、固体密度、固体粒径大小和固体的比表面积。固态特性，特别是多晶型和伪多晶型，可能对药物的生物利用度和对药品的生产有影响。应参考通则 5.9“多晶型”中的

内容。

A procedure recommended for the determination of crystallinity is given in general chapter *5.11. Characters section in monographs*.
通则 5.11“各论中的性状”中给出了测定结晶度的推荐程序。

Solid-state properties of excipients that are relevant for functionality may be covered in the FUNCTIONALITY-RELATED CHARACTERISTICS section (see part II.12).
与功能性相关的辅料的固态特性，可在“功能性指标”部分被涵盖（见第 II.12 部分）。

The inclusion of a statement of polymorphism in a monograph is intended to alert users to the need to evaluate this phenomenon during the development of a medicinal product, see also part on infrared absorption spectrophotometry (II.6.3)
在各论中加入多晶型的声明是为了提醒用户，在药品研发过程中需要评估这一现象，另见红外吸收分光光度法部分（II.6.3）。

Two cases are to be distinguished when polymorphism is known to exist:
在已知存在多晶型的情况下，应区分两种情况。

- usually, the monograph does not exclude any of the possible crystalline forms;
  通常，各论并不排除任何可能的药物结晶形态；

- exceptionally, if the substance is only used in solid dosage forms and one form has been preferred for bioavailability reason or by virtue of having a better safety/efficacy profile, then the monograph may be limited to that form by adding the following sentence: “*Preparation: examine the substances without prior treatment*”. The techniques required to identify the form are included in the IDENTIFICATION section.
  在特殊情况下，如果该物质仅用于固体制剂，并且由于生物利用度的原因或由于具有更好的安全性/有效性，一种晶型是首选的，那么可能通过添加如下句子将各论限制为该晶型：“制备：不经事先处理来检查这些物质”。鉴别这种晶型所需的技术要求将在“鉴别”部分收载。

II.5.8. Other characteristics 其他特性

Other physical characteristics that may be useful for information purposes, but which are not sufficiently precise to be defined under the IDENTIFICATION or TESTS sections, may be stated in the CHARACTERS section. This would typically apply to a melting point that is insufficiently precise to allow a range to be quoted; if a range can be quoted, the melting point may be included in the IDENTIFICATION section.
Any potential for decomposition must be stated. Other general characteristics that may need to be states in the CHARACTERS section include an indication of direction of optical rotation in a particular solvent or, in the case of radioactive materials, a statement of the half-life of the radionuclide and the type of radiation that it emits.
其他物理特性作为信息可能是有用的，但在“鉴别”和“检测”部分又不能充分准确的定义，可以在“性状”部分进行说明。这通常适用于熔点不够精确，不能准确报告熔点范围的情况；如果范围可以引用，熔点可以包括在“鉴别”部分。必须说明任何分解的可能性。其他可能需要在“性状”部分说明的一般特性包括在特定溶剂中的旋光性指示，或者如果是放射性材料的情况，说明放射性核素的半衰期和它所发出的辐射类型。

II.5.9. Behaviour in solution 溶液的特性

In cases where it is known that rapid degradation may occur in solution, a warning is included in the text. In this context:
如果知道在溶液中可能发生快速降解，应在注意事项中列出。这种情况如下：

- "Freshly prepared solution" means that the solution is prepared each time the test/assay is to be carried out and is used within 24 h;
  "新制备的溶液"是指每次进行试验/分析时都要新配制溶液，并在 24 小时内使用；

- "*Immediately before use*" indicates that the stability of the corresponding solution(s) was found to be critical during the elaboration of the text. The time between preparation and use must be kept to a minimum.
  "临用新配"表示在起草标准时发现相应溶液的稳定性至关重要。制备和使用之间的时间必须尽量缩短。

Furthermore, and where applicable in the tests, it should be indicated that the solutions are to be stored at a certain temperature and kept at a certain temperature in an autosampler.
此外，在检测中适用的情况下，应说明溶液要在一定的温度下储存，并在自动取样器中保持一定的温度。

II.6. IDENTIFICATION 鉴别

II.6.1. General 一般鉴别

The purpose of the IDENTIFICATION section of a monograph is to provide confirmation of the identity of the substance in question. Identification according to the Ph. Eur. is thus generally much more limited in scope than the identification and/or structural elucidation of an unknown substance or the determination of the composition of an unknown mixture. The task of identifying a material is not to be confused with the assessment of its purity or the determination of its strength, although ultimately all three aspects are complementary.
各论中鉴别部分的目的是鉴定所述物质的身份。因此，根据欧洲药典方法所做的鉴别和或未知物的结构阐释或者未知混合物的组分测定相比，通常适用范围非常有限。一种物质的鉴别活动不能与纯度评估或规格含量测定相混淆，尽管这三个方面最终都是互相补充的。
Thus, when taken together, the physical and/or chemical tests and reactions included in 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 from each other. The tests must not be too sensitive (false reactions caused by the presence of tolerated impurities are to be avoided) and they must not require more experimental effort than necessary in order to differentiate the substance in question from other commercially available pharmaceutical substances. The time needed to perform a test is also taken into account when considering experimental effort.
如此，将鉴别部分包含的物理和/或化学测试和反应综合起来，尽可能确保专属性。鉴别试验的专属性应保证结构相似的活性物质和辅料能相互区分开。鉴别试验也不能太灵敏（避免因允许限度内的杂质引起错误反应），除了将所述物质与其它市售的药物能够区分外，鉴别试验也不需要（比必须的）更多的试验要求。在制定鉴别试验时，也要考虑鉴别试验所需的时间。

Typically, a single set of identification tests is given; however, some monographs may give two or more alternative sets of identification tests that are equivalent and may be used independently. The intended purpose of the alternative sets of tests is the same (e.g. verification that the correct enantiomer is present).
通常情况下，只给出一套鉴别试验方法。但是，一些各论可能会给出两套或多套可供选择的鉴别测试，这些测试是等同的，可以独立使用。这些替代性测试的目的是相同的（例如，验证是否存在正确的对映体）。

In addition, for some substances used in community pharmacies or hospital pharmacies, a second series of identification tests is given (see part II.6.2). This second identification series should not be confused with the alternative sets mentioned above.
此外，对于一些医院或社区药房使用的药物，要给出第二个一系列的鉴别测试（见II.6.2 部分）。这

第二个识别系统不应该与上边提到的其他鉴别方法相混淆。

Some of the purity tests in a monograph may also be suitable for identification purposes, possibly in a modified form. A system of cross-references to the TESTS or ASSAY section can be used. This is particularly relevant if distinction between closely related materials depends on properties that are also parameters in purity or composition control (water content of different hydrates, chiral chromatography of enantiomers or optical rotation, viscosity of chain-length homologues of a polymer, etc.). Cross-reference to the ASSAY section often consists of identification via comparison of retention times and peak sizes (areas) of the substance to be examined with those of a reference substance. Acceptance criteria (e.g. permitted deviations in retention times) are not typically given in the monograph but should be defined in the internal quality management systems on the user's site. The IDENTIFICATION section in the monograph suffices to identify the article even if it includes cross-references to other sections.
各论中的纯度检查法在经过适当的修订后，也可能适用于鉴别试验。“检测”部分和“含量”部分可以被相互参照。如果药物与有关物质之间的区别在于药物本身的性状，而药物的这些性状又是药物纯度或药物组分间比例控制的参数时(不同水合物的含水量、对映异构体的手性色谱或旋光性、链长不同的同源高聚物的粘度等)，特别适用于上述格式。交叉参照含量项下的鉴别试验通常包括通过对比待测物质与对照物质的保留时间和峰值大小（面积）进行鉴别。可接受标准(例如，保留时间的允许偏差)通常不会在各论中给出，但应在用户现场的内控质量管理体系中规定。各论中鉴别项下的试验为了满足鉴别需要，可以参见其他项下的方法。
The monograph of a substance must not be treated in isolation. When an identification series is being investigated, it is desirable that other similar substances, regardless of whether they are the subject of pharmacopoeial monographs, are examined at the same time to ensure that a particular combination of tests within a series will successfully distinguish between two similar substances.
不能孤立的处理物质的各论。当研究一个鉴别系列方法时，最好同时对其他类似的物质进行检查，不管它们是否是药典各论中的品种，以确保一个鉴别系统中的特定测试组合能够成功区分两个类似物质。
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.
对于药典中性状类似的品种，为了能将每个物质与其他类似物质区分开来，有时需要增加非特异性但具有区分性的鉴别试验法。

Examples of methods of identification are listed below and detailed guidance concerning some of them is given throughout part II.6.
下面列举了一些鉴别方法并在 II.6 中对其中一些方法进行了详细的指导。

Instrumental methods:
工具性方法

- Spectroscopic analysis, such as recording of infrared (IR) or nuclear magnetic resonance(NMR) spectra;
  光谱分析，如记录红外(IR) 或核磁共振(NMR)光谱；
- Chromatographic examination by means of gas chromatography (GC) or liquid chromatography (LC).
  通过气相色谱法(GC)或液相色谱法(LC)进行色谱检查。

Other methods may be used if appropriate:
如果合适的话，还可以使用其他方法。

- Determination of physical constants such as melting point, freezing point, boiling point, specific optical rotation, ultraviolet spectrum, specific absorbance, relative density, refractive index and viscosity.
  测定物理常数，如熔点、冰点、沸点、比旋度、紫外光谱、吸收系数、相对密度、折光率、粘度。
- 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).

化学反应，如颜色或沉淀反应(包括形成衍生物或降解产物，随后可进行物理检查)和测定化学值(皂化、酯、羟基和碘值)。

- Chromatographic examination by thin-layer chromatography (TLC) or high-performance thin-layer chromatography (HPTLC).
  通过薄层色谱(TLC)或高效薄层色谱(HPTLC)进行色谱检查。

II.6.2. First and second identification series 第一和第二鉴别测试系列

Some monographs have subdivisions (i.e. series) entitled “First identification” and “Second identification”.
有些各论中有题为“第一鉴别”和“第二鉴别”的分项（即系列）。
The test(s) that constitute the “First identification” may be used in all circumstances.
构成“第一鉴别”的试验可用于所有情况。
Second identification testing is only intended to be used by community pharmacies or hospital pharmacies that compound unlicensed pharmaceutical preparations provided it can be demonstrated that the substance is fully traceable to a batch certified to comply with all the requirements of the monograph and that this is documented in a certificate of analysis.
第二鉴别测试仅适用于社区药店或医院药房配制未经许可的药物制剂，但可以证明该物质可完全追溯到经认证符合各论中所有的要求的批次，并在分析报告中予以记录。
The implementation of the tests in the second identification series is subject to national regulation.
第二个鉴别系列中试验的实施须遵守国家规定。
A second identification series is not intended to be applied by manufacturers for quality control purposes for approved medicinal products (it is implied that good manufacturing practice is applied).
第二个鉴别系列不打算由制造商用于已批准药品的质量控制目的(这意味着采用了优良生产规范)。
The aim of the tests in the second identification series is to confirm the identity of the substance using affordable analytical instrumentation and accessible implementation methods, rather than relying on complex technologies.
第二鉴定系列测试的目的是使用负担得起的分析仪器和可获得的实施方法来确认该物质的身份，而不是依赖复杂技术。
Wherever possible, it is recommended to use the principles of mixed melting point, refractive index and, as required, miniature TLC complemented by wet-chemical testing.
只要有可能，建议使用混合熔点、折光率的原则，并根据需要辅以湿化学微型 TLC 试验。
Second identification tests should provide the user with at least two results that confirm the identity of the substance.
第二鉴别试验应向使用者提供至少两个结果，以确认物质的身份。
These results can either be obtained by two independent tests or by a single test that provides two or more pieces of information about the identity of the substance.
这些结果既可以通过两次独立的试验获得，也可以通过一次试验获得，该试验提供了两条或更多关于该物质身份的信息。
The combination of refractive index with relative density is an example of the former; a TLC with the application of a detection reagent is an example of the latter.
折射率与相对密度的组合是前者的一个例子；应用检测试剂的 TLC 是后者的一个例子。
In order to introduce a second identification series, it should be assessed on a case-by-case basis whether concrete knowledge is available that the substance is used:
为了引入第二个鉴别系列，应逐一评估是否有具体的资料说明使用了该物质:

- in a magisterial formulary or a pharmacopoeia; or
  在权威的处方集或药典中；或
- in formulations made for special target groups or distinct medicinal indications where no licensed product exists; or
  在没有许可产品的情况下，为特殊目标群体或独特医药适应症制作的配方；或
- for pharmacy compounding (e.g. when they are offered for this purpose by suppliers).
  用于药物配制(例如，当供应商为此目的而提供)。

II.6.3. Infrared absorption spectrophotometry 红外吸收分光光度法

This is generally considered to be a satisfactory single method for verifying the identity of non-ionised organic substances other than salts of organic acids or bases. This analytical technique always requires the use of a reference substance or a reference spectrum. Reference substances are preferred to reference spectra; the latter are used where there are practical difficulties with providing a reference substance (e.g. in cases of particular toxicity or instability).
这通常被认为是验证除有机酸或碱盐以外的非电离有机物质身份的令人满意的单一方法。这种分析技术总是需要使用标准物质或标准光谱。更倾向于使用标准物质而不是标准光谱；后者用于在提供标准物质有困难的情况下(例如，在具有特殊毒性或不稳定性的情况下)。

Organic salts of organic substances and some inorganic salts of organic substances (e.g. phosphates and sulfates) can readily be distinguished from each other. In the case of sulfates, however, it is necessary to extend the usual range of recording from 4000-650 cm^{-1} to 4000-400 cm^{-1}
有机物质的有机盐和有机物质的一些无机盐(如磷酸盐和硫酸盐)可以很容易地区别开来。然而，在硫酸盐的情况下，有必要将通常的记录波数范围从 4000-650 cm^{-1} 扩展到 4000-400cm^{-1}。

Since monographs do not typically prescribe a specific mode, all modes described in general chapter 2.2.24 (e.g. ATR mode, transmission mode) may be used. The type of sample preparation (disk, halide salt plate, mull, etc.) is not specified unless this has been found to be necessary during the elaboration of the monograph in order to obtain a satisfactory spectrum.
因为各论通常不规定特定的模式，在通则 2.2.24 中描述的所有模式(例如 ATR 模式、透视模式)都可以使用。样品制备的类型（压片，卤化盐夹片，糊法等）没有指定，除非在各论的起草过程中发现有必要这样做以获得满意的光谱。

In certain cases, the infrared spectrum alone is not sufficient to confirm the identity of a substance and other tests must also be performed.
在某些情况下，仅靠红外光谱不足以确认某种物质的身份，还必须进行其他测试。

- Salts of organic acids or bases: for several ions or groups that form part of an organic substance (counter-ion), more than one identification test may be described in general chapter 2.3.1.
  有机酸或碱的盐：对于构成有机物质一部分的若干离子或基团(反离子)，可以在通则第 2.3.1 章中描述一种以上的鉴别试验。
- However, it is usually only necessary to use one of them.
  然而，通常只需要使用其中的一个。
- Chemically related substances: in the case of substances closely related to the substance to be examined where variations in the spectra are not considered sufficient for unambiguous identification, the infrared identification test is accompanied by another simple test (e.g.melting point or TLC with the use of a reference substance).
  化学相关物质：针对与待测物质密切相关的物质，如果认为光谱变化不足以进行明确的鉴别，则红外鉴别测试同时应进行另一种简单的测试（例如熔点或使用标准物质的 TLC 测试）。
- Polymorphism: the sentence “It shows polymorphism” is added only when more than one crystalline forms is used in approved medicinal products and the different forms are available for testing.
  多晶型：只有在已批准的药品中使用一种以上多晶型物料，且有不同的晶型可供测试时，才会添加“它显示多晶型”这句话。
- General chapter 2.2.24. Absorption spectrophotometry, infrared allows for “recrystallisation” before recording of the spectrum.
  总则 2.2.24 章“吸收分光光度法，红外”允许在在记录光谱之前进行“重结晶”。
- If a monograph mentions polymorphism, a method for “recrystallisation” is described, unless the intention is to limit the scope of the monograph to the crystalline form represented by the chemical reference substance, in which case the monograph indicates that the spectrum is recorded “without recrystallisation”.
  如果某一各论提到多晶型，则描述“重结晶”的方法，除非其目的是将该各论的范围限制在化学

标准物质所代表的结晶形式，在这种情况下，该各论表明光谱被记录为“没有重结晶”。

- In exceptional cases, if the monograph describes a specific crystalline form or forms and when the IR spectrum is not characteristic, an additional test is introduced.
  在特殊情况下，如果各论描述了一个或多个晶体形态，当这种红外光谱不具有专属性时，需引入额外的测试。
- Optical isomers: to identify a particular enantiomer or a racemate, see part II.6.6.
  光学异构体：识别特定的对映体或外消旋体，见第 II.6.6 部分。

II.6.4. Absorption spectrophotometry (ultraviolet and visible)

吸收分光光度法（紫外和可见光）

Unlike IR spectroscopy, this method is usually not specific enough for identification purposes unless the absorption curve exhibits several maxima and minima, unusually strong or weak regions of absorption, etc.
与红外光谱不同，该方法通常用于非专属性的鉴别，除非吸收光谱表现出几个最大和最小吸光度，或者出现特别强或者特别弱的吸收区等现象。

Reference substances are not generally used for identification. The UV-Vis spectrum of a substance is therefore rarely used as the sole identification criterion.
标准物质一般不用于鉴别。因此，一个物质的 UV-Vis 光谱极少能独立用作鉴别的判断依据。
The concentration of the solution to be examined is such that the absorbance preferably lies between 0.5 and 1.5, measured in a 1 cm cell.
供试品溶液的浓度应适当，使样品在 1cm 的吸收池的吸光度值在 0.5 - 1.5 之间。
The range of wavelengths to be explored must be stated; it does not typically extend to the region where end-absorption and solvent interference may be expected. The wavelengths of sharp maxima and minima are indicated by a single number, signifying ± 2 nm, while for broader bands a range is given. When it is considered necessary to mention the wavelength of shoulders, the term “about” may be used.
必须规定要扫描的波长范围，一般不应扩展到可能出现末端吸收和溶剂干扰的波长范围。尖锐的最大值和最小值的波长用整数表示，当给出较宽的吸收峰（谷）范围时，允许有±2 nm 的波动。当有必要给出肩峰的吸收波长时，可以使用“大约”来表示。

Specific absorbances are also given as a range (usually ± 5%) in order to cover variations in content of absorbing substance and experimental error. It is to be noted that the instrument tolerance for absorbance is ± 0.010 or 1%, whichever is greater, which means that the deviation due to this source of variability will depend on the absolute levels of absorbance. Furthermore, the content of absorbing substance will vary with the permitted content of water (or other solvents); when the latter does not exceed 1% or is within well-defined limits, it will usually be adequate to calculate the specific absorbance for the substance “as is” and to set the limits accordingly.
考虑到吸收物质浓度的变化和实验误差，吸收系数也可以用一个范围来表示（通常为±5%）。需要注意的是，仪器对吸光度的允许误差为±0.010 或 1%，以较大者为准，因此，由于仪器允许误差引起的偏差取决于该物质的绝对吸光值。另外，具有紫外可见吸收物质的含量会随着含水分（或其他溶剂）的允许含量变化而变化。当后者不超过 1%或其含量符合严格的限度规定，通常可以“按原样”计算物质的吸收系数，并设定相应的限度。

When more than a single maximum is present in the spectrum, the ratio(s) between their absorbances can be substituted for the individual specific absorbances, providing the ratio is less than or equal to 5, thus avoiding having to correct the absorbances for the solvent content of the substance.
当吸收光谱中存在一个以上的最大吸收时，就可以用相对吸收值来代替单个波长的吸收系数，如果吸收值比值不超过 5，这样就可以不用考虑样品中溶剂的影响，即不用对样品的吸光度值进行校正。

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

examined.
为了避免可能影响样品吸光度值的杂质引入，必须非常认真的选择溶剂以及在紫外-可见吸收光谱方面的溶剂纯度。

In certain cases, the resolution of the instrument can be a critical factor in observing the required spectral features (e.g. benzenoid-type spectra showing a fine structure). The minimum resolution required may be indicated in the monograph. In order to determine this figure, the slit-width setting is deliberately varied to the point where the spectrum obtained is just adequate for the intended purpose. The resolution corresponding to this setting is then experimentally defined on the basis of an absorbance ratio for a 0.02% V/V solution of toluene R in hexane R or preferably heptane R as prescribed in general chapter 2.2.25.Absorption spectrophotometry ultraviolet and visible. The minimum ratio is indicated in the monograph to two significant figures.
在某些情况下，仪器的分辨率是获得预期特征图谱的关键因素（比如芳香族化合物的图谱可反映精细结构）。所需的最小分辨率可以在各论中给出。为了测定这一参数，需要刻意改变狭缝的宽度，直到获得预期的满意图谱为止。与此相关的分辨率可以根据实验结果测定，并按照通则 2.2.25“紫外可见吸收分光光度法”中的规定，测定 0.02%V/V 的甲苯的正己烷或者最好是庚烷溶液的吸光度比值。在各论中会给出最小的比值并保留两位有效数字。

Table 3 indicates the approximate relationships to be expected between the spectral slit width and the absorbance ratio.
表 3 所示的狭缝宽度与吸光度比值的预期关系。

Table 3 – Resolution of spectrophotometers according to the slit width
表 3 分光光度计的分辨率与狭缝宽度的关系

Slit width (nm) 狭缝宽度（nm）	Ratio λ_{max}269nm/λ_{max}266nm 比值：λ_{max}269nm/λ_{max}266nm
0.25	2.3
0.5	2.2
1.0	2.0
2.0	1.4
3.0	1.1
4.0	1.0

II.6.5. Melting point, freezing point and boiling point

熔点、凝固点和沸点

These physical constants are of value to 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 must also be taken into account; differences in the melting point must be indicated even when given in the CHARACTERS section. In exceptional cases, when the distinction of a specific crystalline form is necessary, determination of the melting point can aid in excluding the unwanted form(s).
这些物理常数只有在明确定义，并且确定样品不伴随着破坏的情况下，才有鉴别的价值。这些物理常数的测定极度依赖于实际的操作方式。还必须考虑到可能存在的多晶型现象；即使熔点只在“性状”部分给出，也必须给出不同晶型间熔点的差异。在特殊情况下，当需要区别特定的晶型时，可以通过测定熔点帮助排除不需要的晶型。

However, it should be kept in mind that an apparent melting point may be observed: a solid-solid polymorphic transition may take place during testing and the melting point of the resultant form is

measured.
然而，应当注意观察到的溶点可能只是表观熔点：在熔点测定过程中可能发生多晶型间的固-固转化，所测得的结果只是最终晶型的熔点。

For the first identification, neither the melting point alone nor the addition of a chemical reaction is sufficient to confirm the identity of a substance. However, combining one of these two tests with another identification test such as IR will often suffice.For the second identification, please refer to part II.6.2.
单独的熔点测定或者附加的化学反应都不足以完成对一种物质进行鉴别。然而，将这两种测试中的一种与另一种鉴定测试（如 IR）结合起来，往往可以提供足够的鉴别证据。关于第二种鉴别，请参考第 II.6.2 部分。

The melting point determined by the capillary method is defined in the Ph. Eur. (see general chapter 2.2.14. Melting point – capillary method) as the last particle melting point (i.e. clear point or liquefaction point). It must not be confused with the melting interval even though both are given as a range.
药典中规定，通过毛细管法确定的熔点是药物成分最终熔点（即初熔点或全熔点）（见通则 2.2.14. 毛细管熔点测定法）。千万不要与熔程相混淆，尽管有时候熔点和熔程都给出一定的温度范围。

II.6.6. Identification of substances that have one or more stereocentre(s)

鉴别具有一个或多个手性中心的物质

When only the racemate monograph is available in the Ph. Eur., 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.
当欧洲药典收载的药物只有消旋体可供药用时，如果手性物质的比旋度已知，并且旋光度测定能够提供消旋体的特征参数时，在检查项下进行旋光度测定。

When a monograph describes an enantiomer only, the monograph contains a test for enantiomeric purity in the TESTS section and a cross-reference in the IDENTIFICATION section.
当一个各论只描述一个对映体时，该各论的“检测”部分包含一个对映体的纯度测试，并且与“性状”部分有交叉引用。
If this is not possible, a test for specific optical rotation is added in the TESTS section of the monograph and is cross referenced in the IDENTIFICATION section.
如果无法做到这一点，则在各论的“检测”部分增加比旋度的试验，并在“鉴别”部分交叉引用。
If monographs exist for both the racemate and the enantiomer, the monograph of the racemate contains an optical rotation test in the TESTS section and a cross-reference in the IDENTIFICATION section. The use of an optical rotation test is discouraged in other situations due to its lack of specificity.
如果外消旋体和对映体都有各论，则外消旋体的各论在“检测”部分包含一个旋光度试验，在“鉴别”部分交叉引用。由于缺乏特异性，在其他情况下不鼓励使用旋光度测试。

II.6.7. Thin-layer chromatography 薄层色谱法

This identification method requires the use of reference substances. Selectivity may be improved by combining TLC with chemical reactions in situ i.e. by employing appropriate spray or dipping reagents, in which case the same or a similar reaction is not to be repeated on a test-tube scale.
本鉴别方法需要使用对照品。在展开剂的作用下，样品与薄层板相结合，样品的化学性状决定其展开后在薄层色谱中的位置，也就是在薄层展开后用适当的喷雾和浸渍溶剂（显色剂）进行显色，可以增强 TLC 鉴别法的专属性。TLC 中的显色反应在试管中是不能重现的。

Although it is very important to ensure the separation of a critical pair in a related substances test, this plays a minor role in an identification test. The separation of a critical pair in the individual identification tests is no longer required but the separation of a critical pair in the TESTS section is maintained. However, during

development and validation, separation of the substance from similar substances must be demonstrated.
在有关物质检查中，保证对关键化合物的分离是非常重要的，尽管这种分离在鉴别试验中起到很小的作用。鉴别项下并不要求对关键化合物的分离，在检测项下才要求关键化合物的分离度。但是，在方法的建立和验证阶段，必须证明该方法具有将待测药物与其相似物质分离的能力。
A chromatographic separation test for TLC plates is usually described in general chapter 4.1.1. Reagents to verify the performance of the plate type concerned. The test is intended to be a quality control procedure, carried out periodically by the TLC plate user.
为了确证相关薄层色谱板型的性能，通常在 4.4.1 章节试剂中会描述 TLC 板的色谱分离试验。该试验的目的是建立质量控制程序，由 TLC 板用户定期进行检验。
It is clear that such a general procedure is not appropriate for every thin-layer separation problem and that the description of a separation criterion might still be necessary to ensure the identification of the substance. In these exceptional cases, a separation criterion is described in the IDENTIFICATION section.
显然，这种通用程序并不适用于每一个薄层分离系统，为了确保样品的鉴别试验性能，可能仍然需要对色谱条件的分离能力进行规定。在这些特殊情况下，出于保证鉴别试验准确的目的，在鉴别项下会规定分离度要求。
A TLC system applied to purity testing in a monograph is preferred for identification when suitable. In this case, the concentration of the solution to be examined and the corresponding reference solution are generally reduced so that 5-20 µg of each is deposited on the plate or sheet. It may also be necessary to switch to a more discriminating detection system. For more technical requirements on these chromatographic methods, see part II.7.8.
纯度检查项下的 TLC 系统，在合适的情况下，首选用于鉴别方法。用于鉴别试验的供试品溶液和对照品溶液的浓度应适当降低，使点样量在 5~20 ug。也可能需要改用辨别力更强的检测系统。关于这些色谱方法的更多技术要求，见 II 7.8。

II.6.8. Gas chromatography and liquid chromatography

气相色谱法和液相色谱法

The basic principles mentioned under thin-layer identification apply, taking account of the differences between the two. Gas and liquid chromatography are increasingly used for identification purposes; where they are, the IDENTIFICATION section simply refers to a test or assay that applies the method elsewhere in the monograph. These methods are used only if there is no suitable alternative; they are not used as the only identification test. For more technical requirements on gas and liquid chromatography see part II 7.8.
考虑到两者之间的差异，在薄层鉴别中提到的基本原则也适用。气相色谱法和液相色谱法越来越多地被用于鉴别；在这种情况下，“鉴别”部分只在各论的其他地方应用该方法的试验或检测。只有没有适当的替代方法的情况下，才会采用气相和液相色谱鉴别方法。有关于气相和液相的更多技术要求，详见 II 7.8 部分。

II.6.9. Chemical reactions 化学反应鉴别

Several commonly applied identification reactions of a chemical nature are included amongst the general chapters of the Ph. Eur., and these are to be used whenever appropriate. Where several reactions for an ion or group are given in general chapter 2.3.1. Identification reactions of ions and functional groups, it is normally necessary to prescribe only one in the monograph. Note the need to specify the amount of material, or solution of it, to be taken for the identification test in question. The same holds true for tests that have to be described in full in the monograph. Identification reactions using toxic reagents (e.g. REACH reagents) are being slowly phased out; special care should be taken when choosing a chemical reaction to be added to a monograph.
在药典的通则中，收载了几个常用的化学基团鉴别反应，这些反应在适当的时候都会被使用。当通则 2.3.1“离子和官能团的鉴别反应”中某个离子或官能团有多个鉴别反应时，药典各论中一般只需要选择其中一个化学反应作为鉴别试验即可。需要规定试验中可能影响鉴别反应的物料或溶液的量。检查项下的反应也同样适用这一原则，应在各论中详细描述。在选择要添加到各论中的化学反

应时应特别注意有毒试剂的使用，使用有毒试剂（如 REACH 试剂）的鉴别反应正在慢慢淘汰。
Identification criteria that call for the recognition of an odour or a taste are to be avoided.
避免使用气味或者味道作为鉴别项下的判断标准。

Each chemical reaction chosen must demonstrate the presence of a different part of the molecule to be identified.
所选择的每一个化学反应必须能证明药物分子的不同待鉴定基团的存在。

To differentiate substances within a group (family) which differ either by the extent of condensation or by the length of the hydrocarbon chain (e.g. fatty acids), a cross-reference must be added to the appropriate purity test(s) where values are determined (e.g. iodine value, saponification value, etc.).
为了区分一个组（族）内缩合程度或碳氢链长度不同的物质（如脂肪酸），必须增加适当的纯度测试检测结果，交叉参照适当的确定数值（如碘值、皂化值等）。