A Guide to General USP Chapters

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Understanding USP Chapters

Quality and consistency of medicines is crucial to ensure their identity, strength, and purity is at a safe level for human consumption. That's why we rely on strict guidelines – to guarantee medications that make it to the shelves are exactly what they claim to be.

Here's a simple breakdown of USP chapters and what they contain: **General USP chapters below <1000>** provide guidelines on activities related to the tests and procedures in pharmacopeial articles. They may contain descriptions of tests and procedures, information on the interpretation of compendial requirements, and general guidance on official substances or official products. **General chapters above <1000>** don't contain any standards, tests, assays, or mandatory specifications. Instead, these excerpts include pertinent Federal Acts and regulations.

The official requirements for Pharmacopeia can be found in the general notices, individual monographs, and general tests and assays chapters. **Monographs** contain tests, procedures, and criteria to ensure the identity, strength, quality, and purity of an article. A monograph also contains the article's name, definition, specification, and other requirements related to packaging, storage, and labeling.

See below for a 200-year timeline of USP history to understand how it's evolved into the monographs and reference standards we follow today.

1820

The first United States Pharmacopeia (USP) was published.

1938

The Federal Food, Drug, and Cosmetic Act expands the roles for applicable USP and National Formulary (NF) standards to include nonproprietary naming and misbranding.

1975

USP purchased the NF, combining the two publications under one cover to create the United States Pharmacopeia–National Formulary (USP–NF).

2020

200 years of building trust

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USP <232> and <233> Elemental Impurities

Pushing the Limits of Impurities

<232> Elemental Impurities – Restrictions

This chapter plays an important role in drug development. It specifies limits for elemental impurities in all medications. Because acceptable levels depend on the material's use, manufacturers need certain information about the content of elemental impurities in drug substances or excipients in order to meet the criteria.

<233> Elemental Impurities – Procedures

This chapter describes two analytical procedures for the evaluation of elemental impurity levels in medications. It also describes criteria for acceptable alternative procedures. Alternative procedures that meet the validation requirements may be used in accordance with General Notices: 6.30 Alternative and Harmonized Methods and Procedures.

Want to know more? Explore our links.

Read our brochure to learn more about exposure limits for elemental impurities in pharmaceutical products.

Read our application note to learn about testing and validating various antacids for elemental impurities using our NexION 2000 ICP-MS.

Read our application note to learn about analyzing SiO_2 and TiO_2 in medications using ICP-OES.

Read our application note to learn about using ICP-OES to analyze allergy medications.

Read our application note to learn about the determination of trace elements in eye drops using the NexION ICP-MS.

Our Technology Solutions: ICP-MS ICP-OES Microwave Sample Preparation

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USP <467> Residual Solvents

Keeping Residual Solvents Under Control

Residual solvents are organic volatile chemicals that are used or produced in the making of drug substances, excipients, or dietary ingredients. This chapter provides procedures for analyzing residual solvents. In addition, alternative validated methodologies may be used to demonstrate compliance with the defined limits.

Further guidance on USP-verified procedures – or validation of alternative methods for residual solvents – can be found under <1467> Residual Solvents—Verification of Compendial Procedures and Validation of Alternative Procedures.

Want to know more? Explore our links.

Read our application note to learn about residual solvents in pharmaceuticals by USP methodology.

Read our application note to learn about pressure-balanced headspace for residual solvents in pharmaceuticals by USP methodology.

Our Technology Solutions

Gas Chromatography

Automated Headspace Sampler

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USP <671> Performance Testing Containers

Ensuring the Quality of Primary Packaging

When it comes to determining the primary packaging quality of drug products, plastic material is analyzed and accepted based on its identity, biocompatibility, general physiochemical properties, and composition.

This chapter provides standards for drug packaging used for solid oral dosage forms (SODFs) and liquid oral dosage forms (LODFs). It also includes a classification system that allows pharmacists and institutional repackagers to select appropriate containers to repackage these SODFs and LODFs.

Want to know more?

For more about the spectral transmission of pharmaceutical containers in accordance with USP <671>, read our application note.

Our Technology Solutions: DSC TGA FT-IR FT-IR Imaging Systems

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USP <711> Dissolution Testing

The Prescription for Peace of Mind

For pharmaceutical labs like yours, dissolution testing is a crucial step in the drug development process, from early product development to late-stage quality control in commercial manufacturing.

Working with the FDA and USP, we've helped set guidelines, including vibration limit evaluations and settings, including mechanical calibration and USP Performance Verification Test (PVT) services.

USP, the European Pharmacopoeia (EP), and the Japanese Pharmacopoeia (JP) all have different standards. These three groups are working together to create one harmonized chapter with guidelines the global industry can follow.

Want to know more? Explore our links.

Watch our webinar to learn more about taking the strain out of dissolution testing.

Explore our brochure to learn about the right solutions for dissolution testing in your lab.

Our Technology Solutions

UV-Vis

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USP <1663> and <1664> Extractables and Leachables

<1663> Extractables Associated with Pharmaceutical Packaging and Delivery Systems

This chapter provides a guideline for the design, justification, and execution of an extractables assessment for pharmaceutical packaging and delivery systems. It establishes critical dimensions of an extractables assessment and discusses practical and technical aspects of each dimension.

Our Technology Solutions

GC-MS ICP-MS

<1664> Drug Product Leachables Associated with Pharmaceutical Packaging and Delivery Systems

This chapter presents a framework for the design, justification, and implementation of assessments for leachables derived from pharmaceutical packaging and delivery systems. Because leachables can affect drug product efficacy, safety, and quality, this assessment is important to manufacturers and their suppliers to establish the suitability of pharmaceutical packaging and delivery systems.

Want to know more? To learn more about the assessment of extractables and leachables in pharmaceutical packaging, read our white paper.

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USP <857> Ultraviolet-Visible Spectroscopy

Compliance, from Beginning to End

In ultraviolet-visible (UV Vis) spectroscopy, your instrumentation needs to be deemed suitable for analysis. This is done through qualification tests, including: design qualification (DQ); installation qualification (IQ); an initial performance-to-specification qualification, also known as operational qualification (OQ); and an ongoing performance qualification (PQ).

For example, our LAMBDA™ 365 meets the compliance and performance needs of pharmaceuticals, analytic chemists, geneticists, and manufacturing QA/QC analysts everywhere. With 21 CFR Part 11 compliant software available, the LAMBDA system is ready to support everything from standard methods and applications to regulatory compliance.

Want to know more?

For more information about data integrity of UV WinLab Enhanced Security (ES) software for UV Vis, read our whitepaper.

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USP <1058> Analytical Instrument Qualification

Maintaining Data Quality

This informational chapter provides you with scientific, risk-based approaches for carrying out analytical instrument qualifications (AIQs). It explains various terms, acronyms, and activities common to analytical laboratories and validation disciplines like yours.

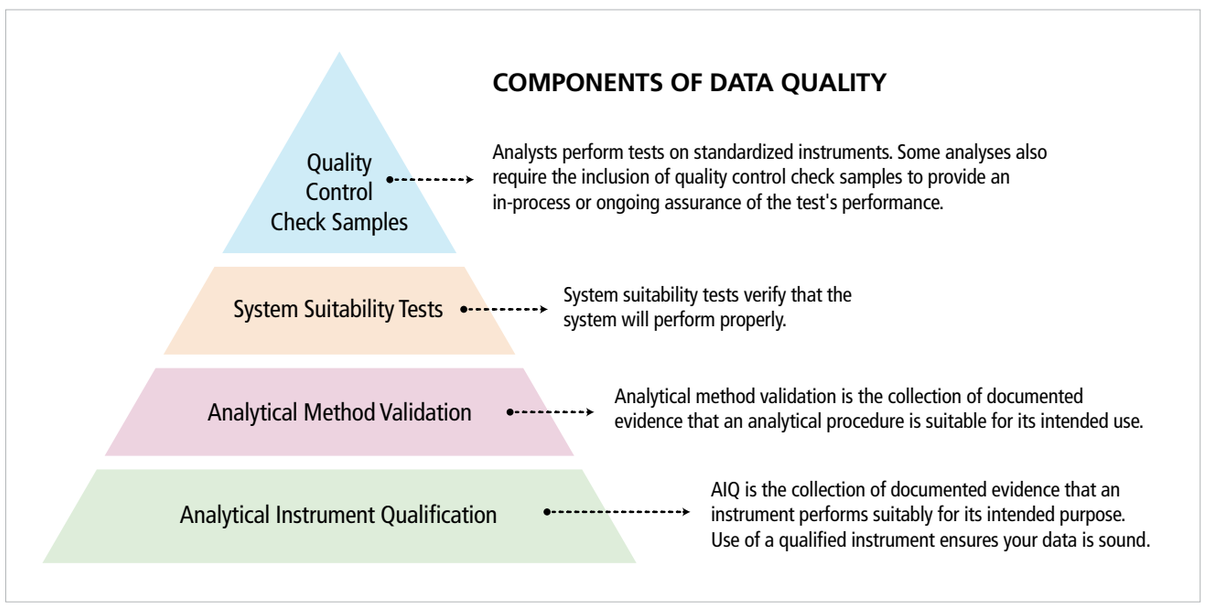
We offer several traditional qualification protocols and services for lab instruments, ensuring complete, consistent, and accurate data.

Our services provide:

- Qualification protocols using calibration standards
- Custom protocol development
- Execution of customer-developed protocols
- IQ/OQ protocol library

Want to know more?

For more on instrument qualification, click here.



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Chromatographic Columns Selection Guide

Never Miss a Peak

Whatever your separation challenge, your choice of liquid chromatography (LC) column can make all the difference. Click on each type of LC column below to choose one that fits your lab's needs.

Ibuprofen and Pseudoephedrine Hydrochloride Tablets	**Trihexyphenidyl Hydrochloride Extended-Release Capsules**	**Trihexyphenidyl Hydrochloride Oral Solution**	**Trihexyphenidyl Hydrochloride Tablets**	**Trihexyphenidyl Hydrochloride**
Thiotepa	**Clindamycin Hydrochloride Capsules**	**Orbifloxacin**	**Orbifloxacin Tablets**	**Simvastatin**

Want to know more? Read our application briefs:

- Indoxyl Sulfate
- Clopidogrel
- Cephalosporins
- Ibuprofen
- Atorvastatin
- Tramadol
- Penicillin and Amoxicillin
- Simvastatin
- Ciprofloxacin
- Naproxen
- Warfarin
- Azithromycin

For our full range of consumables, click here and browse by technology.

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Service and Support

We're Here for You, Whenever You Need Us

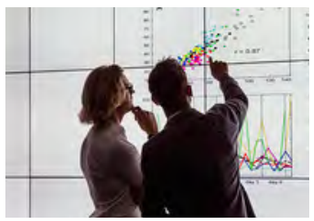
From instrument qualification and computer system validation to data integrity, our services and support ensure that your data is complete, consistent, and accurate. It's important to meet or exceed qualification regulations, and we have everything you need to keep your science on track.

INSTRUMENT QUALIFICATION

Instrument Qualification methods guide your lab through automated, secure electronic or traditional paper qualification procedures with standard OQ protocols customized to your specifications. Click here to learn more.

COMPUTER SYSTEM VALIDATION

We offer CSV support to ensure your instrument data is error free. We promote efficiencies wherever possible and offer simple approaches to enable you to meet validation requirements. Click here to learn more.



DATA INTEGRITY

Ensuring the integrity of your data is crucial. Our OneSource solution is based on centralized monitoring and continual improvements that enable you to pursue science with integrity – and compliance. Click here to learn more.

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For more information on our pharmaceutical QA/QC solutions, click here.

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