EXPEDITE PHARMACEUTICAL DEVELOPMENT

ACS REAGENT CHEMICALS *IS A TRUSTED REFERENCE FOR ANALYTICAL REAGENTS*

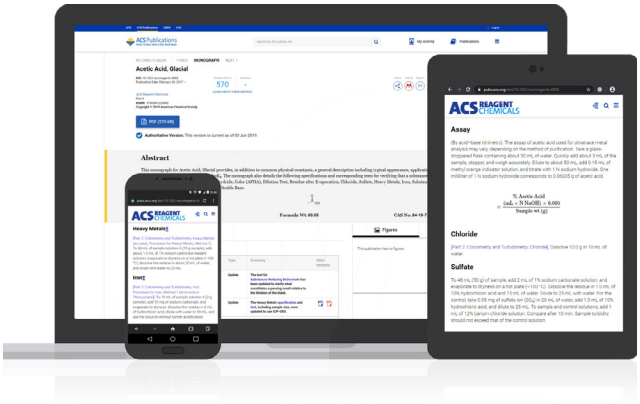
ACS REAGENT CHEMICALS

ACS Publications
Most Trusted. Most Cited. Most Read.

HIGH QUALITY ANALYTICAL REAGENTS ACCELERATE PHARMACEUTICAL DEVELOPMENT

United States Pharmacopoeia–National Formulary (USP–NF) tests underpin a wide range of drug development and manufacturing processes, from the synthesis of active pharmaceutical ingredients (APIs) and biotherapeutics through to quality assurance and quality control measures. These tests are referenced and enforced by the Food & Drug Administration (FDA) and other global regulatory bodies. USP–NF tests rely on ACS Reagent Grade chemicals, the "gold standard" for quality analytical reagents and reference materials.

Using low quality or inferior grades of analytical reagents and analytical standards can impact the accuracy of assays used in pharmaceutical processes, resulting in erroneous results that delay decisions and hold back work schedules.



1.1 ACS (American Chemical Society) Reagent Grade

Where it is directed to "Use ACS reagent grade", it is intended that a grade meeting the corresponding specifications of the current edition of Reagent Chemicals, published by the American Chemical Society (ACS), shall be used.

Reagents Introduction, US Pharmacopeia
(DOI: 10.31003/USPNF_M2984_01_01).

Likewise, failure to update analytical procedures in line with USP–NF standards and regulatory requirements can result in lost time and resources if the methods used to generate data are non-compliant. With pharmaceutical development comprising multiple teams and moving parts, even small delays can have a substantial impact downstream, potentially leading to missed milestones and additional costs.

Overcoming planning and procurement challenges

When planning studies, tests and assays for efficient pharmaceutical development, establishing the quality of the chemicals being procured and how these align with the requirements of your application is essential. Knowing how to test for impurities in a particular material is important for understanding the limitations of a specific analytical method and the claims that can be made. For cGMP-compliant FDA-regulatory processes, access to up-to-date specifications and procedures is critical. Without the right references, researching the best analysis methods can take time and effort. Worse still, incorrect or out of date information could lead to costly mistakes and non-compliance.

Setting the gold-standard for over 100 years

The ACS Committee on Analytical Reagents sets purity specifications for nearly 500 reagent chemicals and over 500 standard-grade reference materials. These specifications have become the "de facto" standards for chemicals used in the pharmaceutical industry and beyond.

The ACS Committee on Analytical Reagents evolved from the Committee on the Purity of Chemical Reagents, established in 1903. For more than a century, the Committee has sought to ensure analytical methods and specifications reflect current best practices. All *ACS Reagent Chemicals* content is regularly reviewed and evaluated by the Committee, which consists of experienced scientists from the pharmaceutical and chemical industries, academia, and government agencies.

The current chair of the ACS Committee on Analytical Reagents is Tom Tyner, recently retired Vice President of Quality Assurance/Quality Control at Spectrum Chemical Manufacturing Corporation. Tom has served as chair since 2017 and has been a committee member since 1998. He has extensive understanding and experience of the pharmaceutical and chemical industry's analytical needs, having overseen Spectrum's Quality Management Systems and current Good Manufacturing Practice (cGMP)-compliant laboratories for over 20 years.

1903
The Committee on the Purity of Chemical Reagents, later known as the ACS Committee on Analytical Reagents, is established.

1925
Early specifications are published in *Industrial and Engineering Chemistry* (I&EC).

1950
The First Edition of Reagent Chemicals publishes as a standalone book based on previous specifications published in I&EC.

1961
The Fourth Edition collects new analytical methods into Reagent Chemicals, including flame emission and spectroscopy.

1993
The Eighth Edition adds gas chromatography, atomic absorption, and coulometric methods.

2005
The Tenth Edition celebrates 100 years and adds ICP-MS methods, better indexing, and green testing methods.

2017
The new online edition of ACS Reagent Chemicals goes live.

ACS REAGENT CHEMICALS

ACS REAGENT CHEMICALS: YOUR ONLINE REFERENCE FOR QUALITY ANALYTICAL REAGENTS

ACS Reagent Chemicals is the definitive reference for methods and specifications for analytical reagents approved by the ACS Committee on Analytical Reagents. This one-stop resource for trusted information is available directly from the ACS. With content regularly maintained and updated by the ACS Committee on Analytical Reagents, it serves as the single best source of information on analytical standards and methods used in the pharmaceutical and chemical industries.

ACS Reagent Chemicals provides details on Committee-approved analytical methods, tests, and standard solution preparations as well as general physical properties and analytical uses for reagent chemicals. Building on its reputation as a trusted reference for quality analytical reagents, ACS Reagent Chemicals is referenced by organizations that set requirements for pharmaceutical products, as well as agencies including the US Environmental Protection Agency (EPA) and ASTM.

ACS Reagent Chemicals provides everything scientists need to ensure the chemicals used in the laboratory and manufacturing settings meet the standards required to safeguard accuracy and ensure safety.

ACS Reagent Chemicals features a dynamic table of contents for easy browsing.

Quick and easy access to information

ACS Reagent Chemicals is now a fully searchable online resource, making critical information on analytical reagents and methods even easier to access. The platform features live links between reagents and methods, with access to clickable, copyable information in both HTML and printable PDF formats. *ACS Reagent Chemicals* is also mobile-friendly, providing additional accessibility and convenience for users looking up information in the laboratory or on the move.

To enable rapid access to the latest guidance, *ACS Reagent Chemicals* includes permanent URLs to current versions and at-a-glance summaries of historic changes. The intuitive platform also supports full-text and keyword searching by IUPAC or common name, CAS number, formula weight, and other descriptors, for rapid retrieval of relevant information. Each page highlights key practical information including safety issues, handling requirements, and stock solution preparations.

UP TO DATE CONTENT FOR EFFICIENT, HIGH-QUALITY PHARMACEUTICAL RESEARCH AND MANUFACTURING

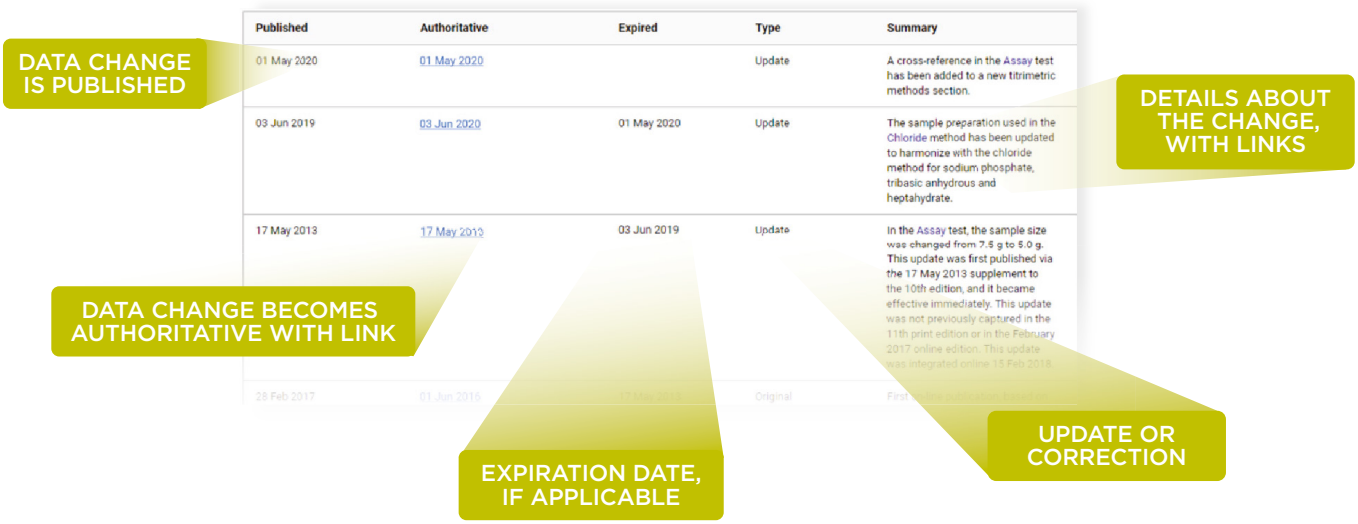
Standards change with new technology, and ensuring methods meet current requirements is important for many regulatory applications. ACS Reagent Chemicals is available online, and it is continually updated to provide easy access to the latest information to meet pharmaceutical industry requirements. Users can clearly view future and previous versions, including wet chemistry techniques and modern instrumental methods.

ACS Reagent Chemicals also receives and responds to customer feedback. Customer questions have inspired necessary updates, clarifications, or technical support by the ACS Committee on Analytical Reagents. The Committee draws on its members' broad expertise from across industry, academia, and government to review all feedback. The Committee endeavors to respond to inquiries within 48 hours, provided no further method assessment is necessary. The dynamic online-only platform ensures scientists can trust *ACS Reagent Chemicals* as the go-to source for current information on ACS-approved methods and analytical reagents.

Improve quality in pharmaceutical testing with *ACS Reagent Chemicals*

ACS Reagent Chemicals is the definitive online reference source for the latest information on ACS-approved methods and

Monograph updates and additions are clearly presented for transparency.



analytical reagents, and it is backed by regular and continual updates that ensure content is always up to date and relevant. With seamless access to this trusted online reference on methods, standards and reagent specifications, scientists working in pharmaceutical research and manufacturing will save time and reduce errors, accelerating the development and manufacture of pharmaceuticals.

"*ACS Reagent Chemicals* provides everything scientists need to ensure the chemicals used in the laboratory and manufacturing settings meet the standards required to safeguard accuracy and safety"

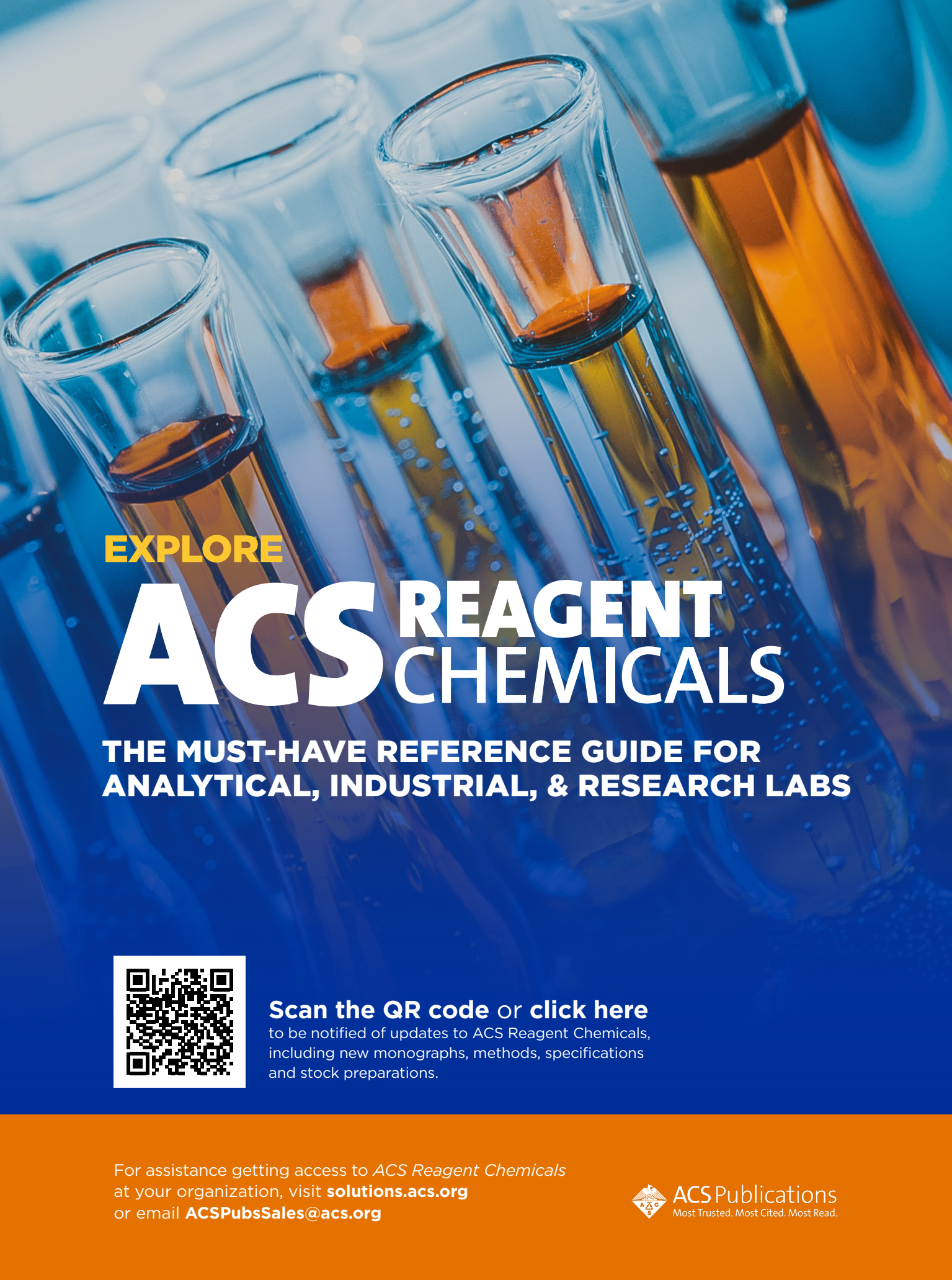
CASE STUDY

Updating protocols for heavy metal testing in pharmaceutical manufacturing

Determining heavy metals in reagent chemicals has traditionally involved sulfide precipitation-based colorimetric methods. However, this approach requires a visual comparison of sample and reference standard solutions, which is subject to analyst interpretation and can lead to inconsistent results. Method reliability is further affected by the sample matrix, and procedures are time-consuming and labor-intensive.

Inductively coupled plasma—optical emission spectroscopy (ICP–OES) and inductively coupled plasma—mass spectrometry (ICP–MS) are modern instrumental techniques that are more accurate and precise for heavy metal determination, and they overcome many of the limitations associated with colorimetric methods. The ACS Committee on Analytical Reagents worked closely with the USP–NF to update and align methods and reagent specifications for ICP-based heavy metal analysis to ensure applicability across a comprehensive range of reagent chemicals and monographs. *ACS Reagent Chemicals* is continually updating methodology and specifications using these plasma spectrochemistry techniques alongside traditional wet chemistry approaches.

Monograph specifications for magnesium nitrate hexahydrate and heavy metals analysis details.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