Cheatography

Chemicals & Reagents: Seven Most Common Grades Cheat Sheet

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Introduction

Chemicals and reagents play a critical role in the manufacturing and testing of pharmaceutical products, medical devices, biologics, cell- and tissue-based products, and many other healthcare-related solutions. Laboratories and researchers who use chemicals and reagents trust that their manufacturers have properly identified the grades of each chemical and ensured that the chemicals have met all regulatory and compliance standards for their intended use. It is imperative that everyone in the custody supply chain know and understand the different grades of chemicals and their uses, which are explained in this article.. When making a solution, the manufacturer must first decide what degree of chemical purity is needed based on the intended use. The following list describes the seven most common grades for chemicals and reagents, from highest to lowest grade/purity:

Credit: http://www.labmanager.com/business-management/2017/11/-the-seven-most-common-grades-for-chemicals-and-reagents

1. ACS Grade

ACS grade meets or exceeds purity standards set by the American Chemical Society (ACS). This grade is acceptable for food, drug, or medicinal use and can be used for ACS applications or for general procedures that require stringent quality specifications and a purity of ≥95%.

2. Reagent Grade

Reagent grade is generally equal to ACS grade (≥95%) and is acceptable for food, drug, or medicinal use and is suitable for use in many laboratory and analytical applications.

3. USP Grade

USP grade meets or exceeds requirements of the United States Pharmacopeia (USP). This grade is acceptable for food, drug, or medicinal use. It is also used for most laboratory purposes, but the USP being followed should always be reviewed prior to beginning to ensure the grade is appropriate for that methodology.

Reagents

4. NF Grade

NF grade meets or exceeds requirements of the National Formulary (NF). The USP and the NF (USP– NF) jointly publish a book of public pharmacopeial standards for chemical and biological drug substances, dosage forms, compounded preparations, excipients, medical devices, and dietary supplements. The listings here should be reviewed to determine which would be considered equivalent grades

5. Laboratory Grade

Laboratory grade is the most popular grade for use in educational applications, but its exact levels of impurities are unknown. While excellent for teaching and training, it is not pure enough to be offered for food, drug, or medicinal use of any kind.

6. Purified Grade

Purified grade, also called pure or practical grade, meets no official standard; it is not pure enough to be offered for food, drug, or medicinal use of any kind.

7. Technical Grade

Technical grade is used for commercial and industrial purposes; however, like many others, it is not pure enough to be offered for food, drug, or medicinal use of any kind

Conclusion

ACS, Reagent, and USP-NF grades are typically equivalent and interchangeable but, even so, appropriateness should always be confirmed before application. This can be done by reviewing the applicable regulatory requirements.

With seven different and inequivalent types of chemical purity grades, it is crucial to understand how they can impact products. Using a lower-purity grade than a product's intended use requires could be a costly mistake. Similarly, using a higher-purity grade when not required could result in unnecessary costs. Add in the increased regulatory scrutiny and it becomes even more important to have a complete understanding of the components that your process requires.