The United States Pharmacopeia

TWENTIETH REVISION

Official from July 1, 1980

The National Formulary

FIFTEENTH EDITION

Official from July 1, 1980

United States Pharmacopeial Convention, Inc.
12601 Twinbrook Parkway, Rockville, Md. 20852

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USP XX

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regardless of whether the values are expressed as percentages or as absolute numbers, are considered significant to the last digit shown.

Equivalence Statements in Titrimetric Procedures—The directions for titrimetric procedures conclude with a statement of the weight of the analyte that is equivalent to each ml of the standardized titrant. In such an equivalence statement, it is to be understood that the number of significant figures in the concentration of the titrant corresponds to the number of significant figures in the weight of the analyte. Blank corrections are to be made for all titrimetric assays, where appropriate (see *Titrimetry* ⟨541⟩).

The limits specified in the monographs for Pharmacopeial articles are established with a view to the use of these articles as drugs, except where the monograph indicates that the article is intended for use in in-vitro diagnostic procedures or as a medical device. The use of the molecular formula for the active ingredient(s) named in defining the required strength of a Pharmacopeial article is intended to designate the chemical entity or entities having absolute (100 percent) purity.

The quantity of each ingredient used in preparing the dosage forms shall be equivalent to not less than 100 percent of the quantity called for in the formula or of the amount declared on the label.

The tolerances and limits stated in the definitions in the monographs for Pharmacopeial articles allow for analytical error, for unavoidable variations in manufacturing and compounding, and for deterioration to an extent considered insignificant under practical conditions. Notwithstanding these tolerances, the objective of the Pharmacopeial standards for a dosage form or a finished device is to achieve a product whose strength is 100 percent of the quantity of the absolutely pure chemical entity or entities named on the label as the active ingredient(s).

The specified tolerances are based upon such attributes of quality as might be expected to characterize an article produced from suitable raw materials under recognized principles of good manufacturing practice.

The existence of compendial limits or tolerances does not constitute a basis for a claim that an official substance that more nearly approaches 100 percent purity "exceeds" the Pharmacopeial quality. Similarly, the fact that an article has been prepared to closer tolerances than those specified in the monograph does not constitute a basis for a claim that the article "exceeds" the Pharmacopeial requirements.

ALCOHOL

All statements of percentages of alcohol, such as under the heading, *Alcohol content*, refer to percentage, by volume, of C_2H_5OH at 15.56°. Where reference is made to "C_2H_5OH," the chemical entity possessing absolute (100 percent) strength is intended.

Alcohol—Where "alcohol" is called for in formulas, tests, and assays, the monograph article *Alcohol* is to be used.

Dehydrated Alcohol—Where "dehydrated alcohol" (absolute alcohol) is called for in tests and assays, the reagent *Dehydrated Alcohol* (see in the section, *Reagents, Indicators, and Solutions*) is to be used.

Denatured Alcohol—In the manufacture of Pharmacopeial preparations in which alcohol is used only as a solvent and does not remain in the finished product, alcohol specially denatured by the addition of volatile substances, in accordance with federal statutes and regulations of the Internal Revenue Service, may be substituted but the preparations so made must be identical with those prepared by the processes given in the monographs and must conform to the Pharmacopeial standards set forth.

REAGENT STANDARDS

The proper conduct of the Pharmacopeial tests and assays and the reliability of the results depend, in part, upon the quality of the reagents used in the performance of the procedures. Unless otherwise specified, reagents are to be used that conform to the standards set forth in the current edition of *Reagent Chemicals* published by the American Chemical Society. Where such ACS reagent standards are not available or where for various reasons the required purity differs, compendial specifications for reagents of acceptable quality are provided. (See *Reagents, Indicators, and Solutions.*) Listing of these reagents, including the indicators and solutions employed as reagents, in no way implies that they have therapeutic utility; furthermore, any reference to USP in their labeling shall include also the term "reagent" or "reagent grade."

REFERENCE STANDARDS

USP Reference Standards and U. S. Reference Standards for antibiotics are authentic specimens that have been verified for suitability for use as comparison standards in compendial tests and assays. (See *USP Reference Standards* ⟨11⟩.)

Where first referred to in a monograph, the name of a USP Reference Standard is generally spelled out in full. However, where a USP Reference Standard is referred to thereafter in an assay or a test in this compendium, the words "Reference Standard" are abbreviated to "RS."

Where a test or an assay calls for the use of a compendial article, rather than a USP Reference Standard, as a material standard of reference, a substance meeting all of the requirements of the monograph for that article is to be used.

UNITS OF POTENCY

For those products for which it is necessary to express the potency in terms of units by reference to a suitable working standard (usually a USP Reference Standard), the individual monographs refer to USP Units of activity. Unless otherwise indicated, USP Units are equivalent to the corresponding international units, where such exist, and to the units of activity established by the Food and Drug Administration in the case of antibiotics and biological products.

INGREDIENTS AND PROCESSES

Pharmacopeial dosage forms and finished devices are prepared from ingredients that meet the requirements

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