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General Notices and Requirements

Applying to Standards, Tests, Assays, and Other Specifications of the United States Pharmacopeia

Guide to GENERAL NOTICES AND REQUIREMENTS

In determining an appropriate period of time during which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take into account, in addition to any other relevant factors, the nature of the drug; the container in which it was packaged by the manufacturer and the expiration date thereon; the characteristics of the patient's container, if the article is repackaged for dispensing; the expected storage conditions to which the article may be exposed; and the expected length of time of the course of therapy. Unless otherwise required, the dispenser may, on taking into account the foregoing, place on the label of a multiple-unit container a suitable beyond-use date to limit the patient's use of the article. Unless otherwise specified in the individual monograph, such beyond-use date shall be not later than (a) the expiration date on the manufacturer's container, or (b) one year from the date the drug is dispensed, whichever is earlier.

VEGETABLE AND ANIMAL SUBSTANCES

The requirements for vegetable and animal substances apply to the articles as they enter commerce; however, lots of such substances intended solely for the manufacture or isolation of volatile oils, alkaloids, glycosides, or other active principles may depart from such requirements.

Statements of the distinctive microscopic structural elements in powdered substances of animal or vegetable origin may be included in the individual monograph as a means of determining identity, quality, or purity.

Foreign Matter—Vegetable and animal substances are to be free from pathogenic organisms (see *Microbiological Attributes of Nonsterile Pharmaceutical Products* ⟨1111⟩), and are to be as free as reasonably practicable from microorganisms, insects, and other animal contamination, including animal excreta. They shall show no abnormal discoloration, abnormal odor, sliminess, or other evidence of deterioration.

The amount of foreign inorganic matter in vegetable or animal substances, estimated as *Acid-insoluble ash*, shall not exceed 2 percent of the weight of the substance, unless otherwise specified in the individual monograph.

Before vegetable substances are ground or powdered, stones, dust, lumps of soil, and other foreign inorganic matter are to be removed by mechanical or other suitable means.

In commerce it is seldom possible to obtain vegetable substances that are without some adherent or admixed, innocuous, foreign matter, which usually is not detrimental. No poisonous, dangerous, or otherwise noxious foreign matter or residues may be present. Foreign matter includes any part of the plant not specified as constituting the substance.

Preservation—Vegetable or animal substances may be protected from insect infestation or microbiological contamination by means of suitable agents or processes that leave no harmful residues.

WEIGHTS AND MEASURES

The International System of Units (SI) is used in this Pharmacopeia. The SI metric and other units, and the symbols commonly employed, are as follows.

Ci	= curie	Eq	= gram-equivalent weight (equivalent)
mCi	= millicurie	mEq	= milliequivalent
μCi	= microcurie	mol	= gram-molecular weight (mole)
nCi	= nanocurie	Da	= dalton (relative molecular mass)
Mrad	= megarad	mmol	= millimole
m	= meter	Osmol	= osmole
dm	= decimeter	mOsmol	= milliosmole
cm	= centimeter	Hz	= hertz
mm	= millimeter	kHz	= kilohertz
μm	= micrometer (0.001 mm)	MHz	= megahertz
nm	= nanometer*	MeV	= million electron volts
kg	= kilogram	keV	= kilo-electron volt
g	= gram **	mV	= millivolt
mg	= milligram	psi	= pounds per square inch
μg; mcg	= microgram†	Pa	= pascal
ng	= nanogram	kPa	= kilopascal
pg	= picogram	*g*	= gravity (in centrifugation)
dL	= deciliter		
L	= liter		
mL	= milliliter; ‡		
μL	= microliter		

* Formerly the symbol mμ (for millimicron) was used.

** The gram is the unit of mass that is used to measure quantities of materials. Weight, which is a measure of the gravitational force acting on the mass of a material, is proportional to, and may differ slightly from, its mass due to the effects of factors such as gravity, temperature, latitude, and altitude. The difference between mass and weight is considered to be insignificant for compendial assays and tests, and the term "weight" is used throughout *USP* and *NF*.

† Formerly the abbreviation mcg was used in the Pharmacopeial monographs; however, the symbol μg now is more widely accepted and thus is used in this Pharmacopeia. The term "gamma," symbolized by γ, is frequently used for microgram in biochemical literature.

NOTE—The abbreviation mcg is still commonly employed to denote microgram(s) in labeling and in prescription writing. Therefore, for purposes of labeling, "mcg" may be used to denote microgram(s).

‡ One milliliter (mL) is used herein as the equivalent of 1 cubic centimeter (cc).

The International System of Units (SI) is also used in all radiopharmaceutical monographs. The symbols commonly employed are as follows.

Bq	= becquerel	GBq	= gigabecquerel
kBq	= kilobecquerel	Gy	= gray
MBq	= megabecquerel	mGy	= milligray

CONCENTRATIONS

Molal, molar, and normal solution concentrations are indicated throughout this Pharmacopeia for most chemical assay and test procedures (see also *Volumetric Solutions* in the section, *Reagents, Indicators, and Solutions*). Molality is designated by the symbol *m* preceded by a number that is the number of moles of the designated solute contained in one kilogram of

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