



U.S. Pharmacopeia
The Standard of Quality™

Dietary Supplement Lexicon

The following terms are frequently used when referring to the United States Pharmacopeia's (USP) Verification Program for dietary supplements and for dietary supplements in general.

Amino Acids—Amino acids are the basic structural units of proteins that play crucial roles in virtually all biological processes.

Botanicals—Botanicals are obtained from plant material and may include leaves, roots, bark and/or seeds. The plant material is typically processed by milling and/or extraction to produce the botanical dietary ingredient.

Contaminants—A foreign compound in a dietary supplement that may be dangerous to a person's health. Noxious contaminants generally include heavy metals, pesticide residues, pathogenic microorganisms, or aflatoxins (a toxin from naturally occurring mold).

Dietary Supplement—A dietary supplement is a product intended to supplement the diet that contains one or more dietary ingredients. Dietary supplements may be prepared from extracts or concentrates, in common dosage forms intended for ingestion, such as tablets, capsules, soft gels, liquids, or powders.

Dietary Supplement Health Education Act (DSHEA)—The Dietary Supplement Health and Education Act of 1994 (DSHEA), amended the Federal Food, Drug, and Cosmetic Act to establish standards and provisions that apply to dietary supplements. The provisions of DSHEA define dietary supplements and dietary ingredients; establish a new framework for assuring safety; outline guidelines for literature displayed where supplements are sold; provide guidelines for use of claims and nutritional support statements; require ingredient and nutrition labeling; and grant the Food and Drug Administration (FDA) the authority to establish good manufacturing practice (GMP) regulations. The law also established an Office of Dietary Supplements within the National Institutes of Health.

Good Manufacturing Practices (GMP)—DSHEA granted FDA the authority to establish GMP regulations governing the manufacturer's preparation, packaging, and storage of dietary supplements under conditions that ensure their safe and appropriate manufacture. The FDA has proposed such mandates but they are not yet official. While the law requires that dietary supplements adhere to GMPs, currently there are no uniform requirements.

Health Claims—Health claims describe a relationship between a dietary supplement and the structure and/or function of the body, a nutrient deficiency disease or related condition.

Ingredients—Dietary supplements contain both dietary ingredients and inactive ingredients. The dietary ingredient is the substance that affects the structure or function of the body. An inactive ingredient, also known as an excipient, is any component, other than the active substance(s), intentionally added to a dosage form, such as coating agents, colors, flavors, solvents, sweetening agents, and tablet binders.

Marker Compound—A compound that occurs naturally in botanical material, and aids in the identification and/or monitoring of the amount quality or stability of the botanical.

Minerals—Minerals are obtained from soluble inorganic salts and are essential to many basic tasks the body must perform. For instance, calcium and phosphorous are important in bone structure and growth; potassium and sodium for electrolyte balance; and iron for oxygen transport. Some enzymes need metal ions obtained from minerals to aid chemical reactions in the body.

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Nutraceutical—A term that combines the words “nutrition” and “pharmaceutical” to describe products that contain nutritional supplements.

Performance Standards—Performance standards, as indicated within the *United States Pharmacopeia* and *National Formulary (USP–NF)*, include disintegration and in-vitro dissolution. Disintegration is a laboratory test that indicates how fast a tablet or capsule breaks into small pieces in order for the nutritional ingredients to be dissolved. If a tablet or capsule does not break down within a certain amount of time, its nutrient ingredients may pass through the body without being absorbed. Dissolution is a laboratory test that indicates how fast a vitamin, mineral or other dietary ingredient dissolves in the intestinal tract once the tablet or capsule has disintegrated. If the tablet or capsule does not disintegrate and dissolve within an appropriate amount of time, its nutrient ingredients may not be absorbed by the body.

Shelf Life—The time period for which the product must conform to applicable specifications when stored under labeled conditions, thereby retaining its integrity.

Specifications—Includes the various tests, test methods, and acceptance criteria that define the standard of quality for a material. Specifications for many dietary ingredients and dietary supplements are provided in monographs in the *U.S. Pharmacopeia* and *National Formulary (USP–NF)*.

Structure/Function Claims—DSHEA created another category of statements, generally referred to as “structure/function” claims that may be made for dietary supplements. These statements may claim a benefit related to a nutrient deficiency disease (e.g. vitamin C and scurvy), as long as the statement also indicates how widespread such a disease is in the U.S. Structure/function claims also may describe the role of a nutrient or dietary ingredient intended to affect a structure or function of the human body; for example, “calcium builds strong bones.” In addition, the claims may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, “fiber maintains bowel regularity,” or “antioxidants maintain cell integrity.” Also, claims may describe general well being from consumption of a nutrient or dietary ingredient.

Vitamins—Vitamins are organic compounds synthesized by plants, however, some vitamins can be produced synthetically. Vitamins are either oil soluble (A, D, E, K) or water soluble (B vitamins, C, biotin, folic acid). Vitamins help maintain normal body functions such as preventing night blindness (A), acting as an antioxidant (C, E), or assisting metabolic functions (B vitamins).

Sources:

U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition Website
(<http://www.cfsan.fda.gov/~dms/ds-oview.html> and <http://www.cfsan.fda.gov/~dms/hclaims.html>)

United States Pharmacopeia and National Formulary (USP–NF)