

Standardization

Many of the herbal preparations in this book upon which clinical trials were conducted are characterized as “standardized.” This is one of the most misunderstood concepts in botanical medicine. While usually referring to the chemical process of “normalizing,” “adjusting,” or fixing a particular chemical or groups of chemicals, the concept of standardization has several meanings that warrant clarification.

There are numerous areas in which standardization occurs in the field of preparing botanical medicines and dietary supplements. First, there is nomenclature. The scientific terms (Latin binomials) are a standardized means used in botany and other sciences. In the U.S., there is also an initiative to standardize common names; the American Herbal Products Association (AHPA) has published a listing of about 1,650 herbs used in commerce in the U.S., with the “standardized common name” linked to the most recent Latin binomial; “other common names” are also noted, although they are not preferred.¹ An earlier version of this self-regulatory initiative listing approximately 550 herbs was published in 1992.² In 1997, the U.S. Food and Drug Administration (FDA) adopted *Herbs of Commerce* as an official list for common names of herb products sold in the U.S. and thus federal regulations [21 C.F.R. Sec 101.4(h)(1)-(2)] require that common names used on herbal dietary supplement products be consistent with the names standardized in the 1992 edition of *Herbs of Commerce*. It is possible that the FDA will also similarly acknowledge the later publication.

The most frequently employed meaning of standardization refers to chemistry. *Standardization* often refers to the control of a particular marker

compound or group of compounds (see discussion below). However, in a larger sense standardization can also refer to the entire process of controlling the supply chain of raw material quality and manufacturing process including, but not limited to, controlling various chemical components of the preparation.³

“Standardized” herbal products contain botanical ingredients that are chemically “standardized” to contain a consistent level of a major active constituent or marker compound or the botanical extract is defined by declaring the drug-to-extract ratio (e.g., 7–8:1), the extraction solvent (e.g., ethanol 60%), and the grade or quality of raw material that was used to make the extract (e.g., Senna Leaf USP). Chemical standardization has allowed manufacturers to offer greater consistency from batch to batch. In general, however, the term *standardization* encompasses far more than guaranteeing specific levels or ranges of certain constituents occurring in the final preparation. It involves the use of consistent, documented processes and standards throughout every step of production including adherence to Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), among others. AHPA has published its standardization guidance manual in 2001.³

Standardizing herbal products does not necessarily guarantee potency because the medicinal activity is often not due to a single chemical but to a mixture of constituents (many still unidentified), and often to the additive, synergistic (or antagonistic) activity of several components.⁴ It is inherently difficult to control all the factors that affect a plant’s chemical composition. For

example, hypericins, a group of two naphthodianthrone, have long been held to be the active constituent of St. John’s wort (*Hypericum perforatum*) (even though most commercial extracts incorrectly state that they are standardized to hypericin [singular] instead of hypericins). However, recent research suggests that the phloroglucinols hyperforin and adhyperforin, may be the prime active principles, and flavonoids such as amentoflavone have received consideration lately as possible active compounds.⁵ Other components may also be involved in biological activity.

References

1. McGuffin M, Kartesz JT, Leung AY, Tucker AO. *Herbs of Commerce* 2d ed. Silver Spring, MD: American Herbal Products Assn; 2000.
2. Foster S. *Herbs of Commerce*. Austin, TX: American Herbal Products Assn; 1992.
3. Eisner S, managing ed. *Guidance for Manufacture and Sale of Bulk Botanical Extracts*. Silver Spring, MD: American Herbal Products Assn; 2001.
4. Robbers JE, Tyler VE. *Tyler’s Herbs of Choice: The Therapeutic Use of Phytomedicinals*. New York, NY: Haworth Herbal Press; 1999.
5. Awang DVC. Standardization of herbal medicines. *Alternative Therapies in Women’s Health* 1999;July:57–9.