strength, quality, or purity, unless labeled to show all respects in which the drug differs. In addition, to avoid being deemed misbranded, drugs recognized in the USP-NF also must comply with compendial standards for packaging and labeling.

Many pharmaceutical products on the market, especially combinations of therapeutic ingredients, are not described in formulation or dosage form monographs in the official compendia. However, the individual components in these products are described in monographs in the compendia, in supplements to the compendia, or in drug applications for marketing approved by the U.S. Food and Drug Administration (FDA).

An example of a typical monograph for a drug substance appearing in the USP is shown in Figure 1.3. This monograph demonstrates the type of information that appears for organic medicinal agents.

The initial part of the monograph consists of the official title (generic or nonproprietary name) of the drug substance. This is followed by its graphic or structural formula, empirical formula, molecular weight, established chemical names, and the drug's Chemical Abstracts Service (CAS) registry number. The CAS registry number identifies each compound uniquely in the CAS computer information retrieval system. Appearing next in the monograph is a statement of chemical purity, a cautionary statement that reflects the toxic nature of the agent, packaging and storage recommendations, and chemical and physical tests, and the prescribed method of assay to substantiate the identification and purity of the chemical.

In each monograph, the standards set forth are specific to the individual therapeutic agent, pharmaceutical material, or dosage form product/preparation to ensure purity, potency, and quality.

Other Pharmacopeias

In addition to the USP and the NF, other references to drug standards, such as the *Homeopathic Pharmacopeia of the United States* (HPUS) and the *Pharmacopeia Internationalis*, or *International Pharmacopeia* (IP), provide additional guidelines for drug quality required by certain practitioners and agencies. HPUS is used by pharmacists and homeopathists as well as by law enforcement agencies that must ensure the quality of homeopathic drugs. The term homeopathy was coined by Samuel Hahnemann (1755–1843) from the Greek *homoios*, meaning similar, and *pathos*, meaning disease. In essence, the basis of homeopathy is the law of similars, or that like cures like: that is, a drug that produces symptoms of the illness in healthy persons will also be capable of treating those same symptoms and curing the disease. Embodied in the homeopathic approach are (*a*) the testing of a drug on healthy persons to find the drug's effects so that it may be employed against the same symptoms manifesting a disease in an ill person; (*b*) the use of only minute doses of drugs in therapy, employed in dilutions expressed as "1X" (a 1:10 dilution), "2X" (a 1:100 dilution), and so on; (*c*) the administration of not more than one drug at a time; and (*d*) the treatment of the entire symptom complex of the patient, not just one symptom (4–6). The HPUS is essential for pharmacists who prepare drugs to be used in the practice of homeopathy.

The IP is published by the World Health Organization (WHO) of the United Nations with the cooperation of member countries. It is intended as a recommendation to national pharmacopeial revision committees to modify their pharmacopeias according to international standards. It has no legal authority, only the respect and recognition accorded it by the participating countries in their effort to provide acceptable drug standards on an international basis. The first volume of the IP was published in 1951. It has been revised periodically since that time.

Over the years, a number of countries have published their own pharmacopeias, including the United Kingdom, France, Italy, Japan, India, Mexico, Norway, and the People's Republic of China. These pharmacopeias and the *European Pharmacopeia* (EP or Ph Eur) are used within their legal jurisdictions and by multinational pharmaceutical companies that develop and market products