

really account for the therapeutic action reported for the herbal drugs. As pointed out earlier, apart from these variable factors, other factors, such as the method of extraction and contamination with microorganisms, heavy metals, pesticides, and the like, can also interfere with the quality, safety, and efficacy of herbal drugs. For these reasons, pharmaceutical companies prefer using cultivated plants instead of wild-harvested plants, because they show smaller variation in their constituents. Furthermore, and certainly more relevant, when medicinal plants are produced by cultivation, the main secondary metabolites can be monitored, and this permits definition of the best period for harvesting.

The recent advances that occurred in the processes of purification, isolation, and structure elucidation of naturally occurring substances have made it possible to establish appropriate strategies for the analysis of quality and the process of standardization of herbal preparations, in order to maintain as much homogeneity of the plant extract as possible. Among others, thin-layer chromatography (TLC), gas chromatography (GC), high-performance liquid chromatography (HPLC), mass spectrometry (MS), infrared spectrometry (IRS), ultraviolet/visible (UV/VIS) spectrometry, and the like, used alone or in combination, can be used successfully for standardization and control of the quality of both the raw materials and the finished herbal drugs.

### 10.2.3 Efficacy and Safety

Although clinical trials with herbal drugs are feasible, few well-controlled double-blind (placebo-controlled) trials have been carried out with herbal medicines. Several factors might contribute to the explanation of such discrepancies, for example:

- Lack of standardization and quality control of the herbal drugs used in clinical trials
- Use of different dosages of herbal medicines
- Inadequate randomization in most studies, and patients not properly selected
- Numbers of patients in most trials insufficient for the attainment of statistical significance
- Difficulties in establishing appropriate placebos because of the tastes, aromas, and so on
- Wide variations in the duration of treatments using herbal medicines

However, a large number of clinical trials have been performed with some herbal drugs, including:

- *Ginkgo biloba* (used for the treatment of central nervous system and cardiovascular disorders)
- *Hypericum perforatum* (St. John's wort), used as an antidepressant
- *Panax ginseng* (ginseng) herb, used as a tonic