

Book Review

Handbook of Analytical Methods for Dietary Supplements; F Jaksch, M Wang and M Roman, American Pharmacists Association, Washington, DC, 2005.

This 215-page volume represents a unique compilation of analytical methods for 38 popular and commonly available dietary supplements, the majority of them being of botanical origin. The authors hold scientific credentials and have extensive industrial and academic experience in the isolation of bioactive compounds from natural substances by chromatographic separation.

The book is introduced with an emphasis on the need for the establishment of good manufacturing practices (GMP's) for dietary supplements in order to assure product quality, as authorized under the Dietary Supplement Health and Education Act of 1994 (DSHEA). Although not yet finalized, testing of both starting materials and final products for the content of markers or actives as stated in labeling, as well as contaminants and adulterants is recommended. The key points and challenges presented by the FDA's Proposed Rule on Dietary Supplement GMP's are highlighted.

A chapter on methods validation serves as both a brief review for the expert and an excellent summary of highlights for the novice attempting to develop reliable and valid methods for analyzing dietary supplements in single or multiple lab situations to meet a variety of regulatory requirements. Consideration, along with much good advice, is given to determining the performance of a method in five functional qualities, namely scope and applicability, selectivity, precision and reproducibility, reliability, and range of accuracy and precision. A glossary of key terms is also included.

The authors provide a variety of referenced and, in some cases, unpublished methods for each supplement included in the monograph section, with consideration given to chromatographic methods of separating and

detecting analytes and impurities. Each entry in the monographs section is well organized with a description of the supplement's botanical and common names, the parts of the plant used (where applicable) and a brief description of its use and mode of action. The reader should be aware, however, that the uses given for approximately two-thirds of the monographs would not follow the terms of the DSHEA disclaimer under "treatment, prevention, cure and diagnosis" of disease, as defined according to the Standing Rule on Disease Claims of 2000. Particularly useful is a list of chemical markers and relevant chemical structures provided in each monograph. Of major interest, of course, are the various methods of analysis (3 per supplement on average, 114 in all) with validation data, where possible. Sample chromatograms are given for 23 supplements. The average number of references per monograph is 10, plus or minus 6 citations.

The ideal audience for this volume would include anyone working in the industrial sector charged with developing and validating reliable and robust methods of analysis for dietary supplement starting materials and/or finished products. Researchers in the academic environment who are learning to isolate and identify bioactive components of natural origin would also benefit from studying this volume, or having it available as a reference. One of the most appealing aspects of the monographs presented in this work is, analyses may be accomplished for most of the methods presented using equipment and reagents commonly available to most laboratories, even those with less-than-extravagant budgets.

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