W03 Efficacy, safety and quality monographs of Iberoamerican herbal medicinal products

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The biodiversity of Iberoamerica is well known as a potential source of new drugs. The traditional use of hundreds of plants for medicinal purposes is documented. Although some of these plants are widely used and preliminary data on validation is available, international information on efficacy, safety and quality is still lacking.
After a survey on the needs for technification of the phytopharmaceutical industry in Iberoamerica, it was evident a diverse legal situation of herbal medicinal products in the region, and the lack of reliable information on the native American plants. In the framework of the Iberoamerican Network on Phytopharmaceutical Products (RIPROFITO), the first problem conducted to the publication of a compilation of specific legislations from 17 countries, and the second was tackled by organizing international teams to elaborate monographs from specific plants. These should be: Native to the American continent, proven efficacy, lack of toxicity, knowledge of its agrotechnology, matter of commerce, and should not be included in any known pharmacopoeia. The monographs are of the mixed type, including: botanical and pharmacognostical descriptions, quality control, preclinical and clinical information, including therapeutic indications.
Since 1998, 24 plants were selected as fulfilling the characteristics required. After information compilation, preliminary preparation of monographs, and a review of the potential of each plant, eight species were selected for international evaluation and validation of analytical methods: *Achyrocline satureidoides, Croton lechlerii, Maytenus illicifolia, Mimosa tenuifolia, Phlebodium aureum, Psidium guajava, Smilax* spp. (*S. chiriquensis, S. domingensis*), and *Uncaria tomentosa*. Based on this information, an international project was submitted to CYTED, waiting for its approval.

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W04 Challenges in the establishment of pharmacopeial standards for botanicals and their dosage forms

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Establishment of pharmacopeial standards for botanicals and their dosage forms marketed in the United States as dietary supplements are receiving greater emphasis in the standards –setting program at the United States Pharmacopeia since 1995. USP Council of Experts's approach thus far has been to identify those are widely used and do not present safety risk associated with their use. Acceptable articles, recognized as having fitness for use, could be defined adequately only by a full range of standards-identity, strength, quality, purity, packaging, labeling and where necessary absorption. The standards should be established with reference to the intended use. In the standardization of botanical dosage forms, the USP approach has been to establish standards first for the plant materials and their extracts. This three–pronged approach to botanicals has been time consuming and long. Challenges in the establishment of limits for pesticides, microorganisms and other closely related but unwanted contaminant species will be discussed. Further USP's approach to establishment of *in vitro* dissolution standards for oral solid botanical dosage forms will be discussed.