

Botanical derivatives in the pharmaceutical field: new perspectives

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The Plant Kingdom still represents a strategic source of Active Pharmaceutical Ingredients (API). API can be divided into two main typologies being one constituted by single components, purified products or semisynthetic products obtained from purified synthones, and the second one represented by multicomponent mixtures, such as standardised extracts.

In both cases, the whole manufacturing procedure, starting from the harvesting or cultivation of the raw material UP to the industrial preparation of the API, has to comply in Western Countries with well established guidelines. Under this aspect, a particular difficult task is related to the second typology of products, the so called ' multicomponent mixtures'.

Nowadays the preparation of rigorously standardised extracts is feasible by following the Good Agricultural Practices (GAP) and the Good Manufacturing Practices (GMP).

By using this approach and with the help of sophisticated combined analytical techniques such as HPLC, ¹H- and /or ¹³C-NMR or NIR Spectroscopy, it is possible to prepare very well characterised and reproducible extracts which can be submitted to rigorous preclinical and clinical investigations according to pharmaceutical guidelines.

Examples of these highly standardised products, such as standardised extracts obtained from *Ginkgo biloba*, *Hypericum perforatum*, *Vitis vinifera* and others, are now available.

The use of modern analytical techniques is also a good mean to discriminate among several products the phytoequivalence of these botanical derivatives.