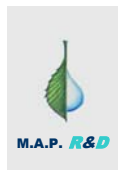


Herbal medicine and herbal nutritional supplements: Quality issues and consumer safety

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Introduction

Quality and safety are not only key issues of licensed drugs, but also of nutritional supplements, especially when these are produced from herbal starting materials.

New guidelines affecting the collection of herbal plant raw material are currently being implemented within the EU countries. EC directives 178/2002/EC and NTA Vol 2B Ed. July 2003 regulate the traceability of herbal raw materials for food and drug use, and the WHO guideline "Good Agricultural and Collection Practice" is defining the rules by which the herbal material should be collected (WHO 2003). Both guidelines, traceability and collection practice, should lead to total transparency of the whole chain of production of most herbal medicines from the plant down to the finished product.

So far the theory. In practice, most herbal raw materials are still harvested or wild crafted under completely uncontrollable conditions (Lange 2004). The risk of adulteration is not only a question of economic fraud, it is directly related to product safety. Even if a given herb can be considered as safe, the adulterants may not be harmless.

Properly applied, the WHO GACP guideline serves many good purposes:

- Unambiguous botanical identification of herbs
- Selection of cultivars tailored to the use of the final product
- Decreasing danger of adulterations, and thus of accidental toxicity
- Amelioration of the reproducibility of the clinical effects of herbal medicines
- Protection of the environment.

Herein, we want to present two examples for the improvement of the quality and safety of herbs: Saffron and *Hoodia*.

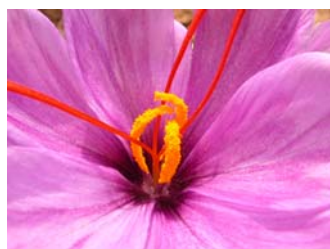
Saffron

Saffron is one of the most expensive spice and medicinal plants existing. It has been valued since ancient times, and its costs have invited deliberate adulterations since antiquity. Even today the origin and trading channels of saffron are obscured: Even though Spain has largely abandoned saffron cultivation, more saffron is labelled "Spanish saffron" than the country can possibly export. In reality, 85% of the world harvest is of Persian origin. The remainder comes mostly from the Mediterranean countries, such as France, Greece, Spain or Maroc.



Saffron consists of the stigmas of the flowers of *Crocus sativus*, a species of the family of Liliaceae.

In harvesting of saffron the three orange-red coloured filaments are hand-picked, which also justifies the price of approximately 1500 US\$ per kilogram: For one kilogram of saffron, 450.000 stigmas have to be picked, corresponding to 150.000 flowers!



This situation has invited fraudulent behaviour since antiquity. Typical adulterants are tiny red-coloured paper strips, fibres from dried meat, strips of anilin dyes, cut flowers from Calendula or other red to orange species, or even pre-extracted and re-dried stigmas. In the medieval ages, those who sold adulterated saffron were burnt at the stake. Today the counter-measures are less strict, but so are the controls.

In a recent study of the "Direction générale pour la repression des fraudes" 102 samples of commercial saffron were examined. From these 102 samples, 85 (corresponding to 83.3 %) turned out to be adulterated. This situation is likely to have consequences for the safety of application.

Toxicological consequences are also caused by the vernacular name: Some cases of toxicity could be attributed to the use of "Meadow saffron", *Colchicum autumnalis*!

Uses of saffron

Traditional medicine has attributed numerous virtues to saffron:

- Tonic, enhancement of concentration
- Antidepressant
- Gastrointestinal
- Tumour-preventive
- Aphrodisiac
- Anti-stress and immunomodulating
- Antioxidative
- Cardiovascular

All these uses were confirmed in modern research.

Project: Quality and traceability

Our project was aimed on the selection of high performance cultivars according to the needs of the producers of saffron-containing products. We were able to select cultivars optimized for various uses (e.g., more stimulant or more chemopreventive), and to perform agricultural research programs on the optimization of *Crocus* propagation and harvesting time.



We have established a GMP conform and fully traceable production of saffron with full analytical control.



Only recently, we developed a standardized liquid extract and methods for its transformation into dry extracts, including stability testing.

We are currently involved in a pharmacologic and phytochemical research program on saffron.

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Hoodia gordonii

Hoodia gordonii is a plant native to Southern Africa. Its growth characteristics remind of a cactus, it is, however, a succulent member of the family of Asclepiadaceae.

Lately, *Hoodia* has gained worldwide attention through the discovery of appetite suppressant effects. The subsequent *Hoodia* boom has rapidly led the plant to the edge of extinction through destructive wild collection and overharvesting. With the rarification came the adulterations. A huge percentage of products currently on the market is adulterated, especially in the United States, where additions of cheap *Opuntia* powder were detected in *Hoodia* products, next to unknown replacements.

The obvious solution consisted in the organisation of a controlled cultivation of *Hoodia*, which, however, is no easy task. The slow growth of the herb warrants a good planning ahead.



At the same time we have organized phytochemical and pharmacological research work on *Hoodia* and related species, and are currently working towards clinical testing with traceable and well-characterized plant material.

Goals already achieved

We have now achieved

- an implementation of a controlled cultivation of saffron and *Hoodia* with full traceability
- the development of different galenical forms of saffron extract
- the initiation of botanical and phytochemical screenings of related species and cultivars of saffron and *Hoodia*
- stability testing of saffron extract
- methods for an antibacterial treatment without the use of gasses or irradiation.

We are currently preparing:

- the pharmacological testing of saffron and *Hoodia*
- new analytical standards

References

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