Quality Control of Herbal Products
Quality Control of Herbal Products

Known X Unknown

Different strategies

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Single X Multiple

Different strategies

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What are the strategies?

Quality Control of the Complete Process

From Plant Cultivation to the Elaboration of a Medicine

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Following the Good Manufacturing Practice (GMP) Standards, perform the complete quality control taking into account:

- Pharmacognostic Methods
- Characteristic Fingerprint Chromatograms
- Defined amounts of Marker Substances
- Physicochemical Characteristics
- Microbiological Monitoring

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Pharmacognostic Methods:
Following all the tests written in official documents (Pharmacopoeias).

Botanical QC (Macro X Micro)
Chemical QC

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Available online at www.sciencedirect.com


Review

Extraction methods and chemical standardization of botanicals and herbal preparations

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Some of the common herbal products, their uses and side effects [3, 6]

<table>
<thead>
<tr>
<th>Botanicals</th>
<th>Common medicinal uses</th>
<th>Side effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aloe vera</td>
<td>Short-term treatment of occasional constipation</td>
<td>Abdominal spasms and pain may occur after even single dose. Overdose can lead to colicky abdominal spasms and pain, as well as the formation of thin, watery stools. Overdose will result in electrolyte imbalance.</td>
</tr>
<tr>
<td>Echinacea</td>
<td>To support and promote the natural powers of resistance of the body, especially in infectious conditions, such as influenza and cold in the nose and throat. External uses include promotion of wound healing and treatment of inflammatory skin conditions.</td>
<td>Chills, short-term fever reaction and nausea and vomiting may occur.</td>
</tr>
<tr>
<td>St. John’s Wort</td>
<td>For psychovegetative disturbances, depressive moods, anxiety and nervous unrest</td>
<td>Photosensitization is possible, especially in fair skin individuals.</td>
</tr>
<tr>
<td><em>Ginkgo biloba</em></td>
<td>For symptomatic treatment of disturbed performance in organic brain syndrome within the regimen of a therapeutic concepts, with the following principal symptoms: memory deficiencies, disturbances in concentration, depressive emotional conditions, dizziness, tinnitus and headache.</td>
<td>Very seldom, cases of stomach or intestinal upset, headaches or skin allergic skin reaction.</td>
</tr>
<tr>
<td>Galic</td>
<td>As a support to dietary measures at elevated levels of lipids in the blood and as a measure for age dependanct vascular changes.</td>
<td>In rare instances, there may be gastrointestinal symptoms, changes to the flora of the intestine, or allergic reaction.</td>
</tr>
<tr>
<td>Ginseng</td>
<td>A tonic for invigoration and fortification times of fatigue and debility or declining capacity for work and concentration.</td>
<td>None</td>
</tr>
<tr>
<td>Liquorice root</td>
<td>For bronchitis, peptic ulcer, chronic gastritis, rheumatism and adrenocorticoic insufficiency.</td>
<td>On prolong use and higher doses, sodium and water retention and potassium loss may occur, accompanied by hypertension, edema, hypokalemia and in rare cases, myoglobinuria.</td>
</tr>
</tbody>
</table>

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Comparison of *Radix scutellariae* extracted from different batches of medicinal plants by PLE at 120 °C with HPLC [31]

<table>
<thead>
<tr>
<th>Batch No.</th>
<th>Amount of Baicalein (mg/g)</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20.65 ± 0.20</td>
<td>18.13 ± 0.75</td>
</tr>
<tr>
<td>2</td>
<td>21.47 ± 0.28</td>
<td>17.63 ± 1.65</td>
</tr>
<tr>
<td>3</td>
<td>12.80 ± 0.16</td>
<td>11.88 ± 0.25</td>
</tr>
<tr>
<td>4</td>
<td>19.34 ± 0.16</td>
<td>17.00 ± 0.58</td>
</tr>
</tbody>
</table>

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Pharmaceutical prerequisites for a multi-target therapy

U. Kroll*, C. Cordes

Steigerwald Arzneimittelwerk GmbH, Darmstadt, Germany
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**Plant material**
- Drug or fresh plant
- Harvesting, frozen or drying/cut

**Initial control**
- EP monograph or Steigerwald monograph
- TLC, LC, spectrophotometry, essential oil

**Extraction**
- Plant extracts
  - Interim storage, Filtration

**Quality control**
- Identity TLC, Assay LC or GLC

**Mixing of all extracts**
- Interim Storage (two weeks), Sterile Filtration

**Iberogast®**

**Final control:**
- Identity (TLC-Fingerprints), purity (ethanol, microbiology)
- assay of nine components (LC, GLC)

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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iberogast® contains in 100 ml</td>
<td></td>
</tr>
<tr>
<td>Ethanolic extract (extracting agent: ethanol 50% (v/v)) of fresh plants of</td>
<td></td>
</tr>
<tr>
<td>Bitter candytuft (1: 1.5–2.5)</td>
<td>15.0 ml</td>
</tr>
<tr>
<td>Angelica root (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
<tr>
<td>Chamomile flower (1: 2–4)</td>
<td>20.0 ml</td>
</tr>
<tr>
<td>Caraway fruit (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
<tr>
<td>Milk thistle fruit (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
<tr>
<td>Balm leaf (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
<tr>
<td>Peppermint leaf (1: 2.5–3.5)</td>
<td>5.0 ml</td>
</tr>
<tr>
<td>Celandine herb (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
<tr>
<td>Liquorice root (1: 2.5–3.5)</td>
<td>10.0 ml</td>
</tr>
</tbody>
</table>

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Extract of caraway fruit

Extract of peppermint leaf

Extract of chamomile flower

Extract of angelica root

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Extract of celandine herb

Extract of milk thistle fruit

Extract of liquorice root

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Iberogast HPLC

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Review

Understanding the traditional aspect of Chinese medicine in order to achieve meaningful quality control of Chinese materia medica

Pei-Shan Xie\textsuperscript{a,b,*}, Albert Y. Leung\textsuperscript{c}

\textsuperscript{a} Zhuhai Chromap Institute of Herbal Medicine Research, Zhuhai 519085, China
\textsuperscript{b} Macau Institute for Applied Research of Medicine and Health, Macau SAR, China
\textsuperscript{c} Phyto-Technologies, Inc., Woodbine, IA 51579, USA
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HPLC Fingerprint profile of two samples of the same herb from different habitats showing that plant taxonomical equivalence does not always mean:

chemical equivalence.

Pharmacological equivalence

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TLC fluorescent images from two samples of Ginseng from different sources showing lack of standardisation for the ginsenosides profile. Sample B was not cultivated properly – probably by using extra quantities of chemical fertilizer.

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The new trend in modern phytotherapy is the use of standardized extracts. In this way, the importance of chromatographic techniques is huge.

Application of Hyphenated Techniques

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Application of Hyphenated Techniques

- HPLC-MS
- HPLC-NMR
- GC-MS
- HRGC-MS

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However, Chinese Traditional Medicine still uses Herbs, specially mixture of herbs which makes things much more complicated.

Introduction of Herbolome concept as oppose as Metabolome

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Not only the QC of the preparations per se but also the pharmacological validation of them.

Important to develop proper models for the evaluation of the proposed activities.

Holistic information should be taken into account.

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Fig. 1. Three-dimensional HPLC profile of the methanol solution of Choto-san water extract (CSE)
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Fig. 2. Three-dimensional HPLC profile of the methanol solution of *U. sinensis* water extract (USE).
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New perspectives for the success of phytotherapy by the use of omic-techniques.

Genomics - Transcriptomics - Proteomics - Metabolomics

Genetic map – Expressed mRNAs – Proteins synthetised – Secondary molecules synthetised

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Quality Control of Herbal Material and Phytopharmaceuticals with MS and NMR Based Metabolic Fingerprinting

Fig. 1 Schematic flowchart of NMR-based metabolomic analysis.
Cell Inclusions – Potato Starch

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Herbal Drugs used in the Practicals – Senna SV
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Herbal Drugs used in the Practicals – Senna Powder
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Herbal Drugs used in the Practicals - Senna
Herbal Drugs used in the Practicals - Stramonium

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Herbal Drugs used in the Practicals – Celery TS

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Herbal Drugs used in the Practicals – Peppermint TS
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Herbal Drugs used in the Practicals – Peppermint TS
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Herbal Drugs used in the Practicals – Peppermint TS
Herbal Drugs used in the Practicals – Cascara TS

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