Questions & Answers for the Identification of Herbal Materials

May 2004

Flow Chart: Identification of Herbal Materials\(^1\) (excluding extracts)

(this does not replace the need to comply with relevant statutory requirements)

What identification testing is needed for herbal materials\(^1\) prior to use in production?

Is there an applicable BP monograph?

YES

Compliance with all identification tests in the relevant BP monograph (including, where relevant, organoleptic, chemical and morphological tests), is required.

NO

Options available

Comparison against an authoritative literature source\(^2\)

Comparison against an authenticated reference specimen\(^3\)

Use the scientific literature (including current editions of other National Pharmacopoeias\(^5\)) to choose an authoritative literature source\(^2\).

The comparison must include three or more of the following:
- macroscopical characters
- microscopical characters
- chromatographic procedures
- chemical reactions.

A suitably qualified person\(^4\) must perform a comparative analysis between the consignment and the literature reference.

A suitably qualified person\(^4\) must perform a comparative analysis between the consignment and the authenticated reference specimen.

\(^1\) Whole, fragmented or cut (including chopped), plants, parts of plants (including leaves, roots, flowers, seeds, bark etc), in an unprocessed state, usually in dried form. For the purposes of this flow chart, herbal powders (herbal material that is dried and ground to a powder) are also included in this definition.

\(^2\) To be considered suitable as an authoritative literature source, the content must reflect the types and ranges of tests found in the current BP (including botanical examination and chromatographic profile) and clearly state that the identification tests in the literature source were performed on an authenticated specimen. Any chemical identity testing not performed using BP / National Pharmacopoeia must be validated for specificity (see the Identification subsection for Herbal Materials in the ARGCM Appendix – Herbal Ingredients – Quality).

\(^3\) A herb evaluated and certified by a qualified person (see footnote 4).

\(^4\) A person suitably qualified in the field of botanical authentication is necessary for the morphological examination of samples. The qualified person may or may not be independent of the manufacturer.

\(^5\) National Pharmacopoeias include European, United States (of America), Chinese, German, Indian, Japanese etc. The pharmacopoeias must be issued by or endorsed by the relevant government authority. (Note that the word ‘pharmacopoeia’ in the title of a text does not mean it is a government-endorsed text). Sponsors should contact the Office of Complementary Medicines (OCM) if they are unsure as to the suitability of a pharmacopoeia.