

Appendix II: General Quality Control Method

General quality control method includes “Description”, “Identification”, “Tests”, “Extractives” and “Assay”. A scheme for the examination of CMM is outlined in the paragraphs below.

- (1) Follow the method for sampling of CMM as set out in Appendix I for CMM examinations.
- (2) Whenever necessary, use a reference herb that complies with the requirements listed in the Appendix of the current edition of Pharmacopoeia of the Peoples’ Republic of China to verify the results of the examinations.
- (3) **“Description”** refers to the macroscopic and organoleptic characteristics including form, size, colour, texture, fracture, gross internal structures, odour/smell, taste, and other relevant information of CMM samples. Safety precautions should be taken in handling the samples.
 - (a) **“Form”** refers to the shape of dried CMM samples. In general, it is observed without preliminary treatment while wrinkled herbs, leaves or flowers can be moistened or softened and spread for the examination. For some fruits and seeds, the pericarp or seed coat can be softened and removed, if necessary before the examination of the inner characteristics.
 - (b) **“Size”** indicates the length, diameter and thickness of CMM samples, measured by a millimeter ruler. A few variations from the defined values are acceptable. For fine seeds, arrange 10 seeds closely in a row on a piece of paper with a millimeter scale, measure and calculate the average value.
 - (c) The **“colour”** of CMM samples is observed in daylight. For a description of a combination of two colours, the latter is the main colour. For example, in ‘yellowish-brown’, the main colour is brown.
 - (d) The **“surface characters”, “texture”** and **“gross internal structure”** (including fracture characteristics) of CMM samples are observed without preliminary treatment. If the striations of the fracture surface are difficult to observe, it should be re-examined with a smooth cut surface.
 - (e) The **“odour/smell”** of CMM samples can be examined by smelling directly, or after fracturing and rubbing. When necessary, the examination can be carried out after the samples are moistened with hot water.

- (f) The “**flavour**” of CMM samples can be examined by tasting a small amount of sample directly or by tasting its water extract.
- (4) “**Identification**” refers to the verification of CMM samples by means of microscopic examination of cross sections and powders, physical and chemical tests and chromatographic analysis.
- (a) “**Microscopic identification**” refers to the observation of the characteristics of structural features, cells and ergastic substances in section, powder, disintegrated tissue or surface slides of CMM samples. It is usually carried out by making slides in an appropriate way as detailed in Appendix III.
- (b) “**Physicochemical identification**” refers to the testing of the representative constituents in the samples by physical or chemical methods.
- (c) “**Chromatographic identification**” refers to the identification of samples by means of TLC, HPLC/UHPLC or GC.
- (5) “**Tests**” refers to the qualitative and quantitative detection of heavy metals, pesticide residues, mycotoxins (aflatoxins), sulphur dioxide residues, foreign matter, ash, water content and other chemical components in the CMM which should be monitored.
- (6) “**Extractives**” refers to the soluble contents of a CMM as extracted by water, ethanol or other appropriate solvents.
- (7) “**Assay**” refers to the quantitative determination of the active ingredients or markers of CMM samples.
- (8) Chemical reference substances of high purity should be used. In considering the commercial availability and to improve the stability, alternative salt, solvate or hydrate of the marker compounds can be selected as chemical reference substances. For TLC, the purity should not be less than 95%. For FP and Assay, the purity should not be less than 98%.
- (9) In case claimed value of chemical reference substance such as the certified value of the certified reference substance or the property value of the reference standard is provided by the manufacturer, the value should be included in calculations used in the monograph. For reference standards that do not bear a property value or in accompanying document, assume the reference standard is 100.0% pure for the quantitative applications.