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Part III Appendix 1
Example Format for Draft Compositional Guidelines for Complementary Medicine Substances

Name of the substance

This name must refer to the current or proposed Australian Approved Name (AAN) of the substance.

Character of the substance

Provide a brief, general description of the substance, its source and how the substance relates to its original source. It is important to include details of any processes that would distinguish the substance from similar yet different substances. For example: Compound X is a salt of citric acid and sodium hydroxide.

Table 1. Substance specific requirements

Requirement	Method(s)	Limits
Description Give a physical description of the substance including such items as physical form, colour, texture, viscosity, crystallinity (if solid) and organoleptic qualities. *eg. white to straw crystalline solid.* Describe other, more-specific tests such as: - melting point / boiling point - moisture content / loss on drying - solids content - pH of aqueous solution	Visual or otherwise Refer to pharmacopoeial methods where possible (attach details of proprietary methods)	Complies
Identification Describe qualitative or general tests that distinguish the substance from similar yet different substances For example: - limit tests - refractive index - optical rotation - ultraviolet or infra-red spectrum - colour tests for anions or cations	List methods of identification Refer to pharmacopoeial methods where possible (attach details of proprietary methods)	Complies
Assay Describe quantitative or specific tests that determine the presence and amount of a specific substance. More than one substance can be assayed.	State and if necessary describe methods of assay or provide brief details	Limits for assay(s) taking into account practical but reasonable biological, physical and chemical variation

Table 2. Incidental constituents

Requirement	Method(s)	Limits
Solvent residues Specifically address those solvents that are included in the BP Appendix VIII C. Address any additional solvents that may be used in the production, preparation, manufacturing or formulation	List methods of assay eg. BP 2003 Appendix VIII C	Total limit of solvents Solvent specific limits
Incidental metals and non-metals Specifically address the metals in the *British Pharmacopoeia* (BP) limit test for heavy metals (Appendix VII). Include any limits for specific metals or non-metals eg cadmium, arsenic, lead, mercury.	List methods of assay Eg. BP 2003 Appendix VII	Total limit of heavy metals Metal specific limits
Microbiology Consider including limits for those micro-organisms in the Therapeutic Goods Administration Laboratories microbiological guidelines for finished products. Investigate any additional micro-organisms that may be specific for the substance eg. for substances derived from chicken consider salmonella and campylobacter limits.	List methods	Total and specific microbiological loading
Pesticide residues (including agricultural and veterinary substances) Specifically address the limits stipulated in the BP2003 Appendix XI L and whether the product would comply with these limits. In addition state any additional residue limits that may be relevant.	List methods of assay eg. BP2003 Appendix XI L	eg. complies with limits in BP2003
Other organic or inorganic impurities or toxins Include other substances that may be of safety or therapeutic significance. What specific substances are assayed ? eg. dioxins, PCBs, mycotoxins. Give consideration to by-products, co-extracted substances, inactive isomers and degradation products.	List methods of assay	Total limit of impurities in substance Impurity specific limits