earlier version in ARGCM May 2006 R12/874136

Part III Appendix X

Example format for a Compositional Monograph for an ingredient composed of an extract or isolate of plant material, alga or fungus

Name of the Ingredient

This name must refer to the current or proposed ANZTPA approved name of the ingredient.

Definition of the Ingredient

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 ingredient from similar yet different substances.

Ingredient specific requirements

Requirement	Method(s)	Limits
Description Give a physical description of the substance including such items as appearance, physical form, colour and /or texture.	Visual or otherwise Refer to pharmacopoeial methods where possible (attach details of proprietary methods)	Complies
Characteristics (if applicable) Characteristic properties of the ingredient can be specified. For example: - smell - taste - feel	Organoleptic	Complies with stated property
Identification Describe semi qualitative or qualitative tests that distinguish the authentic substance. **Expected:** - Chemical fingerprinting (E.g. HPLC, GC or TLC) - ultraviolet or infra-red spectrum Guidance can be obtained at http://www.tga.gov.au/cm/idherbal.htm under Herbal extract	Methods of identification may refer to pharmacopoeial methods, methods from authoritative publications, or proprietary methods.	Complies with authenticated reference material or standard generated from an authenticated material

Requirement	Method(s)	Limits
Assay Describe quantitative or specific tests that determine the presence and amount of specific components. More than one substance can be assayed and this may also contribute to the identification.	State and if necessary describe methods of assay or provide brief details	Limits for assay(s) taking into account practical but reasonable physical and chemical variation
Residue after ignition (solid substance) Specify tests that provide a qualitative value for the content of non-volatile (inorganic) components in the substance. For example: - Ash - Sulphated ash - Acid insoluble ash	State and if necessary describe method. BP or pharmacopeial methodology	Limit(s) taking into account realistic content of non-volatile inorganic content in the substance
Loss on Drying (solid substance) Provide a limit for the allowable water content in the botanical substance	State and if necessary describe method.	Limit(s) taking into account realistic content of water in the substance
Supplemental tests (where applicable) Additional tests that ensure the quality of the Ingredient : E.g. - Alcohol content - Refractive index (essential oils) - density	State and if necessary describe method. USP pharmacopeial methodology may refer	Limits for assay(s) taking into account practical but reasonable physical and chemical variation

Table 1. 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 Appendix VII	Total limit of heavy metals Metal specific limits

Requirement	Method(s)	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.	List methods	Total and specific microbiological loading
Pesticide residues (including agricultural and veterinary substances) Specifically address the limits stipulated in the BP 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. BP Appendix XI L	eg. complies with limits in BP
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