Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for *Lepidium meyenii* (dried tuber)

Name of the ingredient

Lepidium meyenii (AHN)

Definition of the ingredient

The ingredient is the dried powdered tuber of *Lepidium meyenii* Walpers, which is found growing widely all over the Peruvian Central Andes but is now widely cultivated.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Beige/brown powder (powdered dried tuber).
Identification		
HPLC	BP (Appendix III D)	The retention time of the principal peak in the chromatogram of the test solution matches that of the solution of the authenticated reference material
Assay		
Total macamides[1]	HPLC-UV, MS/MS	Not less than 0.0016% w/w (McCollom et al. 2005)
Notes:		
1. The term 'macamides' refers specifically to N-benzylhexadecanamide, N-benzyl-(9Z)-octadecenamide, N-benzyl-(9Z, 12Z, 15Z)-octadecatrienamide, N-benzyl-(9Z, 12Z)-octadecadienamide and N-benzyloctadecanamide.		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
While ingredient manufacturers are encouraged to include limits for Incidental metals and non-metals, it is the product into which those substances are formulated that contains the ingredient, alone or in combination with other ingredients, must comply with the acceptance criteria set in the United States Pharmacopeia - National Formulary (USP-NF) general chapter '<2232> Elemental Contaminants in Dietary Supplements'. When testing is performed at the raw material stage, calculation of the total daily exposure in the finished product should be performed. This calculation is based on the quantity of each ingredient present in the product, the maximum potential contamination given the proposed limits for each raw material and the daily dose of the product.		
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues Foreign matter	BP (Appendix XI L) BP (Appendix XI D)	Complies Complies
Microbiology		
While substance manufacturers are encouraged to include limits for objectionable microorganisms, it is the product into which those substances are formulated that is subject to a legally binding set of criteria. The Therapeutic Goods Order No. 77 *'Microbiological Standards for Medicines'* mandates that any finished product that contains the ingredient, alone or in combination with other ingredients, must comply with the microbial acceptance criteria set by Clause 9 of the Order.		

Key to abbreviations:

BP = British Pharmacopoeia

HPLC-UV = High-pressure liquid chromatography with ultraviolet detection

MS/MS = Tandem mass spectrometry

USP = United States Pharmacopoeia