

Therapeutic Goods Administration

Compositional Guideline for Deer velvet antler slice

Name of the ingredient

Deer velvet antler slice (ABN)

Definition of the ingredient

The above-named substance is sliced, dried deer antler, including velvet, which has been obtained from the stags of the following deer species: red deer (*Cervus elaphus*), elk/wapiti (*Cervus canadensis*) or a crossbreed of the two. The age of antler at the time of removal is between 40–85 days from previous harvest or casting.

The stags from which the substance is obtained must have been bred and raised in New Zealand and fulfil the requirements for animals suitable for human consumption (as provided by the *Animal Products Act 1999* (New Zealand) and the regulations made under that Act). Antlers must be removed according to the National Velvetting Standards Body (NVSB) Code of Practice.¹

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria		
Description				
Appearance	Visual	Brown solid disks		
Characteristics				
Loss on drying	BP (Appendix IX D)	No more than 15% w/w		
Identification				
TLC	NZFSA OMAR 06/22: Korea: export of sliced deer velvet	Matches standard		
Assay				
Calcium	ICP or AAS	0.1-17.7% w/w		

Test	Method reference	Acceptance criteria		
Total protein as amino acids	AOAC 982.30, AOAC 988.15, AOAC 985.28	39.4–98.5% (sum of all procedures)		
Notes				
National Velvetting Standards Body (NVSB) (April 2009). Farmer Velvet Antler Removal Manual. Deer Industry New Zealand.				

Table 2.Incidental constituents

Test	Method reference	Acceptance criteria		
Residual Solvents				
Ethanol	BP (Appendix VIII L, Residual solvents), Ph Eur method 2.4.24)	No more than 0.5% w/w		
Incidental metals and non-metals				
Lead	ICP or AAS	No more than 1.0 ppm		
Arsenic	ICP or AAS	No more than 3.0 ppm		
Cadmium	ICP or AAS	No more than 0.05 ppm		
Mercury	ICP or AAS	No more than 0.1 ppm		
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)				
Lignocaine	GC-MS or HPLC-MS	No more than 0.1 ppm		
Xylazine	GC-MS or HPLC-MS	No more than 0.5 ppm		
Other organic or inorganic impurities or toxins				
Ash	Gravimetric	1.5-47.6%		
Microbiology				
While substance manufacturers are encouraged to include limits for objectionable				

Test Method reference Acceptance criteria

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: - insert or delete as required

AAS = Atomic absorption spectrometry

AOAC = Association of Official Analytical Communities

BP = British Pharmacopoeia

GC = Gas chromatography

HPLC = High-pressure liquid chromatography

ICP = Inductively coupled plasma spectrometry

MS = Mass spectrometry

NZFSA OMAR = New Zealand Food Safety Authority Overseas Market Access Requirements

Ph Eur = European Pharmacopoeia

TLC = Thin layer chromatography