Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for Larix arabinogalactan

Name of the ingredient

Larix arabinogalactan (AAN)

Definition of the ingredient

Larix arabinogalactan is a highly branched polysaccharide derived from *Larix occidentalis* (Western larch) or *Larix laricina* (Eastern larch) wood by extraction with water. The ratio of galactose and arabinose subunits occurring in the substance is approximately 6:1.

Molecular formula (nominal): $[(C_5H_8O_4)(C_6H_{10}O_5)_6]x$

Molecular mass range: 15000–60000

Cas Number: 9036–66–2

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Free flowing powder	Visual	Complies
Colour	Visual	White to light brown
Odour	Organoleptic	Pine
Characteristics		
Bulk density	USP <616>	0.27 – 0.40 g/mL
Viscosity (30%)	Ph Eur method 2.2.8	≤ 15 mPas
Loss on drying	Ph Eur method 2.2.32	≤ 6.0%
Solubility in water	BP (General notice)	Freely soluble in water
Identification		
Test 1: IR	Ph Eur method 2.2.24	IR and ^{1}H-NMR spectra comply with those of authenticated references
Test 2: ^{1}H-NMR	NMR	

Test	Method reference	Acceptance criteria
Assay		
Polysaccharides (as arabinogalactan)	HPLC (Alessa method)	≥ 85.0%

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Incidental metals and non-metals		
Total heavy metals	USP <231>; Ph Eur method 2.4.8	≤ 5 ppm
Lead	USP <730>; Ph Eur method 2.2.57	≤ 0.1 ppm
Arsenic Cadmium Mercury	USP <730>	≤ 0.4 ppm ≤ 0.25 ppm ≤ 0.3 ppm
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)	BP (Appendix XI L); Ph Eur method 2.8.13	Complies
Other organic or inorganic impurities or toxins		
Ash	AOAC 923.03	≤ 12.0%
Related substances: Fat Protein	 AOAC 922.06 / 920.85 AOAC 930.29 / 991.20	 ≤ 1.0% ≤ 0.3%
Phenolics	Not specified – an appropriately validated method should be used	≤ 2.0%

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 which 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: -

AOAC = Association of Analytical Communities

BP = British Pharmacopoeia

mPas = millipascal second

HPLC = High-pressure liquid chromatography

IR = Infrared spectrophotometry

^{1}H-NMR = Nuclear magnetic resonance spectroscopy

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia