Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for Conifer phytosterol complex

Name of the ingredient

Conifer phytosterol complex (AAN)

Definition of the ingredient

Conifer phytosterol complex is a by-product of the wood pulping process used for coniferous trees. There are four main steps in the production of conifer phytosterol complex: (i) alkaline digestion of wood chips to produce tall oil soap; (ii) a solvent extraction process to yield an organic phase; (iii) complexation-washing process of the organic extract to produce the crude sterol mixture; and, (iv) crystallisation of purified sterols from the crude sterol mixture. The bulk anhydrous substance meets the requirements shown in the following table.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to off-white crystalline, waxy powder, free from foreign matter
Odour	Organoleptic	None or slight chemical odour
Characteristics		
Residue on ignition	USP <281>	≤ 0.1%
Loss on drying	Weight loss after 2 h at 96°C under vacuum	≤ 5%
Identification		
	GC	Chemical profile of major components comply with authenticated reference material

Test	Method reference	Acceptance criteria
Assay		
Phytosterol content	GC	≥ 95%
Sitosterol	GC	36 – 79%*
Sitostanol (Stigmastanol)	GC	6 – 34%*
Campesterol	GC	4 – 25%*
Campestanol (Ergostanol)	GC	2 – 12%*
Related substances (C_{15}-C_{25} aliphatic alcohols)	GC	≤ 0.5%*
Notes * % w/w on an 'anhydrous' basis		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Solvent residues Solvents	USP <467>	< 0.5%
Incidental metals and non-metals		
Total heavy metals	US EPA method 200.15 (ICP/AES)	≤ 10 ppm
Lead	US EPA method 7000A (Graphite furnace AAS)	≤ 0.25 ppm
Arsenic	US EPA method 200.15 (ICP/AES)	≤ 5 ppm
Cadmium	US EPA method 200.15 (ICP/AES)	≤ 1 ppm
Mercury	US EPA method 245.1 (CVAA)	≤ 1 ppm
Pesticide residues and environmental contaminants:		
Pesticide residues	Ph Eur 2.8.13	Complies

Test	Method reference	Acceptance criteria
Microbiology		
Total aerobic count	Sponsor's method	≤ 10^4 CFU/g
Combined moulds & yeasts	Sponsor's method	≤ 100 CFU/g
Coliforms	Sponsor's method	Negative
E. coli	Sponsor's method	Negative
Salmonella	Sponsor's method	Negative

Microbiology	While specifications for this substance include limits for objectionable microorganisms, it is the product into which the substance is 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, must comply with the microbial acceptance criteria set by Clause 9 of the Order.

Key to abbreviations:

BP = British Pharmacopoeia

CFU = Colony forming units

CVAA = Cold vapour atomic absorption spectrometry

GC = Gas Chromatography

ICP/AES = Inductively coupled plasma-Atomic emission spectrometry

Ph Eur = European Pharmacopoeia

US EPA = United States Environmental Protection Agency

USP = United States Pharmacopoeia