Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for Sugar cane wax alcohols

Name of the ingredient

Sugar cane wax alcohols (SCWA) (AAN)

Definition of the ingredient

SCWA is the powdered crystalline extract obtained from the wax of the stem and leaves of the sugar cane plant (*Saccharum officinarum* L.) by a saponification/extraction process. The material consists primarily of high molecular weight straight-chain alcohols and aliphatic acids.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Off-white
Odour	Organoleptic	Odourless
Characteristics		
Residue on ignition	USP	< 0.85%
Loss on drying	BP	< 1.0%
Melting Point		78.0 – 82.0°C
Identification		
GC profile	GC	GC chromatogram shows peaks for the individual higher aliphatic primary alcohols specified in the assay

Test	Method reference	Acceptance criteria
Assay		
Total content of higher aliphatic primary alcohols	GC	≥ 85.0%, but < 90.0% by weight
1-tetracosanol ($C_{24}H_{49}OH$)	GC	0.0 - 0.3%
1-hexacosanol ($C_{26}H_{53}OH$)	GC	3.0 – 8.0%
1-heptacosanol ($C_{27}H_{55}OH$)	GC	0.1 – 3.0%
1-octacosanol ($C_{28}H_{57}OH$)	GC	60.0 – 70.0%
1-nonacosanol ($C_{29}H_{59}OH$)	GC	0.1 – 2.0%
1-triacontanol ($C_{30}H_{61}OH$)	GC	10.0 – 15.0%
1-dotriacontanol ($C_{32}H_{65}OH$)	GC	5.0 – 10.0%
1-tetratriacontanol ($C_{34}H_{69}OH$)	GC	0.1 – 5.0%

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Solvent residues	ICH topic Q3C*	Complies
Incidental metals and non-metals		
Total heavy metals	USP 23	< 10 ppm
Sodium content	AAS or flame photometry	< 0.01% (100 ppm)
Potassium content	AAS or flame photometry	< 0.45% (4500 ppm)
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)	BP (Vol IV, Appendix XI L, Pesticide residues; Ph Eur method 2.8.13)	Complies
Microbiology	While substance manufacturers are encouraged to 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.	

Notes
* International Conference on Harmonisation Topic Q3C- Impurities: Guidelines for residual solvents (1997)

Key to abbreviations: -

AAS = Atomic absorption spectrometry

BP = British Pharmacopoeia

GC = Gas chromatography

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia