Compositional Guideline for Tocotrienols complex – palm

Name of the ingredient

Tocotrienols complex - palm (AAN)

Definition of the ingredient

Tocotrienols complex – palm is a mixture of α-tocopherol and tocotrienols derived from the oil of the palm fruit, *Elaeis guineensis*. The manufacturing process involves either alcoholic trans-esterification followed by distillation or multiple distillation steps. The phyto-tocotrienols complex should contain 'α-tocopherol' and 'total tocotrienols'[1] in a ratio of approximately 1:3.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Amber to reddish coloured oil suspension
Characteristics		
Moisture	USP<921>	Not more than 1%
Identification		
Tocotrienols complex - palm	HPLC	Complies with the chromatogram for the authenticated reference materials
Assay		
Phyto-tocotrienols complex[2]	HPLC	20–60%
Alpha-tocopherol	HPLC	3.5–18.0%

Test	Method reference	Acceptance criteria
Alpha-tocotrienol	HPLC	4.5–17.0%
Beta-tocotrienol	HPLC	0.3–2.0%
Gamma-tocotrienol	HPLC	6.0–24.0%
Delta-tocotrienol	HPLC	1.0–9.0%
Monoglycerides/diglycerides/ triglycerides	GC	10.0–70.0%
Phytosterol complex	GC	1.0–12.0%
Palm squalene	GC	1.0–15.0%
Notes		
1. The sum of alpha-tocotrienol, beta-tocotrienol, gamma-tocotrienol and delta-tocotrienol 2. The sum of alpha-tocopherol, alpha-tocotrienol, beta-tocotrienol, gamma-tocotrienol and delta-tocotrienol		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	Ph Eur method 2.4.24	Complies
Incidental metals and non-metals		
Heavy metals (as lead)	BP (Appendix VII)	Not more than 20 ppm
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	Ph Eur method 2.8.13	Complies
Other organic or inorganic impurities or toxins		

Test	Method reference	Acceptance criteria
Peroxide value	BP (Appendix X F)	Not more than 5
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

GC = Gas chromatography

HPLC = High-pressure liquid chromatography

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopeia