



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for Zeaxanthin

Name of the ingredient

Zeaxanthin (AAN)

Definition of the ingredient

Zeaxanthin is (3R, 3'R)-dihydroxy- β -carotene.
It is obtained by chemical synthesis.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Orange-red crystalline powder
Colour and clarity of solution	0.05% w/v in chloroform	Clear, orange-red solution
Characteristics		
Loss on drying	BP (Appendix IX D); determined by drying 1.000 g in vacuo at 80°C for 18 hr	$\leq 0.2\%$
Identification		
Test A	TLC	Complies with a reference standard
Test B	HPLC	Complies with a reference standard
Assay		
Content of trans zeaxanthin*	HPLC	96.0 – 101.0%
Isomeric purity of trans zeaxanthin: (3R, 3'R)-zeaxanthin	HPLC	$\geq 98.0\%$
Notes: *Trans zeaxanthin is a mixture of (3R, 3'R)-zeaxanthin, (3S, 3'S)-zeaxanthin, and (3R, 3'S)-(3S,3'R)-mesozeaxanthin.		

Table 2. Incidental constituents

Test		Method reference	Acceptance criteria
Residual solvents			
Residual solvents		BP	Complies
Incidental metals and non-metals			
Cadmium		AA	≤ 1 ppm
Mercury		AA	≤ 1 ppm
Arsenic		AA	≤ 1 ppm
Lead		AA	≤ 5 ppm
Nickel		AA	≤ 10 ppm
Palladium		AA	≤ 10 ppm
Other organic or inorganic impurities or toxins			
<u>Related substances</u>			
Cis-isomers of zeaxanthin		HPLC	≤ 2.0%
C ₂₅ -zeanylaldehyde		HPLC	≤ 0.1%
7',8'-dihydrozeaxanthin		HPLC	≤ 0.1%
7',8'-didehydrozeaxanthin		HPLC	≤ 0.1%
Triphenylphosphine oxide		HPLC	≤ 10 ppm
Sulfated ash		BP (Appendix IX A)	≤ 0.1%
Peroxide value		BP (Appendix X F)	≤ 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 <i>'Microbiological Standards for Medicines'</i> 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:

AA = Atomic absorption

BP = British Pharmacopoeia

HPLC = high-pressure liquid chromatography

Ph Eur = European Pharmacopoeia

TLC = Thin layer chromatography