Compositional guideline for Hydroxycitrate complex

Name of the ingredient

Hydroxycitrate complex (AAN)

Definition of the ingredient

Hydroxycitrate complex is derived from the fruit rind of *Garcinia quaesita* Pierre or *Garcinia zeylanica* Roxb. It contains one or more of the three salts (calcium, potassium or sodium) of hydroxycitric acid. Varying amounts of plant material from *G. quaesita* or *G. zeylanica* may still be present in the substance depending on the manufacturing process employed, **but should not exceed 10% of the final preparation.**

This compositional guideline is applicable to each of the salts of hydroxycitric acid as defined above and also applies to mixtures of the above salts.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Cream to white colour powder
Characteristics		
Loss on drying	USP <921> Method III	Not more than 10%
Identification		
Hydroxycitric acid	TLC or HPLC	Complies with authenticated reference material
Calcium and/or Potassium and/or Sodium	AAS or ICP-MS*	Complies with authenticated reference material

Test	Method reference	Acceptance criteria
Specific optical rotation	BP Appendix V F. Determination of optical rotation and specific optical rotation	-10° to -20°
Assay		
hydroxycitric acid	HPLC	Not less than 50% by wt hydroxycitric acid
lactone of hydroxycitric acid	HPLC	Not more than 20% by wt lactone of hydroxycitric acid
citric acid	HPLC	Not more than 10% by wt citric acid
Notes		
*only tested if present		

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual solvents		
Solvent residues	BP (Vol IV, Appendix VIII L Residual solvents; Ph Eur method 2.4.24)	Complies
Incidental metals and non-metals		
Lead	BP (Vol IV, Appendix VII Limit test for heavy metals; Ph Eur method 2.4.8)	Not more than 20 ppm
Pesticide residues and environmental contaminants: (including agricultural and veterinary substances)		
Pesticide residues	BP (Vol IV, Appendix XI L, Pesticide residues; Ph Eur	Complies

Test	Method reference	Acceptance criteria
	method 2.8.13)	
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.		
Notes		
· Hydroxycitrate complex can also be derived from the fruit rind of *Garcinia gummi-gutta* (syn. *Garcinia cambogia*). The TGA notes that there is a *United States Pharmacopeia-National Formulary* monograph for 'Powdered Garcinia Hydroxycitrate Extract' that includes *G. gummi-gutta* as a source of hydroxycitrate complex. · Labels must declare the amount of hydroxycitrate complex and the equivalent amount of hydroxycitric acid that is present. In the case of sodium hydroxycitrate, the amount of sodium should be declared where the total sodium content of the formulation is greater than 120 mg of sodium per maximum recommended daily dose (refer to Therapeutic Goods Order no. 69 '*General requirements for labels for medicines – Schedules and Supplementary Notes*').		

Key to abbreviations:

AAS = Atomic absorption spectroscopy

BP = British Pharmacopoeia

HPLC = High-pressure liquid chromatography

ICP-MS = Inductively coupled plasma-mass spectrometry

Ph Eur = European Pharmacopoeia

TLC = Thin layer chromatography

USP = United States Pharmacopoeia