Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Calcium L-threonate

Name of the ingredient

Calcium L-threonate (AAN)

Definition of the ingredient

(2R,3S)-2,3,4-trihydroxybutyric acid hemicalcium salt; L-Threonic acid calcium salt

Molecular formula: $CaC_8H_{14}O_{10}$

Molecular mass: 310.27

CAS Number: 70753-61-6

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White powder
Characteristics		
Solubility	BP (General notices)	Soluble in water
Appearance of solution (5% aqueous solution)	Ph Eur method 2.2.1 and 2.2.2, Method II	Clear and colourless
pH (5% aqueous solution)	Ph Eur method 2.2.3	6.0 – 8.0
Specific optical rotation (5% aqueous solution)	Ph Eur method 2.2.7	+13.0° to +14.3°
Loss on drying	Ph Eur method 2.2.32	Not more than 1.5% w/w

Test	Method reference	Acceptance criteria
Identification		
Calcium L- threonate	Ph Eur method 2.2.24 (IR)	Complies with authenticated reference standard
Threonic acid	Ph Eur method 2.2.24 (IR)	Complies with authenticated reference standard
Calcium	Ph Eur method 2.3.1 (Qualitative reaction and tests)	Positive
Assay		
Calcium	Ph Eur method 2.5.11	12.7 - 13.2% w/w, on dried basis
Threonic acid	Capillary Electrophoresis – Indirect UV detection	85.8 – 88.4% w/w, on dried basis

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Other organic or inorganic impurities or toxins		
Residual solvents	USP ⟨467⟩	Complies
Carbonates	Ph Eur method 2.3.1 (Qualitative reaction and tests)	Negative
Ascorbic acid	HPLC	Not more than 0.1% w/w
Incidental metals and non-metals		
Heavy metals (as lead)	Ph Eur method 2.4.8	Not more than 10 ppm
Iron	Ph Eur method 2.4.8	Not more than 100 ppm

Test	Method reference	Acceptance criteria
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

HPLC = High performance liquid chromatography

IR = Infrared

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopeia

UV = Ultra violet