Australian Government
Department of Health
Therapeutic Goods Administration

Compositional Guideline: Polaprezinc

Name of the ingredient

Polaprezinc (AAN)

Definition of the ingredient

Zinc L-carnosine
Molecular formula: $C_9H_{12}N_4O_3Zn$
Molecular mass: 289.61
CAS Number: 107667-60-7

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to pale yellow crystalline powder
Characteristics		
Solubility	BP (General notices)	Soluble in dilute hydrochloric acid, dilute nitric acid and sodium hydroxide TS; slightly soluble in acetic acid; practically insoluble in water, methanol, ethanol and ether
Water	BP (Volume V, Appendix IX C.)	Not more than 5.0% w/w
Appearance of solution 1% w/w aqueous solution)	BP (Volume V, Appendix IV A.)	Clear and colourless

Test	Method reference	Acceptance criteria
Identification		
POLAPREZINC	IR spectroscopy BP (Volume V, Appendix II A.)	Complies with authenticated reference material
Specific optical rotation (2% w/w in water, 20 °C)	BP (Volume 5, Appendix V F.)	+ 8.0° to + 9.0°
L-carnosine	Qualitative test (Colorimetric method, based on *Biochem J.*,**1922**; 16(5): 640-54)	Complies
Zinc	Qualitative reaction (BP Appendix VI)	Complies
Assay		
L-carnosine	Potentiometric Titration (BP Volume V, Appendix VIII B)	76.0% - 80.0% w/w on dried basis
Zinc	Complexometric titration (BP Volume V, Appendix VIII D)	21.5% - 23.0% w/w on dried basis

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual solvents		
Residual solvents	BP (Appendix VIII L)	Complies
Incidental metals and non-metals		
While ingredient manufacturers are encouraged to include limits for Incidental metals and non-metals, it is the product into which those substances are formulated that contains the ingredient, alone or in combination with other ingredients, must comply with the acceptance criteria set in the United States Pharmacopeia - National Formulary general chapter '<2232> Elemental Contaminants in Dietary Supplements'. When testing is performed at the raw material stage, calculation of the total daily exposure in the finished product should be performed. This calculation is based on the quantity of each ingredient present in the product, the maximum potential contamination given the proposed limits for each raw material and the daily dose of the product.		

Test	Method reference	Acceptance criteria
Other organic or inorganic impurities or toxins		
Related substances	BP General Notices for 'Substances for Pharmaceutical use (Ph. Eur. monograph 2034)'	Complies
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

IR = Infrared spectrophotometry