Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Calcium pyruvate

Name of the ingredient

Calcium pyruvate (AAN)

Definition of the ingredient

IUPAC name:	Propanoic acid, 2-oxo-, calcium salt	
Molecular formula:	$Ca(C_3H_3O_3)_2$	(anhydrous)
	$Ca(C_3H_3O_3)_2 \cdot 5\ H_2O$	(pentahydrate)
Molecular mass:	214.19 g/mol	(anhydrous)
	304 g/mol	(pentahydrate)
CAS Number:	52009-14-0	(anhydrous)
	1707-07-4	(pentahydrate)

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance (Colour)	Visual	White to cream coloured powder
Characteristics		
Loss on drying - anhydrous - pentahydrate	BP (Appendix IX D)	 Not more than 0.5% w/w 29.1% - 30.1% w/w
Identification		
Calcium pyruvate	BP (Appendix II A)	Calcium pyruvate
Calcium	BP Appendix VI	Complies

Test	Method reference	Acceptance criteria
Assay		
Calcium	Complexometric titration, BP (Appendix VIII D)	18.3 – 19.1% w/w on anhydrous basis
Pyruvate	HPLC, BP (Appendix III D)	79.7 – 82.9% w/w, on anhydrous basis

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual solvents		
Residual solvent	BP (Appendix VIII L and Supplementary Chapter SC IV D)	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 (USP-NF) 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.		
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