Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Magnesium pyruvate

Name of the ingredient

Magnesium pyruvate (AAN)

Definition of the ingredient

Molecular formula: $C_6H_6O_6 \cdot Mg$ (anhydrous)

CAS Number: 18983-79-4

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to cream coloured powder
Characteristics		
Loss on drying	BP (Appendix IX D)	Not more than 5% w/w
Identification		
IR spectrum	BP (Appendix II A)	Complies with authenticated reference material/spectrum
Magnesium	BP Appendix VI	Complies
Assay		
Magnesium	BP 2015 (Appendix VIII D)	12.0-12.5% w/w
Pyruvate	HPLC	86.0-89.5% w/w

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
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-pressure liquid chromatography

IR = Infrared spectrophotometry

USP = United States Pharmacopoeia