Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for D-Ribose-L-Cysteine

Name of the ingredient

D-Ribose-L-Cysteine (AAN)

Definition of the ingredient

Molecular formula: $C_8H_{15}NO_6S$

CAS Number: 17087-36-4

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to pale yellow powder
Characteristics		
pH (0.5 g in 10 ml water)	USP <791>	3.0 – 4.0
Solubility	BP (General notices)	Freely soluble in water; practically insoluble in ethanol and acetone
Clarity of solution (0.5 g in 10 ml water)	BP (Appendix IV A)	Clear
Loss on Drying	BP (Appendix IX D)	Not more than 0.5% w/w
Specific optical rotation (1.0 g per 100 ml)	USP <781>	-125º ±6º

Test	Method reference	Acceptance criteria
Identification		
D-Ribose-L-Cysteine	IR absorbance spectrum BP (Appendix II A)	Complies with authenticated reference material/spectrum
D-Ribose-L-Cysteine	HPLC	Complies with the chromatogram for the authenticated reference material
Assay		
Assay	HPLC	98.0 to 102.0% w/w, on dried basis

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	BP (Appendix VIII L)	Meets the requirements of the BP Supplementary Chapter SC IV D
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.		
Other organic or inorganic impurities or toxins		
Related substances	HPLC	L-cysteine not more than 1.0% w/w L-cystine not more than 1.0% w/w Any other individual impurity not more than

Test	Method reference	Acceptance criteria
		0.15%w/w. Total impurities (other than L-cysteine and L-cystine) not more than 0.5%w/w
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

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia