Australian Government
Department of Health
Therapeutic Goods Administration

Compositional guideline for Ribose

Name of the ingredient

Ribose (AAN)

Synonyms: D-ribose

Definition of the ingredient

D-Ribose is a pentose, monosaccharide sugar

IUPAC name: (3R,4S,5R)-5-(hydroxymethyl)oxolane-2,3,4-triol

Molecular formula: $C_5H_{10}O_5$

Molecular mass: 150.13 g/mol

CAS Number: 50-69-1

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to slightly yellow powder
Characteristics		
Solubility	BP (General notices)	freely soluble in water
Clarity of solution	BP (Appendix IV A)	clear
Loss on Drying	BP (Appendix IX D)	Not more than 0.5% w/w
Identification		
Infra-red spectrum	BP (Appendix II A)	Complies with authenticated reference material/spectrum

Test	Method reference	Acceptance criteria
Specific optical rotation (1 g/mL in water, 20 °C, 10 cm path length)	BP (Appendix V F)	-19.0 ° to -21.0 °
Assay		
Assay	GC post column derivatisation	98% to 102% w/w, on dried basis
Sulphated Ash	BP (Appendix XI J)	0.2% w/w

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual solvents		
Residual solvents	BP 2015 (Appendix VIII L)	Meets the requirements of the BP
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	BP General Notices for 'Substances for Pharmaceutical use'	Complies

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

GC = Gas chromatography

IR = Infrared spectrophotometry