



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional guideline for Hesperidin

Name of the ingredient

Hesperidin (AAN)

Definition of the ingredient

(S)-7-[[6-O-(6-Deoxy- α -L-mannopyranosyl)- β -D-glucopyranosyl]oxy]-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-2,3-dihydro-4H-1-benzopyran-4-one

Molecular formula: C₂₈H₃₄O₁₅

Molecular mass: 610.56

CAS Number: 520-26-3

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Pale yellow – yellow green crystalline, hygroscopic powder
Characteristics		
Solubility	BP (General notice)	Slightly soluble in water and methanol, soluble in solutions of alkali hydroxides
Melting point	BP (Appendix V A)	258–262°C
Optical rotation	BP (Appendix V F)	-74° to -78° (in pyridine), calculated with reference to the dried substance
Water (determined on)	BP (Appendix IX C,	Not more than 5.0% w/w

Test	Method reference	Acceptance criteria
0.100g)	method 1)	
Identification		
IR	BP (Appendix II A)	Spectrum matches that of the authenticated reference material
Assay		
Hesperidin	HPLC	98.0 – 102.0% (anhydrous basis)

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Residual solvents	BP (Appendix VIII L)	Complies
Incidental metals and non-metals		
Heavy metals (as lead)	BP (Appendix VII)	Not more than 10 ppm
Other organic or inorganic impurities or toxins		
Sulfated ash	BP (Appendix IX A)	Not more than 0.4%
Related substances	HPLC	Not more than 1.0% for oxedrine or any other individual impurity, and not more than 2.0% for total impurities
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