



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		
<p>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 <i>'Microbiological Standards for Medicines'</i> 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.</p>		

Key to abbreviations: -

BP = British Pharmacopoeia

HPLC = High-pressure liquid chromatography

IR = Infrared spectrophotometry