Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Compositional guideline for Quercetin dihydrate

Name of the ingredient

Quercetin dihydrate (AAN)

Definition of the ingredient

2-(3,4-dihydroxyphenyl)-3,5,7-trihydroxy-4*H*-1-benzopyran-4-one

Molecular formula: $C_{15}H_{10}O_7.2H_2O$

Molecular mass: 338.2 (302.24 for anhydrous)

CAS Number: 6151-25-3

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Yellow crystals or yellowish powder
Characteristics		
Solubility	BP (General notice)	Practically insoluble in water, slightly soluble in absolute alcohol, soluble in aqueous solutions of alkali
Water (determined on 0.100g)	BP (Appendix IX C, method 1)	9.0%–12.0%
Identification		
Perform either the IR test or both TLC and HPLC tests as below		
IR	BP (Appendix II A)	Spectrum matches that of the authenticated reference material

Test	Method reference	Acceptance criteria
TLC	BP (As prescribed in the monograph for Ginkgo Leaf); Ph Eur monograph 1828	The principal spot in the chromatogram obtained with the test solution corresponds to that obtained with the solution of the reference material Note: This test must be done in conjunction with HPLC
HPLC	BP (Appendix III D)	The retention time of the principal peak in the chromatogram of the test solution matches that of the solution of the authenticated reference material
Assay		
Quercetin	HPLC	98.0–102.0% w/w (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 0.2%
Related substances	HPLC	Not more than 1.0% for any individual impurity, 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

TLC = Thin layer chromatography