Australian Government
Department of Health
Therapeutic Goods Administration

Compositional Guideline for Resveratrol

Name of the ingredient

Resveratrol

Definition of the ingredient

Resveratrol is manufactured by fermentation with genetically modified baker's yeast (*S. cerevisiae*), followed by extensive purification.

Molecular formula:

$C_{14}H_{12}O_3$

CAS Number:

501-36-0

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Off-white to slightly yellow powder	Visual	Must comply
Characteristics		
Water content	Ph Eur 2.5.12	NMT 2 %
Identification		
IR	USP <197K>	IR spectrum must conform with reference standard
HPLC	USP <197K>	IR spectrum must conform with reference standard

Test	Method reference	Acceptance criteria
Assay		
HPLC	Retention time must conform	98 % - 101.0 % (on an anhydrous and solvent-free basis)

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Ethanol	Ph Eur 2.4.24	NMT 5000 ppm
Incidental metals and non-metals		
Heavy metals (total)	Ph Eur 2.4.8	NMT 10 ppm
Lead	Ph Eur 2.2.58 (ICP-MS)	NMT 1 ppm
Cadmium	Ph Eur 2.2.58 (ICP-MS)	NMT 1 ppm
Arsenic	Ph Eur 2.2.58 (ICP-MS)	NMT 1.5 ppm
Mercury	Ph Eur 2.2.58 (ICP-MS)	NMT 0.1 ppm
Other organic or inorganic impurities or toxins		
Dihydroresveratrol	HPLC	NMT 0.5 %
Pinosylvin	HPLC	NMT 0.5 %
Coumaric acid	HPLC	NMT 0.5 %
Cinnamic acid	HPLC	NMT 0.5 %
Phloretic acid	HPLC	NMT 0.1 %
cis-Resveratrol	HPLC	NMT 0.1 %

Test	Method reference	Acceptance criteria
Any single unknown impurity	HPLC	NMT 0.1 %
Total unknown impurities	HPLC	NMT 0.5 %
Microbiology		
Total aerobic plate count (TAMC)	Ph Eur 2.6.12	NMT 1000 CFU/g
Total yeast and mould (TYMC)	Ph Eur 2.6.12	NMT 100 CFU/g
Notes		
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. 100 *'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 11 of the Order.		

Key to abbreviations:

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia

CFU = Colony forming units

NMT = Not more than

HPLC = High-pressure liquid chromatography

IR = Infrared spectrophotometry

ICP-MS = Inductively coupled plasma mass spectrometry