Compositional Guideline for Ubiquinol-10

Name of the ingredient

Ubiquinol-10 (AAN)

Definition of the ingredient

Ubiquinol-10 is 2-[(all-*E*)-3,7,11,15,19,23,27,31,35,39-decamethyltetraconta-2,6,10,14,18,22,26,30,34,38-decaenyl]-1,4-dihydroxy-5,6-dimethoxy-3-methylbenzene. Ubiquinol-10 is a single stereoisomer having the (*E*)-configuration (trans) at each of the double bonds.

Ubiquinol-10 is made via a yeast fermentation process. The substance is anhydrous with no water of hydration.

Molecular formula: $C_{59}H_{92}O_4$

Molecular mass: 865.37

CAS Number: 992-78-9

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	White to pale yellow solid
Characteristics		
Melting point	BP (Appendix V A)	49.5°C
Solubility	BP (general notice)	Very soluble in toluene and ethyl acetate, freely soluble in hexane, sparingly soluble in ethanol, very slightly soluble in methanol, practically insoluble in water

Test	Method reference	Acceptance criteria
Stability		Readily oxidised in air (converts to ubidecarenone); adversely affected by light and moisture
Identification		
Ubiquinol-10	IR absorbance spectrum with potassium bromide (BP, Appendix II A)	Complies with standard
Assay		
Ubiquinol-10	HPLC	96.0–102.0%

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Residual Solvents		
Ethanol	BP (Appendix VIII L)	Not more than 100 ppm
Incidental metals and non-metals		
Heavy metals	Ph Eur method 2.4.8	Not more than 20 ppm
Other organic or inorganic impurities or toxins		
Ubidecarenone	HPLC	Not more than 2.0%
Water	Karl Fischer	Not more than 0.3%
Residue on ignition	USP <281>	Not more than 0.2%
Total other impurities[1]	HPLC	Not more than 1.0%
Other individual impurity	HPLC	Not more than 0.5%

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.
Notes
1. Typically comprise the reduce form of Coenzyme Q9 (that is, the reduced form of impurity D as described in Ph Eur for Ubidecarenone), and to a lesser extent the cis-isomer of Ubiquinol-10.

Key to abbreviations: -

BP = British Pharmacopoeia

HPLC = High-pressure liquid chromatography

IR = Infrared spectrophotometry

Ph Eur = European Pharmacopoeia

USP = United States Pharmacopoeia