

## Ubidecarenone

C<sub>59</sub>H<sub>90</sub>O<sub>4</sub> 863.37

2,5-Cyclohexadiene-1,4-dione,

2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl.

2-[(all-E)-3,7,11,15,19,23,27,31,35,39-Decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl-p-benzoquinone [303-98-0].

Ubidecarenone (Coenzyme Q10) contains not less than 98.0 percent and not more than 101.0 percent of C<sub>59</sub>H<sub>90</sub>O<sub>4</sub>, calculated on the anhydrous basis.

Packaging and storage— Preserve in well-closed, light-resistant containers.

### Identification—

A: [Infrared Absorption](#) [197K](#) .

B: Dissolve about 50 mg of Ubidecarenone in 1 mL of ethyl ether, and add 10 mL of dehydrated alcohol. To 2 mL of this solution, add 3 mL of dehydrated alcohol and 2 mL of dimethyl malonate, add 1 mL of potassium hydroxide solution (1 in 5) dropwise, and mix: a blue color appears.

[Water, Method I](#) [921](#) : not more than 0.2%.

[Residue on ignition](#) [281](#) : not more than 0.1%.

[Heavy metals, Method II](#) [231](#) : 0.002%.

### Chromatographic purity—

Test 1: coenzymes Q7, Q8, Q9, Q11 and related impurities—

**Mobile phase**— Proceed as directed in the Assay.

**Chromatographic system**— Proceed as directed in the Assay. To evaluate the system suitability requirements, use the System suitability preparation, as prepared in the Assay.

Standard solution and Test solution— Use the Standard preparation and the Assay preparation, as prepared in the Assay.

**Procedure**— Proceed as directed in the Assay, measure all the peak areas, and calculate the percentage of impurities in the portion of Ubidecarenone taken by the formula:

$$100(r_i / r_s)$$

in which  $r_i$  is the sum of all peak responses, other than that for ubidecarenone, obtained from the Test solution; and  $r_s$  is the sum of all peak responses. Not more than 1.0% is found.

Test 2: ubidecarenone (2Z)-isomer and related impurities—

Mobile phase— Prepare a filtered and degassed mixture of n-hexane and ethyl acetate (97:3).

System suitability solution— Prepare a solution of [USP Ubidecarenone for System Suitability RS](#) in n-hexane having a concentration of about 1 mg per mL.

Test solution— Prepare a solution of Ubidecarenone in n-hexane having a concentration of about 1 mg per mL.

**Chromatographic system**— The liquid chromatograph is equipped with a 275-nm detector and a 4.6-mm × 25-cm column that contains packing L3. The flow rate is about 2.0 mL per minute.

Chromatograph the System suitability solution, and record the peak responses as directed for

Procedure: the relative retention times are about 0.85 for ubidecarenone (2Z)-isomer and 1.0 for ubidecarenone; and the resolution,  $R$ , between ubidecarenone (2Z)-isomer and ubidecarenone is not less than 1.5.

**Procedure**— Inject a volume of the Test solution (about 20  $\mu$ L) into the chromatograph, record the chromatogram, and measure all the peak responses. Calculate the percentage of impurities in the portion of Ubidecarenone taken by the formula:

$$100(r_i / r_s)$$

in which  $r_i$  is the sum of all peak responses, other than that for ubidecarenone; and  $r_s$  is the sum of all peak responses. Not more than 1.0% is found.

Calculate the percentage of total impurities as the sum of the percentages obtained by Test 1 and

Test 2: not more than 1.5% of total impurities is found.

**Assay**—

Mobile phase— Prepare a filtered and degassed mixture of methanol and dehydrated alcohol (13:7). Make adjustments if necessary.

System suitability preparation— Dissolve accurately weighed quantities of [USP Ubidecarenone RS](#) and [USP Ubidecarenone Related Compound A RS](#) in dehydrated alcohol, heating at about 50 for 2 minutes if necessary, to obtain a solution having known concentrations of about 0.5 mg of each per mL.

Standard preparation— Dissolve an accurately weighed quantity of [USP Ubidecarenone RS](#) in dehydrated alcohol, heating at about 50°C or 2 minutes if necessary, to obtain a solution having a known concentration of about 1.0 mg per mL.

Assay preparation— Transfer about 50 mg of Ubidecarenone, accurately weighed, to a 50-mL volumetric flask, dissolve in dehydrated alcohol, heating at about 50°C or 2 minutes if necessary, cool, dilute with dehydrated alcohol to volume, and mix.

**Chromatographic system**— The liquid chromatograph is equipped with a 275-nm detector and a 5-mm × 15-cm column that contains packing L1, and is maintained at a temperature of 35 . The flow rate is adjusted to obtain a retention time of about 11 minutes. Chromatograph the System suitability preparation, and record the peak responses as directed for Procedure: the relative retention times are about 0.75 for ubidecarenone related compound A and 1.0 for ubidecarenone; the resolution, R, between ubidecarenone related compound A and ubidecarenone is not less than 4; and the relative standard deviation for replicate injections is not more than 0.8%.

Procedure— Separately inject equal volumes (about 5 µL) of the Standard preparation and the Assay preparation into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of C<sub>59</sub>H<sub>90</sub>O<sub>4</sub> in the portion of Ubidecarenone taken by the formula:

$$50C(r_U / r_S)$$

in which C is the concentration, in mg per mL, of [USP Ubidecarenone RS](#) in the Standard preparation; and r<sub>U</sub> and r<sub>S</sub> are the peak responses obtained from the Assay preparation and the Standard preparation, respectively.