## **ROCHEM** INTERNATIONAL, INC.

45 Rasons Court, Hauppauge, NY 11788 Tel: (631) 738-1188 Toll Free: 1-877-6-Rochem Fax: (631) 738-1199 Web: <u>www.rochemintl.com</u>; E-Mail: Sales@rochemintl.com

#### PRODUCT SPECIFICATION

### **COENZYME Q10**

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### **USP/EP**

Product Name:	Coenzyme Q10 (Ubiquinone)
Batch Number:	XXXXXXXXXXXX
Batch Size:	XXXXXX
Manufactured Date:	XXXXXXX
Expiry/Expiration/Retest Date:	XXXXXXX
CAS No.:	303-98-0
ITEMS	SPECIFICATIONS
Appearance:	Yellow to orange crystalline powder
Odor:	Characteristic
Solubility:	Soluble in ether, slightly in dehydrate alcohol; practically insoluble in water.
Melting Point:	48°C ~ 52°C
Identification:	
A: IR	A: Sample spectrum consistent with the spectrum for USP Reference Standard
B: Color reaction: Positive	B: A blue color appears
C: HPLC	C: The retention time corresponds to the reference.
Particle Size:	100% Pass 80 Mesh
	90% Pass 100 Mesh
Water:	NMT 0.2%
Residue on Ignition:	NMT 0.1%
Heavy Metals:	NMT 10ppm
Arsenic:	NMT 1ppm
Cadmium:	NMT 1ppm
Lead:	NMT 0.5ppm
Mercury:	NMT 0.1ppm
Chromatographic Purity:	
Coenzyme Q7, Q8, Q9, Q11 and	NMT 1.0%
related impurities:	
Ubiquinone (2Z)-isomer and related	NMT 1.0%
impurities:	
Total impurities:	Total 1 & 2: NMT 1.5%
Related Substances:	
Any Impurity:	NMT 0.5%
Total Impurities:	NMT 1.0%
Impurity F:	NMT 0.5%
<b>Residual Organic Solvents:</b>	ND 477 5000
Ethanol:	NMT 5000ppm
Isopropyl Ether:	NMT 300ppm
n-Hexane:	NMT 290ppm
Microbial Limits	
Total Plate Count:	$\leq 1000 \text{ cfu/g}$
Yeast & Mold:	$\leq 100 \text{ cfu/g}$
Coliforms:	≤10 cfu/g
E.Coli:	Negative
S. Aureus	Negative

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Salmonella:	Negative
Bulk Density:	0.25 ~ 0.45 g/ml
Assay (HPLC): Anhydrous basis	98.0% ~ 101.0%
Assay (UV):	97.0% ~ 103.0%
Exp Date:	2 Years

Rev.01

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