

Points of Attention about CoQ10 Quality and Presenting Country-of Origin

Petroeuroasia Co., Ltd.

I. Comparison of Quality

CoQ10 manufacturers adopting fermentation method are now four companies in the world; 1) Kaneka Corporation (Japan), 2) Company A, 3) Company B, and 4) Company C. Company A, B, C are all of China.

We, Petroeuroasia Co., Ltd. compared the quality of each Q10 of the four companies.

1. COA

All the four CoQ10 complied with JP, USP and EP in terms of their COA.

2. Profile (HPLC)

Several HPLC peak contents of Chinese Company A, B, C's Q10 deviated threshold of structural determination (0.1%), that of safety (0.15%) ICH Guideline established (PAB Notification no. 1216001 and PFSB/ELD Notification no.1204001).

KanekaQ10, on the other hand, has all peak contents structurally determined. CoQ9 over threshold was formerly developed as pharmaceuticals and its safety is ensured.

It is unclear that all the four companies adopt the same manufacturing method. Therefore it is necessary to identify and analyze each product again not just comparing to each product's profile (HPLC).

3. Dosage as pharmaceutical

CoQ10 is still sold as pharmaceuticals 'ubidecarenone' of which dosage and administration are set as "give orally in a dose of 10mg three times a day after each meal." They are the specification based on the ceiling "30mg/day."

Upper limit of Q10 dosage has not been established yet since it started to be taken as food supplement. But all safety materials that Food Safety Commission quote are based on the results of Q10 made in Japan.

4. Dosage as food supplement

Q10 as food supplement is often taken more than several or ten times as much as that of Q10 as pharmaceutical, so it requires stricter specification than JP which doctors control. Q10 is also used in cosmetics directly touching bare skin. It is essential to carefully considered when using Q10 which has unknown or unidentified impurities.

II. Country-of-Origin

Provided by Dep. of Food Safety (Standard and Evaluation Division) Notification no. 061001, Q10 has a license to be used as essential food component unless its efficacy is claimed and considered as pharmaceutical. Chinese Q10 is only imported as 'food.'

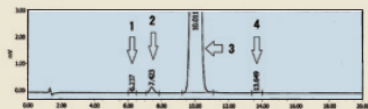
Some Japanese companies and distributors seem to misunderstand that they are allowed to write 'Japanese Q10' on their product if they repack Chinese Q10 within Japan. Consumer Affairs Agency defines country-of origin as 'country where the product content was substantially changed in terms of 'unjust country-of-origin labeling (JFTC Notice no.34, 1973)' complying with Act against Unjustifiable Premiums and Misleading Representations. Manufacturers are required to recognize and present country-of-origin of their product as "China," if manufacturing process occurs mainly in China.

We, Petroeuroasia Co., Ltd. asked directly of Consumer Affairs Agency if manufacturers can represent "Japanese Q10" on their product if they import Chinese Q10 (purity: over 98%) from China and purify it within Japan. They answered as follows;

1. The country-of-origin of Chinese Q10 is still "China", because the material quality does not change even if it is purified or repacked. Food manufacturing process cannot be divided into sections to be permitted.
2. Manufacturers are not obliged to present country-of-origin on their product, but they should tell their consumers that they are using "Chinese Q10" in their product. Finished product itself is recognized as "Made in Japan", but still the country-of-origin of Q10 itself should be informed "China".

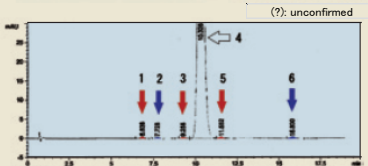
(1) HPLC Peak table 1 (Kaneka Corporation)

Peak no	Area ratio(%)	Compound	Structural verification (Yes or No)
1	0.02	Ubiquinol	Yes
2	0.22	CoQ9	Yes
3	99.74	CoQ10	
4	0.03	CoQ11	Yes



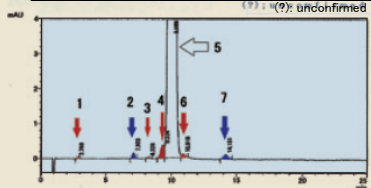
(2) HPLC Peak table 2 (Company A)

Peak no	Area ratio(%)	Compound	Structural verification (Yes or No)
1	0.15	unknown	No
2	0.06	CoQ9(?)	No
3	0.06	unknown	No
4	99.44	CoQ10	
5	0.15	unknown	No
6	0.14	CoQ11(?)	No



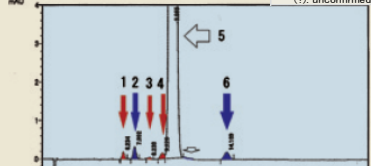
(3) HPLC Peak table 4 (Company B)

Peak no	Area ratio(%)	Compound	Structural verification (Yes or No)
1	0.01	unknown	No
2	0.09	CoQ9(?)	No
3	0.02	unknown	No
4	0.26	unknown	No
5	99.44	CoQ10	
6	0.07	unknown	No
7	0.12	CoQ11(?)	No



(4) HPLC Peak table 4 (Company C)

Peak no	Area ratio(%)	Compound	Structural verification (Yes or No)
1	0.08	unknown	No
2	0.17	CoQ9(?)	No
3	0.02	unknown	No
4	0.10	unknown	No
5	99.45	CoQ10	
6	0.17	CoQ11(?)	No



III. Conclusion

Only Kaneka Q10 ensures high and stable quality ICH Guideline set compared to all other Q10 on shelves now. We found that Chinese Q10 contains residual solvent other than ethanol, unknown and unidentified impurities to be detected.

Q10 has been distributed in Japan and other countries for over 10 years, but health hazards having cause-and-effect relationship with Q10 have never been reported (Dep. of Food Safety Notification no. 0823001). Japan Health Food & Nutrition Food Association also resulted "barely no problems" in terms of health hazard of Q10 according to their post-marketing surveillance.

Recently water-soluble Q10 which has over ten times as much absorptivity as normal Q10 has now the main share of Q10 market. Water-soluble Q10 has higher possibility of absorbing impurities as same as normal Q10, so it is vital to use it under careful consideration in terms of health hazard no matter it is made in Japan or in other countries. It is essential to select raw materials thoroughly complying with laws for food labeling taking in consumer's perspective.