

## Testing method for L-Carnitine Fumarate

(CAS 90471-79-7)

1. Specific rotation:

5g of L-Carnitine fumarate, accurately weighted, dissolved in 100ml volumetric flask, make up 5% water solution, calculate the specific rotation, then calculate according to the calculating forma.

$$[ \alpha ]^{20} = \frac{A}{c \times l}$$

a: data on the meter

c: v/w

l: rotation tube length

2. Residue on ignition:

Take 1g of L-Carnitine fumarate to a crucible of have been ignition to constant weight, Ignite slowly to carbonization, cool to house temperature, add H<sub>2</sub>SO<sub>4</sub> 0.5-1ml, for humidification, heat with low temperature until the total evaporation of H<sub>2</sub>SO<sub>4</sub>, then Ignite at 700-800°C til total carbonization. Move into desiccator, cool to room Temperature. Finally ignite at 700-800°C to constant temperature. Residue on ignition should be less than 0.5%.

3. Heavy metal:

1g of L-Carnitine fumarate, two colorimetric tubes.

Tube A: Add 1ml of standard solution of lead, mix with 2ml of acetate (PH 3.5), dilute into 25ml with water.

Tube B: Add 25ml of test solution, then add 2ml of thioacetamide into each of two Tube, wave the tube, lay up for 2 minutes, put two tubes on white paper, compare the Solution colour. Colour of tube B should not be deeper than colour of Tube A. Heavy metal should be less than 10ppm.

4. Arsenic

Prepare the standard arsenic speckle according to the Gutzeit method. Take 1g of sample, make the arsenic speckle. The colour should not be deeper than the standard arsenic speckle.

5. Solubility: make up 5% water solution. it is clarification.

6. PH: make up water solution (C=1% H<sub>2</sub>O) , PH should be 3.0-4.0

7. water content:

Take L-Carnitine fumarate sample 2.0000g, properly weighted, dry at 105°C for 3 hours, lost weight should be less than 1.0%.

$$\text{water content} = \frac{\Delta w}{w_l} \times 100\%$$

△w: weight lose

Wl: sample weight

8. Assay:

1) L-carnitine content: 58.2±2.0%

Solution preparation: glacial acetic acid 750ml (based in 5.22ml anhydride per 1g water), add perchloride HClO<sub>4</sub> (70%~72%) 8.5ml, shake up, slowly add acetic acid anhydride at room temperature to the volume 1000ml.. Shake up and keep 24 hours. If the sample was not acylized, tester has to determine the water content of the solution first, and then adjust the water content of the solution to 0.01%~0.02% by adding water and acetic acid anhydride.

Calibration: take standard potassium acid phthalate which was dried and weighted under 105 °C, dissolve by adding glacial acetic acid 20ml, add one drop of crystal violet indicating liquid. Slowly add the sample liquid till the mixture turn blue. Blank calibration is applied meanwhile. 1 ml HClO<sub>4</sub> volumetric solution (0.1mol/L) is equal 20.42mg potassium acid phthalate. The content can be calculated by the usage of sample liquid and the potassium acid phthalate.

Titration: take 0.4g sample, add 50ml glacial acetic acid and 3ml formic acid, and add one drop of crystal violet indicating liquid. Add the prepared HClO<sub>4</sub> for titration. Blank calibration is applied meanwhile.

$$\text{L-carnitine content \%} = \frac{v \times c \times M}{W} \times 100\%$$

V: consumed HClO<sub>4</sub> volumn, after the calibration

M: the molecular weight of L-carnitine 161.16

W: sample weight

C: the concentration of HClO<sub>4</sub>

2) fumarate content 41.5±2.0%

0.5g of L-Carnitine fumarate accurately weighted. Add 3ml of formic acid, add 50ml of glacial acetic acid, make it dissolved, and add 2 drops phenolphthalein as titrate. Add 0.1mol/L NaOH to a pink red as terminal.

$$\text{content} = \frac{v \times c_{NaOH} \times 161.16}{2W} \times 100\%$$

v: NaOH volume

c: NaOH concentration