STUDY OF THE ADDITION OF L-CARNITINE IN PEDIATRIC PARENTERAL NUTRITION BINARY MIXTURES

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Introduction :

The parenteral nutrition preparation unit at the Marne-la-Vallee site is located within a cleanroom ISO 8. Using an IMF® automaton placed in an isolator ISO 5, we produce binary mixture individualized and manual lipid syringes. Theses preparations are destined for premature infants from the neonatal resuscitation department at the Meaux site.
L-Carnitine is an endogenous component essential for the transport of fatty acids within mitochondria. Its parenteral use is recommended by ASPEN[1] in newborns. Within the neonatal resuscitation unit, state registered nurses prepare the syringe corresponding to the prescribed dose and then administers it in Y of the binary mixture. This step can increase the risk of error and contamination. This is why we wanted to study the influence of the addition of L-carnitine in binary mixtures produced by the parenteral nutrition preparation unit. This would reduce the number of infusion lines, secure the preparation, reduce septic risk and free up nursing time.

Objective :

Compare the stability of binary parenteral nutrition mixtures in the presence and absence of L-Carnitine.

Materials and methods :

✔ From the analysis of binary parenteral mixture's prescriptions for 6 months, we were able to identify 3 types of formulas according to the risk of low, moderate and high phosphocalcic precipitation.
✔ 2 sets of 18 binary pockets, 9 without and 9 with L-carnitine (0.05mg/mL) were produced, or 6 pockets per formula and series.
✔ Analyses implemented at J0, J2, J4, J7 and J8:
- Biochemical determination by potentiometry, sodium [Na+], potassium [K+], calcium colorimetry [Ca2+], magnesium [Mg2+] then glucose by enzymatic method thanks to biochemistry laboratory.
- Measurement of osmolality.
- BactAlert® sterility analysis and pH measurement.
- Control of the presence of particles:
- visible: visual inspection
- Invisible: UV-visible absorbance spectroscopy and study of dynamic light scatter.

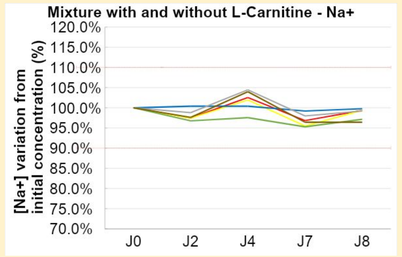
✔ Conservation between 2 and 8°C for 7 days and then 24h at room temperature.

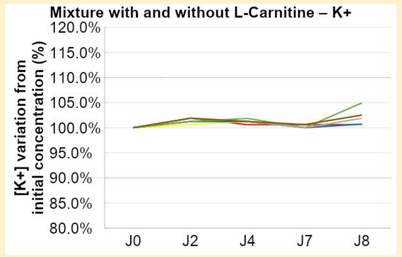
Ingredient – Pharmaceutical specialties	Concentration		
	Formula n°1	Formula n°2	Formula n°3
Sodium - Sodium Chloride 10%	24,0 mmol/L	120 mmol/L	40 mmol/L
Water for Injection (WI)		QSP 200 mL	
Calcium - Calcium Gluconate 10%	13,59 mmol/L	1 mmol/l	33,0mmol/L
Glucose - G50%	150 g/L	200 g/L	100g/L
Oligoélément		5,0 mL/L	
Phosphorus – Phocytan®	13,7 mmol/L (dont 11% par Phosphate monopotassique 13,6%)	10 mmol/L	16,51mmol/L
Potassium - Potassium Chloride 10%		27mmol/L	
Water-soluble vitamin - Soluvit®		5,0 mL/L	
Magnésium – Magnésium sulfate 15%		1,85 mmol/L	
Amino-acid- Vaminolact®	22,85 g/L	29,40 g/L	13,05 g/L
Zinc		0,04 mmol/L	
Ratio Ca/P	1	0,1	2

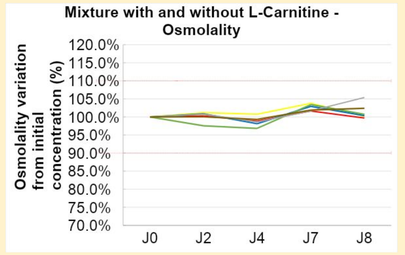
Références :

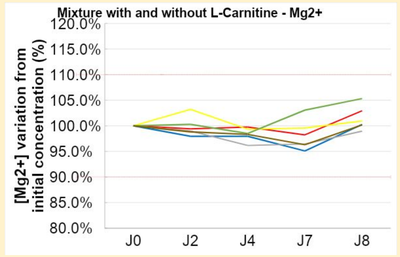
1. A.S.P.E.N. position paper: recommendations for changes in commercially available parenteral multivitamin and multi-trace element products. Vanek VW, Borum P, Buchman A , et al Nutr Clin Pract 2012;27(4):440-91.

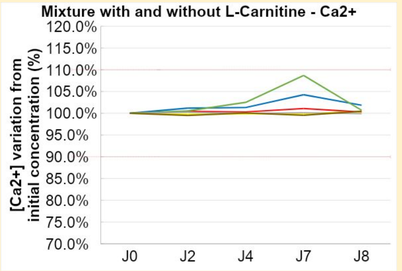
Results :

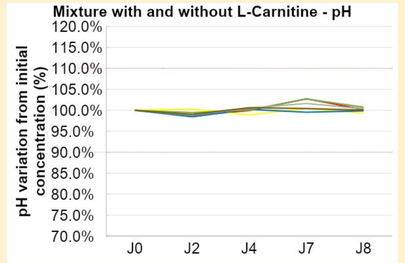


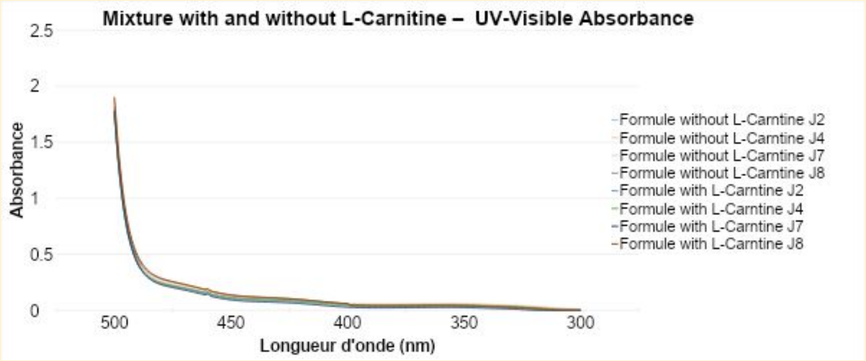


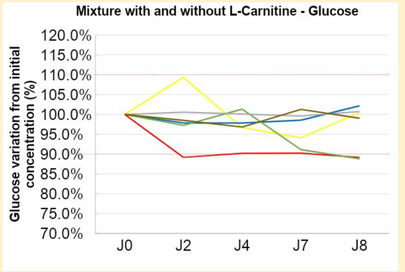


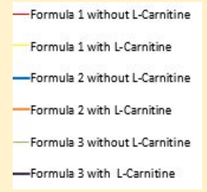












✔ No visible and invisible particles were identified.
✔ No variation > 10% on all elements measured during the 8 days of analysis.
✔ All preparations passed the sterility test.

Discussion and conclusion :

The variability of the glucose dosage is explained by the intermediate manual dilution step, mandatory because of the limitations of our dosing devices adapted to the dosage of urinary glucose. However, analysis of the osmolality monitoring confirms the stability of the glucose concentration. The implementation of this study model required numerous technical means and coordination with several services outside the pharmacy. This type of study requires the presence of an independent monitoring laboratory within the PUI.
This study shows that the addition of L-carnitine does not seem to influence all the analyzes carried out and this for the 3 formulas carried out. The addition of L-carnitine is therefore strongly considered and can be started as soon as possible. It is planned to do a 3rd series in order to confirm the reproducibility of our results. A study of the stability of L-carnitine in these 3 formulas should also complete this work.