



Quality control of parenteral nutritions: analysis of inorganic ions by capillary electrophoresis

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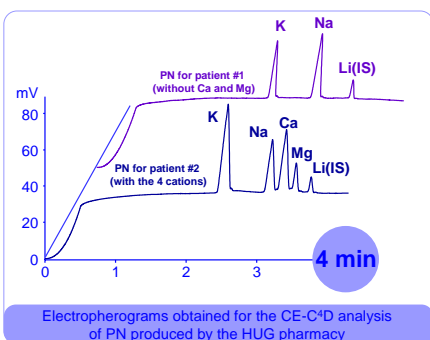
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WHAT
Parenteral nutrition (PN) is the practice of feeding a person intravenously with nutritional formulas containing essential nutrients such as glucose, amino acids, electrolytes and vitamins. In our hospital, individualized solutions are daily prepared and standardized formulations are also regularly produced, using a MM12 MicroMacroR compounder (Baxa, USA). An error in the concentration of the electrolytes induces an increased risk for the patient, especially for neonates. The objective of this study was to develop a quality control method to analyse main electrolytes in TPN before patient administration [1].

HOW
Capillary electrophoresis coupled to a capacitively coupled contactless conductivity detector (CE-C⁴D) was used to simultaneously quantify the inorganic cations: potassium, sodium, magnesium and calcium, in PN preparations. CE is a very attractive technique due to its high efficiency, low cost of capillaries, low organic solvent consumption and rapid method development.

Experimental conditions

CE HP3DCE (Agilent Technologies, Germany)
Cap: Fused-silica capillary, length 64.5 cm, i.d. 50µm
BGE: TRIS-phosphate buffer 100mM pH 4.5 and acetonitrile (80:20,v/v)
Voltage: 30 kV
Inject.: 40 mbar for 10 s
C⁴D TraceDec (IST, Austria)
Output frequency: 150 kHz
Output voltage: 40Vpp
Gain: 50%



Method validation

The validation was based on ICH recommendations and carried out over three series. Each series involved:

- 2 calibration standards at 4 mM for K, Na and 2 mM for Ca, Mg (in water)
- 4 validation standards at 1, 2 and 4 mM for K, Na and 0.5, 1 and 2 mM for Ca, Mg (in a mixture of glucose, amino acids, heparin and trace elements)

No interference due to amino acids, vitamins or another compounds usually present in PN was observed

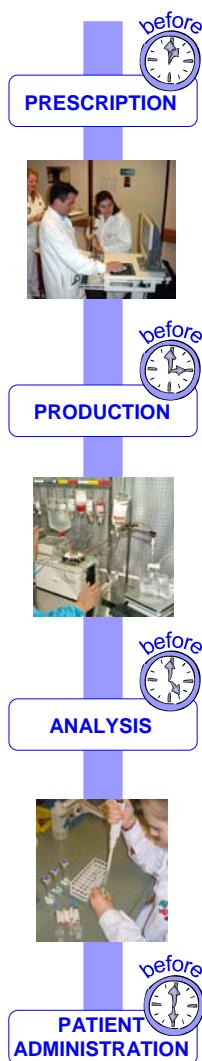
	Theoretical conc. (mM)	Trueness	Repeatability (CV)	Intermediate precision(CV)
K	1	100.6%	1.0%	1.3%
	2	101.8%	1.2%	1.4%
	4	101.6%	1.1%	1.1%
Na	1	100.9%	1.2%	1.5%
	2	101.9%	1.1%	1.5%
	4	99.7%	0.9%	1.2%
Ca	0.5	100.5%	1.1%	1.1%
	1	100.4%	1.3%	1.8%
	2	99.0%	0.4%	1.1%
Mg	0.5	99.1%	1.0%	1.2%
	1	99.2%	0.8%	1.1%
	2	98.6%	0.8%	0.8%

CONCLUSION

CE-C⁴D method

Appropriate for quantify Na, K, Mg and Ca in PN formulations

Successfully applied in our daily quality control.



[1] S. Nussbaumer et al., J. Pharm. Biomed. Anal. In press.