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Stability study of a standardized parenteral nutrition formulation for premature neonates

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Background

Currently
Individual preparations of parenteral nutrition (PN) for premature neonates in intensive care unit (PNI)

Design of a standardized binary (carbohydrates and amino acids) **PN formulation**

- ✓ Hospital preparation: **composition and stability guaranteed** and **available 24h/24** if premature delivery
- ✓ **Tailored to specific needs** of PNI
- ✓ In accordance with **guidelines** HAS (HAUTE AUTORITÉ DE SANTÉ)

Objectif
Assess the stability of our standardized PN formulation

Materials and methods

- n = 5
- Conservation at 2-8°C
- Packaging: single-layer ethylvinylacetate bags

D0 D1 — D7 — D14 — D28 = M1 — D57 = M2

Visual inspection
- Color, homogeneity, clarity
- Visible particles (*European Pharamacopeia (EP) 2.9.20*)

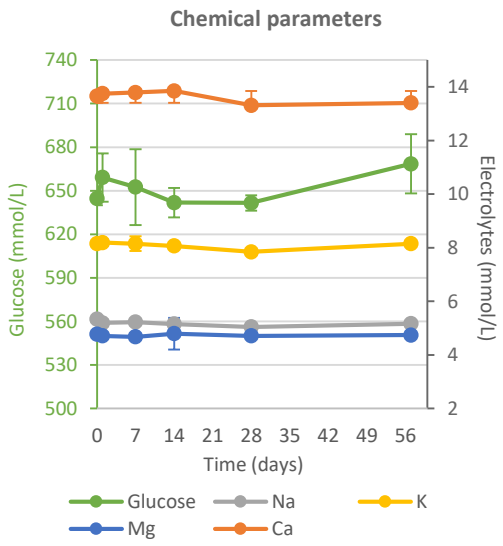
Chemical parameters
- pH (*EP 2.2.3* by pH-meter)
- Indirect glucose assay (*EP 2.9.6* by visible absorption spectroscopy)
- Na^+, K^+, Mg^{2+}, Ca^{2+} assay (*EP 2.9.6* by ICP-AES)

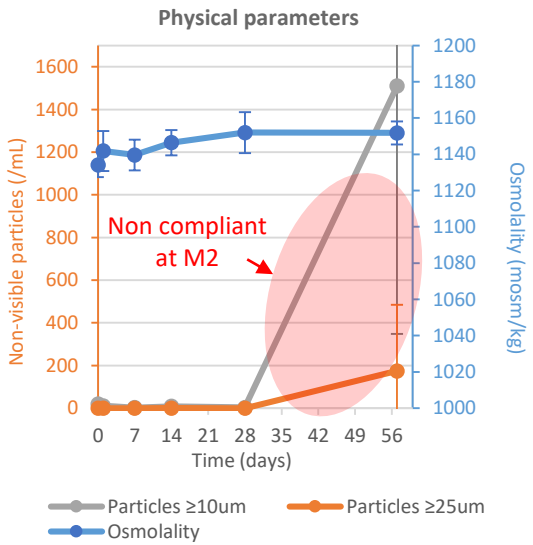
Physical parameters
- Non-visible particles (*EP 2.9.19* by light obscuration)
- Osmolality (*EP 2.2.35* by freezing-point depression)
- Visible absorption spectrum of the solution 400-800nm *(EP 2.2.25)*

Results

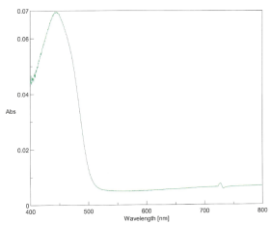
	Parameters	Specifications	D0	D1	D7	D14	D28 = M1	D57 = M2
Visual inspection	Color, homogeneity, clarity	No change	Homogenous clear yellow				Homogenous clear light amber	Dark amber
Visual inspection	Visible particles	None	None					Visible particles
Chemical parameters	pH	4-6	5,04 (±0,01)	5,04 (±0,05)	5,09 (±0,01)	5,06 (±0,01)	5,00 (±0,01)	4,95 (±0,01)
Chemical parameters	Glucose (mmol/L)	≤10% variation						
Chemical parameters	Na^+ (mmol/L)	≤10% variation						
Chemical parameters	K^+ (mmol/L)	≤10% variation						
Chemical parameters	Mg^{2+} (mmol/L)	≤10% variation						
Chemical parameters	Ca^{2+} (mmol/L)	≤10% variation						
Physical parameters	Non-visible particles ≥10µm (/mL)	≤25/mL particles of size ≥10µm						
Physical parameters	Non-visible particles ≥25µm (/mL)	≤3/mL particles of size ≥25µm						
Physical parameters	Osmolality (mosm/kg)	≤10% variation						

Values are expressed as mean ± standard deviation



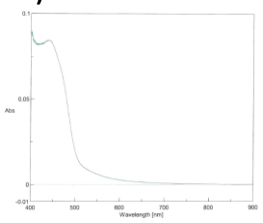


Visible absorption spectra (400-800nm)



D0

Change of the spectrum at M2



D57 = M2

Non compliant at M2

Discussion - conclusion

- ➢ Formulation **stable for the first 28 days** between 2°C and 8°C
- ➢ **BUT** color change and emergence of particles beyond this time point

To be completed by a complementary study of **microbiological, amino acid and vitamin stability** (*in progress*).