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STABILITY OF PARENTERAL NUTRITION ADMIXTURES FOCUS ON PRECIPITATION

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INTRODUCTION

Parenteral nutrition (PN) have a complex composition, so interactions between components lead to instability compromising its safety. Large precipitates can cause thromboembolisms and death. Low concentrations of lipids and amino acids and high concentrations of cations correlate with poorer stability (higher risk of precipitate formation).

PURPOSE

To analyze the stability of PN samples attending to the appearance of precipitates using optical microscopy measurements.
To evaluate the influence of temperature and time on stability.

MATERIAL AND METHODS

We studied 5 PN samples (all-in-one). From a baseline formulation (standard macronutrient ratios), we decreased the lipid concentrations from sample 1 to 5. Micronutrients amounts were greater than those recommended and vitamins (hydrosoluble and lyposolubles) and zinc were also added.

500mL per sample were prepared according to the center's protocols. On day 0, a single stock sample was prepared from which 2 aliquots of 250 mL were separated and stored at room temperature (RT) and in a refrigerator (4ºC) for 14 days.

In order to determine the physical stability of the samples, precipitate formation were assessed using a Fast Read Biosigma® counting camera on a Nikon Eclipse 50i microscope®. Images were taken with a 40X magnification objective.

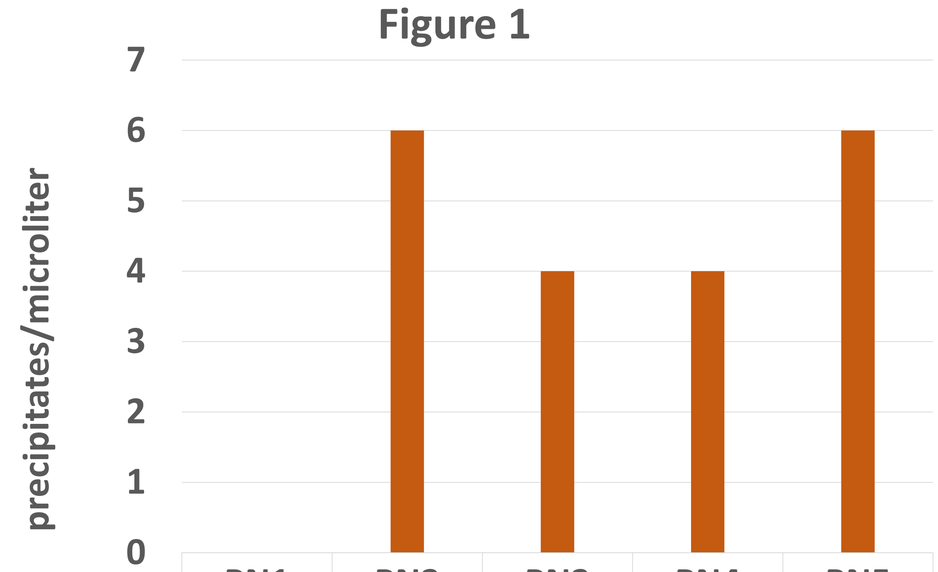
Measurements were taken on the sample on day 1 (4ºC) and day 14 (RT and 4ºC). Only precipitates larger than 5 microns and with a clearly crystalline form were counted in this analysis.

Results are expressed in precipitates per microliter (according to chamber manufacturer's recommendations).

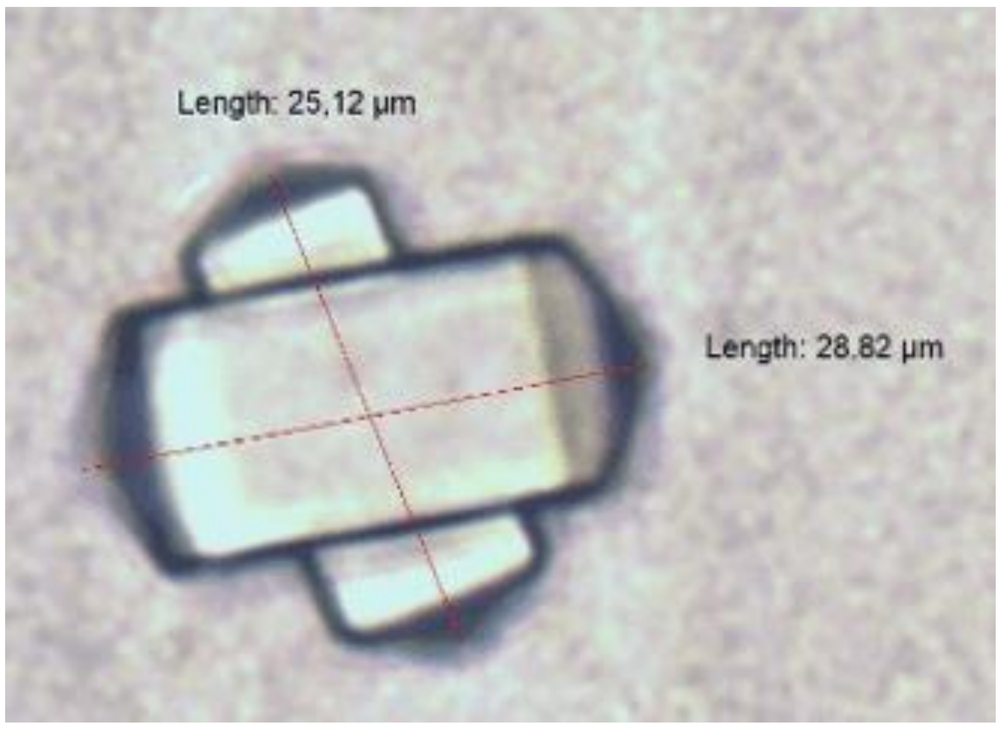
RESULTS

Precipitates were observed in 4/5 samples. All precipitates corresponded to samples analyzed after 14 days of storage at RT, none in those stored in the refrigerator.
Figure 1 represents the data obtained and an example of the type of precipitates found.

Figure 1



	PN1	PN2	PN3	PN4	PN5
day 1 (4ºC)	0	0	0	0	0
day 14 (RT)	0	6	4	4	6
day 14 (4ºC)	0	0	0	0	0



CONCLUSIONS

- Average globule size was stable despite high CAN of samples, but more sensitive analytical techniques may be necessary to detect changes in the fraction of large globules.
- The study time and the different storage temperature didn't influence the average globule size of our samples.
- To establish the overall stability of the PN, more complete studies should be carried out, which analyse more stability-dependent processes.

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