Study of Parenteral Emulsion Stability using the Optical Analyzer Turbiscan®
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1. Introduction

Lipid emulsions are widely used for parenteral nutrition in cases of fatty acid deficiency and as caloric source. They are used either alone or with admixtures of essential compounds (e.g., glucose, amino-acids, vitamins, trace elements) as total parenteral nutrition (TPN) mixtures. Many studies regarding the stability of TPN during storage have been reported using particle size analysis, zeta potential determination, or microscopic examination. However, previous methods require either relatively large amounts of samples or dilution, which complicate further stability analysis. In the present study, stability of TPN was examined using Turbiscan® MA2000 (Formulaction, France), measuring multiple light scattering from undiluted samples at different temperature of storage.

2. Materials and Methods

Seven TPN mixtures from typical clinical prescriptions for adults were aseptically prepared in infusion bags under sterile conditions in a laminar-airflow hood. Ten-ml TPN mixtures were aseptically introduced in a cylindrical glass measurement cells, which were, then, stored vertically either at 4°C, 18°C or 37°C (temperature test) for 12 days (ageing test).

Turbiscan®MA 2000 (Formulaction, France) glass cells were scanned, each 40 µm, by a pulsed near infrared light source (λ = 850 nm) and two synchronous detectors. The transmission detector receives the light through the sample at 0° from the incident beam, while backscattering detector receives the light scattered by the sample at 135° from the incident beam [1] (Fig. 1).

3. Results and Discussion

By measuring BS decrease from the bottom of the sample (z = 0), clarification of TPN might be estimated (Fig. 2). The clarification kinetics were determined at z = 6-12 mm, from the evolution of BS (%), as a function of time and temperature of storage. The clarification kinetics presented an exponential decay : BS (%) = BS0 • exp (-k • t)

where BS0 is the initial BS and k is the clarification constant.

The clarification constants were found linearly dependent of the temperature (C°) of storage (Fig. 3) : 10^5 • k = a • C° + b (R = 0.917, n = 19)

Therefore, the clarification kinetics were re-expressed as :

BS (%) = BS0 • exp [- (a • C° + b) • t]

In the present study, the backscattering measured by Turbiscan® allows to detect destabilisation phenomena of TPN mixtures at a very early stage. Clarification and creaming of TPN mixtures were found exponentially dependent on time and temperature of storage.

4. Conclusion

This study shows that the stability of TPN might be successfully performed using multiple light scattering measurements and would improve the quality control of these preparation for the patient’s safety.

5. References