Long Term Physico-Chemical Stability of Standard Parenteral Nutrition for Neonates
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INTRODUCTION
Two ready-to-use standard parenteral nutrition (PN) have been developed for the first days of life of premature and neonates, together with syringes of lipid emulsion with or without vitamins.

FORMULATIONS

<table>
<thead>
<tr>
<th>Ready-to-use PN</th>
<th>AA¹</th>
<th>D²</th>
<th>Na</th>
<th>K</th>
<th>Ca</th>
<th>PO₄</th>
<th>Heparin</th>
</tr>
</thead>
<tbody>
<tr>
<td>PN Day 0 (D0)</td>
<td>3</td>
<td>10.8</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>1.1</td>
<td>50</td>
</tr>
<tr>
<td>PN Day 1-4 (D1-4)</td>
<td>3</td>
<td>10.8</td>
<td>2</td>
<td>1</td>
<td>1.1</td>
<td>0.86</td>
<td>50</td>
</tr>
</tbody>
</table>

¹ Amino Acids (Vaminolact®) ² Dextrose

Lipids

<table>
<thead>
<tr>
<th>Lipids</th>
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<th>Vitamins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringes</td>
<td>Lipofundin®³</td>
<td>--</td>
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<tr>
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<td>Lipofundin®³</td>
<td>Cernevita⁵</td>
</tr>
</tbody>
</table>

³ long-chain triglyceride and medium-chain triglyceride

METHODS

Physical stability:
- visual inspection
- particles size
- pH and osmolarity

Chemical stability (concentration range: 90%-110%)
- AA, vitamins A, E and C by HPLC
- Dextrose by spectrophotometry (enzymatic method, 340 nm)
- Na, K, Ca by ion specific electrodes, PO₄ by colorimetry
- Lipid peroxidation by Ferrox-Xylenol Orange method

Conditions:
- Carried out for 12 weeks
- Between 2-8°C (F)
- Between 25-30°C (RT)

RESULTS

PN in F remained limpid, whereas a brown coloration was observed in PN at RT after 3 weeks.

Chemical stability:
- All nutrients remained stable for 12 weeks of storage (F and RT).

Lipid globule size analyses

- European Pharmacopoeia limit
- USP limit

Chemical stability:
- Vitamin C: loss > 10% (F and RT) after 2 weeks
- Vitamins A and E: remained stable for 2 weeks (F and RT)

CONCLUSION

Ready-to-use PN:
physically and chemically stable 12 weeks in the F or 2 weeks at RT.

Lipid emulsion syringes:
physically and chemically stable for 1 week in the F because of creaming.

The determined stability for the two ready-to-use standard PN and for lipid emulsion syringes allow their storage in wards. They can be used as soon as needed without any delay which is a major advantage over tailor-made PN.