**TCH-041** STABILITY OF TOTAL PARENTERAL NUTRITION ADMIXTURES FOR PEDIATRIC HOME CARE IN THE PRESENCE OF HIGH CONCENTRATIONS OF ELECTROLYTES

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**Background** In clinical practise electrolyte enrichment of the parenteral nutrition admixtures is a typical request, especially on the neonatal/paediatric wards. The supplementation of parenteral nutrition with high concentrations of electrolytes is an ongoing problem since the stability of lipid emulsions in nutrition admixtures is reduced by bile salt ions.

**Purpose** To examine the stability of 48 different paediatric admixtures designed for home parenteral nutrition. The admixtures investigated were characterised by high concentrations of electrolytes (20–61 mmol/L K+, 9–21 mmol/L Ca2+, 6–20 mmol/L Mg2+).

**Materials and Methods** Parenteral pre-admixtures were prepared in two-chamber ethyl-vinyl-acetate bags, where a lipid emulsion was separated from the other components. Parenteral pre-admixtures (in two chambers) were stored up to 21 days at +4°C. Vitamin preparations were added only after combining the contents of two chambers of the bag.

Visual observations, globule size measurement (optical microscopy, laser diffraction (LD) and photon correlation spectroscopy (PCS)), zeta-potential, pH analysis and surface measurements were performed in complete admixtures at t = 0 and after 24 h at room temperature.

**Results** In microscopic observation all admixtures were characterised by size of oily droplets not larger than 1 μm, which was confirmed using LD and PSC methods (Z-average was 260–310 nm). Oily droplet size did not change during the time of storage. Only in two admixtures were single particles up to 8–10 μm observed, so these admixtures were classified as unstable. The pH values of parenteral admixtures were in the range 5.6–6.7 and zeta potential was –36 to –47 mV and did not change during storage.

**Conclusions** Of the 48 admixtures investigated only two were problematic and the others may be stored for at least 21 days at 4°C. The completed admixtures demonstrated stability for at least 24 h at room temperature. It was possible to obtain stable admixtures despite the high concentrations of electrolytes.

No conflict of interest.

**TCH-043** STABILITY OF SILDENAFIL CAPSULES BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

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**Background** Sildenafil, a phosphodiesterase V inhibitor, is used in paediatrics to treat pulmonary arterial hypertension. However no paediatric formulation was available until a recent launch announced a powder for oral suspension.

**Purpose** To determine the stability of sildenafil capsules for paediatric dilutions. A HPLC assay has been developed for this purpose.

**Materials and Methods** The sildenafil dosing method, developed from a previously published method1, is a reverse phase HPLC with UV detection at 240 nm. The column is a C18, the mobile phase composition is acetonitrile/ammonium acetate 0.2 M (50/50) with a flow set at 1 mL/min. Linearity and precision cheques (repeatability and intermediate precision) have been performed to validate the method. Capsules of 1 mg, 5 mg and 10 mg (of sildenafil base) were prepared with sildenafil citrate and corn starch. Samples were kept at ambient temperature in transparent blister packs sealed with aluminium foil. Uniformity of mass was verified at D0. The visual appearance of the capsules, sildenafil concentrations and chromatographic profiles were checked at D0, D7, D14, D21, D35, D42, D56 and D70.

**Results** The method was linear up to 150 mg/mL. Repeatability and intermediate precision were demonstrated (SD < 2%). Uniformity of mass was verified, no change in visual appearance and no additional chromatographic peaks were observed. The percentages of the remaining concentrations of sildenafil in the capsules compared to initial concentrations were higher than 90% at D70.

**Conclusions** The method has been validated and used in a stability study which demonstrated the stability of sildenafil capsules up to ten weeks under the storage conditions studied. These results led us to apply a shelf life of eight weeks to sildenafil capsules.


No conflict of interest.