Material and methods The pharmaceutical specialty composed of insulin aspart and its two preservatives (phenol and metacresol) were diluted in saline or D5%. The impact of the diluent on the stability of insulin aspart was studied by high-performance liquid chromatography with UV detection (HPLC-UV). A stability indicator method,¹ adapted from the method of Poulsen *et al.*² and developed for insulin aspart diluted in saline, was used. The prospective formation of a new compound in the different diluents was evaluated by HPLC with a mass spectrometry detection (HPLC-MS) in full-scan mode. The kinetic of the new compound's appearance was studied by relative evaluation of HPLC-UV signals during 1 week for insulin at 1 U/mL diluted in D5% (n=4).

Results The three products contained in the pharmaceutical specialty diluted in saline correspond to the three signals identified in HPLC-UV (elution order: phenol, metacresol and insulin aspart). After dilution of insulin aspart in D5%, we noted a fourth signal. pH influence and forced degradation tests failed to attribute this signal to insulin or preservatives' degradation. HPLC-MS analysis revealed a mass difference of 162 daltons between insulin and this product, which corresponds to a glycation phenomenon of insulin aspart. Finally, the kinetics shows that the insulin glycation phenomenon seems to increase with the contact time between insulin and glucose until a plateau is reached after 24 hour of contact.

Conclusion This work highlighted the instability of insulin in D5% and showed the phenomenon of insulin aspart glycation. To better characterise this phenomenon, the biological effect of glycation on insulin activity have to be determined, since a decrease in activity has been observed for human insulin.

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No conflict of interest.

3PC-005 STABILITY STUDY OF A 10% SODIUM BENZOATE ORAL SOLUTION

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Background Defects in the urea cycle are genetic diseases in which nitrogen accumulates as ammonia, resulting as highly toxic, especially in paediatric patients. Sodium benzoate (SB) is conjugated with glycine, giving rise to hippurate, which is excreted in the urine. Currently there are only intravenous SB commercial presentations, but no oral preparation is commercialised. Due to this, its manufacture in hospital pharmacy services is necessary.

Purpose The main objective is to evaluate the stability of an oral solution of 10% SB at different storage conditions for the treatment of urea cycle disorders in paediatric patients.

Material and methods Initially, six 10% SB samples were prepared from the commercial SB powder (Acofarma) and sterile water. Three were kept at room temperature and three were stored at 2°C–8°C during 30 days, protected from light. On the other hand, SB was characterised spectrophotometrically in water, to obtain a calibration curve. We studied

several physical and chemical parameters after preparation (day 0) and after 7 and 30 days. These parameters were colour, opacity and the presence of precipitation, absorbance and pH. Each preparation was visually inspected in front of a black and white background. pH measurements were carried out by pH indicator strips. All absorbance measurements were obtained after dilution of solutions, with a Shimadzu spectrophotometer model UVmini-1240 UV-Vis.

Results All 10% SB solutions were initially homogenous and transparent. A calibration curve was obtained at 223 nm ($y=56\,495x+0.0177$; $R^2=0.9995$), with an average recovery percentage of 99.92% (SD=1.21; CV=1.21). On day 7 post-elaboration, an average degradation of 1.49% of active ingredient was observed in room-temperature stored samples and 2.82% in refrigerated samples. On day 30, the percentage of loss increased to 2.55% and 3.48% respectively. After 30 days, no colour change, no opacity and no precipitation were observed. In all test solutions the pH-values remained unchanged.

Conclusion The results allow us to conclude that our 10% SB oral solution, used in urea cycle defects in paediatric patients, are physically and chemically stable for at least 30 days when stored at room temperature or at 5°C±3°C with protection from light.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-006 ANALYSIS OF THE REGIMENS ESTABLISHED AT THE PHARMACY SERVICE FOR TOTAL PARENTERAL NUTRITION AND THE USE OF GLUTAMINE AS A SOURCE OF NITROGEN

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Background The recommendations for the appropriate composition of total parenteral nutrition (TPN) for adult patients with different pathologies have been changing over the years as new studies are conducted, tending to be higher in protein and lower in total kilocalories.

Different guidelines such as the European and the American Society of Parenteral and Enteral Nutrition (ESPEN and ASPEN) or the Canadian Clinical Practice Guidelines are referents on the subject.

Purpose To analyse the accuracy of the regimens established at the pharmacy service for TPN in 2011 regarding the amount of protein, and also to evaluate whether glutamine is being used as supplementation or as a source of nitrogen to meet the recommendations.

Material and methods A retrospective study covering the period from January 2018 to August 2018 was conducted in a University Hospital evaluating the prescriptions of TPN and whether they were supplemented with glutamine or not. Data were collected from an Acces base designed for the elaboration of the TPN bags.

Then, a review of the total amount of nitrogen in the regimens was conducted.

Results A total of 2296 prescriptions of TPN were received at the pharmacy service. Regarding these prescriptions, 1121