observed in particle size after 60 days in all samples. The organoleptic characteristics (smell, taste and texture) remained unchanged in all of the preparations until the third month.

Conclusion and relevance A stable alcohol free diazepam suspension was achieved. The tablets produced a more stable formulation than the bulk source, especially when stored at a lower temperature. This formulation can solve the problem of shortages, allowing the appropriate administration of paediatric treatments, while allowing compliance with the recommended composition limits of ethanol, by excluding this excipient from its composition.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-029 PAEDIATRIC DRUG RESISTANT EPILEPSY: NITRAZEPAM 1 MG/ML SOLUTIONS TO AVOID CLINICAL THERAPEUTIC ERROR

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Background and importance The management of paediatric patient with drug resistant epilepsy (EDR) is complicated and often requires therapy and dose adjustments. The clinical pharmacist and child neuropsychiatry unit cooperate to prevent clinical therapeutic errors, common in the prescription of drugs with reduced and personalised dosages.

Nitrazepam (NTR) in children is recommended in epileptic spasms, in Dravet, West and Lennox–Gastaut syndromes. There is a probable risk of administration error due to the low prescribed dosage (125 µg/kg)¹ and crushing of commercial tablets.

Aim and objectives To make a liquid formulation with a standard concentration, easily adaptable to paediatric needs as weight changes, that is palatability, suitable and simple to use during hospitalisation and at home.

Material and methods Multiphase study:

- Phase I: data collection.

Retrospective study examined the medical records of children born 2008–2019 with a certain diagnosis of EDR: patient number, sex, age, epilepsy classification according to the International League Against Epilepsy criteria,² antiepileptic therapy and dose of drug were collected.

- Phase II: subject study of nitrazepam, its dosage and the galenic compounding formulation it was possible to use.

- Phase III: chemical–physical–microbiological stability analysis of nitrazepam 1 mg/mL.

Samples were stored for 30 days at 2–8°C and/or ambient at 25°C. Chemical–physical stability was measured by quantitative determination of the molecular ions of nitrazepam C282.1/C236, using high pressure liquid chromatography (HPLC), equipped with a UV detector, interfaced with a triple quadrupole mass detector (mass spectrometer, MS/MS), column Luna C1850 mm, standard nitrazepam D5 100 µg/mL.³ Microbiological stability was assessed according to the Italian Official Farmacopea (FUI).⁴

Results A total of 101 children with EDR (54 males, 47 females) were studied, aged mainly 3–4 years (20%) and 9–10

years (33%). Classifications: focal onset in 34.86%, focal to bilateral tonic–clonic in 17.10%, generalised onset in 47.36% and unclassified in 0.65%. Thirty-one drugs are prescribed, the most used were: levetiracetam (27%), clobazam (25%), topiramate (21%) and NTR (12%). Required dosages of NTR difficult to administer: 0.625 mg, 0.83 mg, 1.25 mg, 1.66 mg and 2.5 mg. Three liquid galenic formulations were set up (NTR from Mogadon 5 mg tablets): NTR 1 mg/mL simple syrup methylcellulose 1%, NTR 1 mg/mL suspension tragacanth gum and NTR 1 mg/mL Syrspend SFalkaDry.⁵

HPLC MS/MS analysis confirmed uniform and steady dosage, and 30 day stability for NTR 1 mg/mL suspension and NTR 1 mg/mL Syrspend SFalkaDry.

Conclusion and relevance Good clinical practice and collaboration between departments allowed better management of epileptic seizures in children affected by severe EDR. Reproducible and safe therapy means improving patient's life and therapeutic compliance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. British National Formulary for Children 2014
2. <https://www.ilae.org/files/ilaeGuideline>
3. <https://www.sigmaaldrich.com>
4. Farmacopea Ufficiale Italiana XII ed.
5. <https://fagron.com/en/product/syrspend-sf-alka-dry>

No conflict of interest.

3PC-030 ANALYTICAL METHOD VALIDATION TO CARRY OUT PHYSICOCHEMICAL STABILITY STUDIES OF METHADONE ORAL SOLUTIONS

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Background and importance On the basis of resolution 189/2018 published by our city health council, the hospital pharmacy service was entrusted with the centralisation of the procedure for the acquisition, compounding, distribution and dispensing of methadone to drug addicts in integral attention centres. In order to improve and increase the beyond use date (BUD) of methadone oral solutions, we carried out a physicochemical stability study.

Aim and objectives To develop an analytical method and validation to carry out a physicochemical stability study of two oral solutions of methadone to increase their BUD. Method development should be made in an effective and reproducible manner.

Material and methods The study was carried out on two formulations of methadone 10 mg/mL, which were prepared with and without parabens as preservatives. A high performance liquid chromatography (HPLC) Agilent 1100 was used, provided with a quaternary pump and an ultraviolet diode array detector to determine methadone. First we carried out the analytical method development to achieve the analytical performance characteristics. Then we performed validation of the analytical method obtaining linearity, instrumental intra-assay and inter-assay precision, and accuracy and recovery percentage.

Results Chromatographic conditions were: flow rate 1.6 mL/min, 55% acetonitrile and 45% phosphate buffer (adjusted to pH=10) as the mobile phase. Injection volume was 50 µL,