BACKGROUND
Prednisone is a corticosteroid used in several inflammatory diseases and cancers. Actually, in our hospital, we produce an oral syrup of prednisone with alcohol (ethanol), sodium benzoate, and simple syrup. However, sodium benzoate can induce neonatal icterus and alcohol is not authorized for children’s behind 3 years.

PURPOSE
The aim of this study was to determine the stability of 5 mg/ml prednisone oral suspension in commercial compounding excipient: Syrspend® SF PH4 (FAGRON).

MATERIAL AND METHODS

Analytic method validation according to the ICH guidelines
- Linearity, accuracy, repeatability, intermediate precision
- Stability indicating method (detection of degradation product)
- Identification prednisone/prednisolone

Quantification of prednisone
- Waters 717plus autosampler, 2487 UV detector, HPLC 515 pump, Empower® Software
- Mobile phase : methanol/water (45:55 v/v)
- Column : XTERRA RP 18 column (150 x 4.6 mm, 5 µm)
- Flow rate: 1 ml/min; λ = 254 nm
- Oven temperature: 45°C

Physical stability
- Visual inspection

Chemical stability
- Quantification of residual concentration of prednisone
- Measure of pH: pHmenonal® VWR pHmeter
- Measure of osmolality: Advanced Instruments Model 3250® Osmometer

RESULTS

Analytic method validation
- Linearity: R²>0,99
- Accuracy: R%= [100,5%; 99,41%; 98,9 %] (respectively for 75 µg/ml, 125 µg/ml and 175 µg/ml)
- Repeatability: CV= 1,64%; 2,16%; 1,37% (respectively for the day 1, 2, 3)
- Intermediate precision: CV=1,72%
- Stability indicating method
- Separation prednisone/prednisolone

Chemical stability
- Prednisone concentrations remained stable within ± 5% of nominal values over 60 days
- No degradation products were detected
- Measure of pH and osmolality

Physical stability
- No macroscopic alteration was observed during the studied period

CONCLUSION
This study showed that 5 mg/mL prednisone oral suspension in Syrspend® was stable for 60 days, at room temperature and protected from light. This new suspension would provide an interesting alternative to the syrup with alcohol and sodium benzoate, especially for pediatric use.

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