Background:
Oxybutynin blocks the release of acetylcholine on the surface of the bladder’s muscle. This drug is used to treat urinary incontinence and symptoms of detrusor muscle hyperactivity. Oxybutynin is a common pediatric prescription but only commercially available in tablet form in France, which is unsuitable for pediatric use. We developed oral suspensions but informations were not available for oxybutynin stability in this form.

Objective:
The aim of this study was to evaluate the physico-chemical stability of 5 mg/mL oxybutynin oral suspension in commercial compounding excipient: Syrspend®.

Materials & methods:
Three batch of oxybutynin powder in Syrspend® at 5mg/mL
Stored at 25°C in Amber vials → protect from light
Measurement on days 0, 3, 5, 8, 10, 15, 30, 60 in triplicate and freezing at -80°C
• microbiological stability: cultures at 36°C on agar
• physical and chemical stability: macroscopic appearance, osmolality, pH

Oxybutynin stability:
Liquid Chromatography High Resolution Mass Spectrometer
Accela pump with a Thermo Fisher C18 Accucore column (100 x 2.1 mm, 2.6μM)
Gradient of 10mM ammonium acetate buffer and 0.1% (v/v) acetonitrile with 0.1% (v/v) formic acid
Data acquired in: Targeted Single Ion Monitoring (t-SIM) mode
Sample dilution 1/1,000,000
Measurement by extracting the mass value of protonated oxybutynin (358.2376 m/z) using 5 ppm mass window

Results:

No culture growth were observed.
Macroscopic appearance was unchanged.
Physical properties remained stable: pH [4.21– 4.29] and osmolality [56 – 78 mOsm/L] (fig2).
Concentration of oxybutynin: was stable until the 8th day (98.5% of Day 0) (fig3).

Conclusion:
Microbiological stability and physical stability are acceptable.
Regarding chemical stability, we decided to set a shelf life to 8 days.
Freezing or chromatographic solvants of HPLC could influence stability of oxybutynin.
Further studies will be conducted such as forced degradation study.

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