

Stability study of 5mg/mL oxybutynin oral suspension in Syrspend®

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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

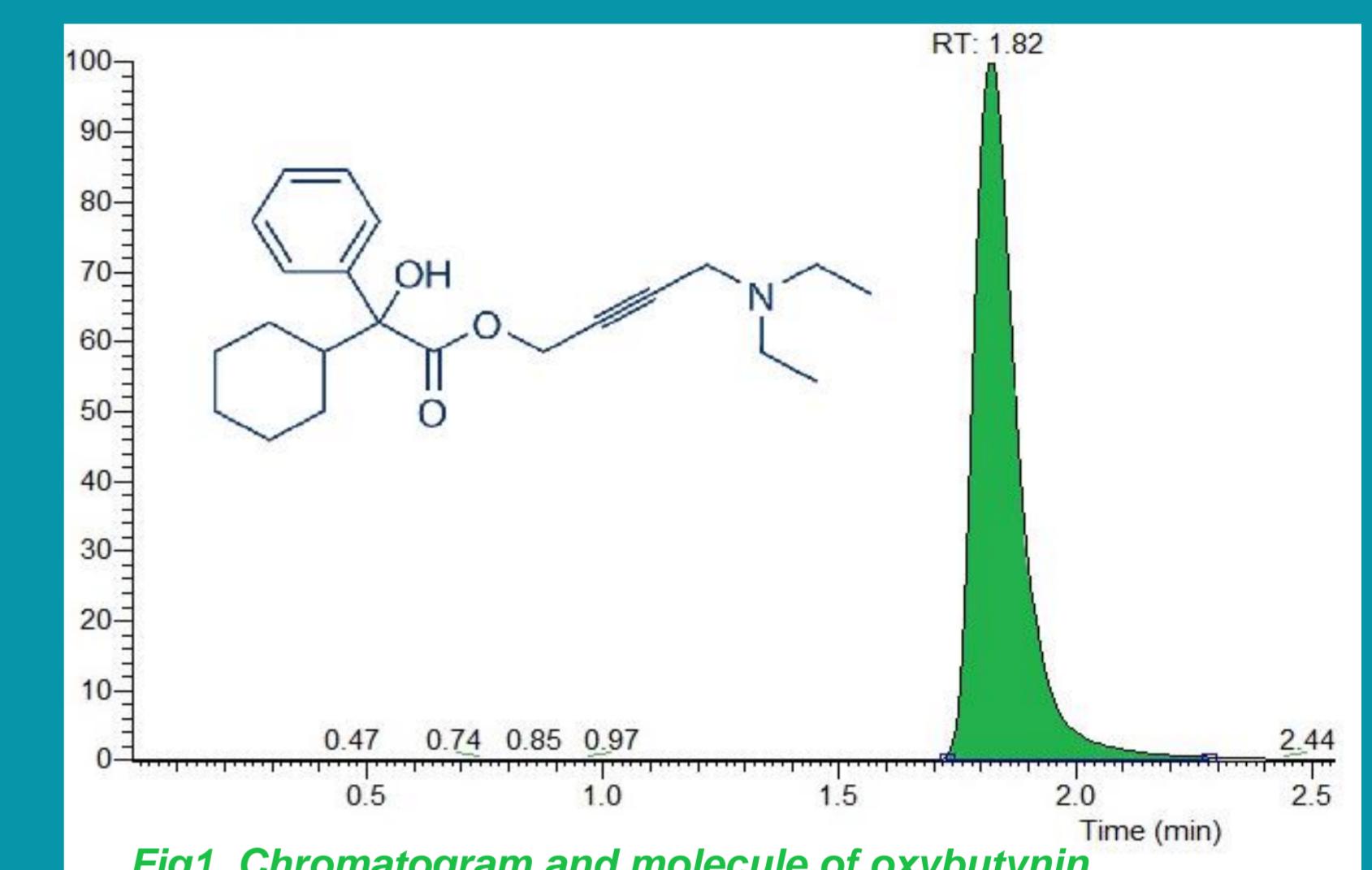


Fig1. Chromatogram and molecule of oxybutynin

Results:

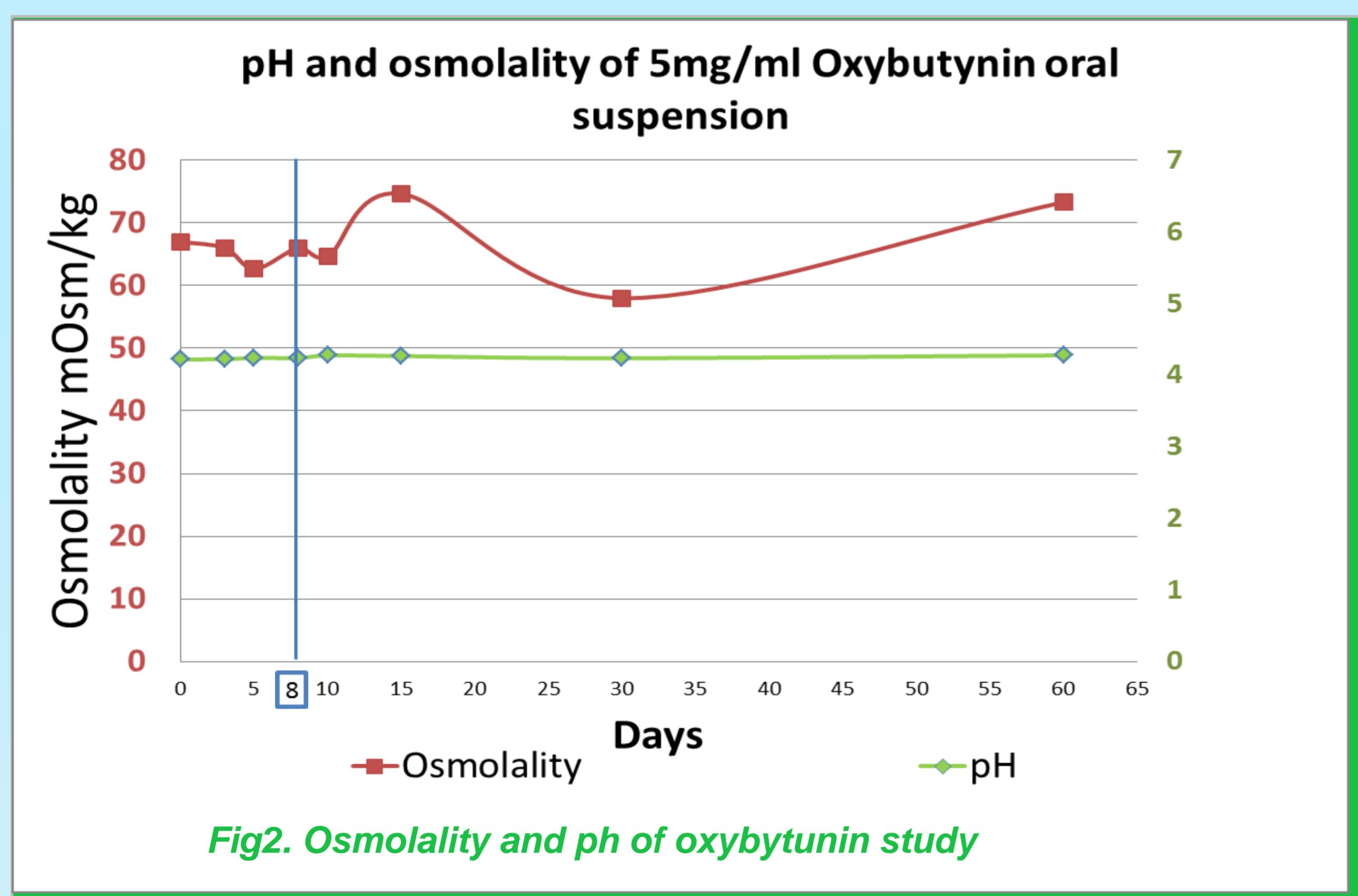


Fig2. Osmolality and ph of oxybutynin study

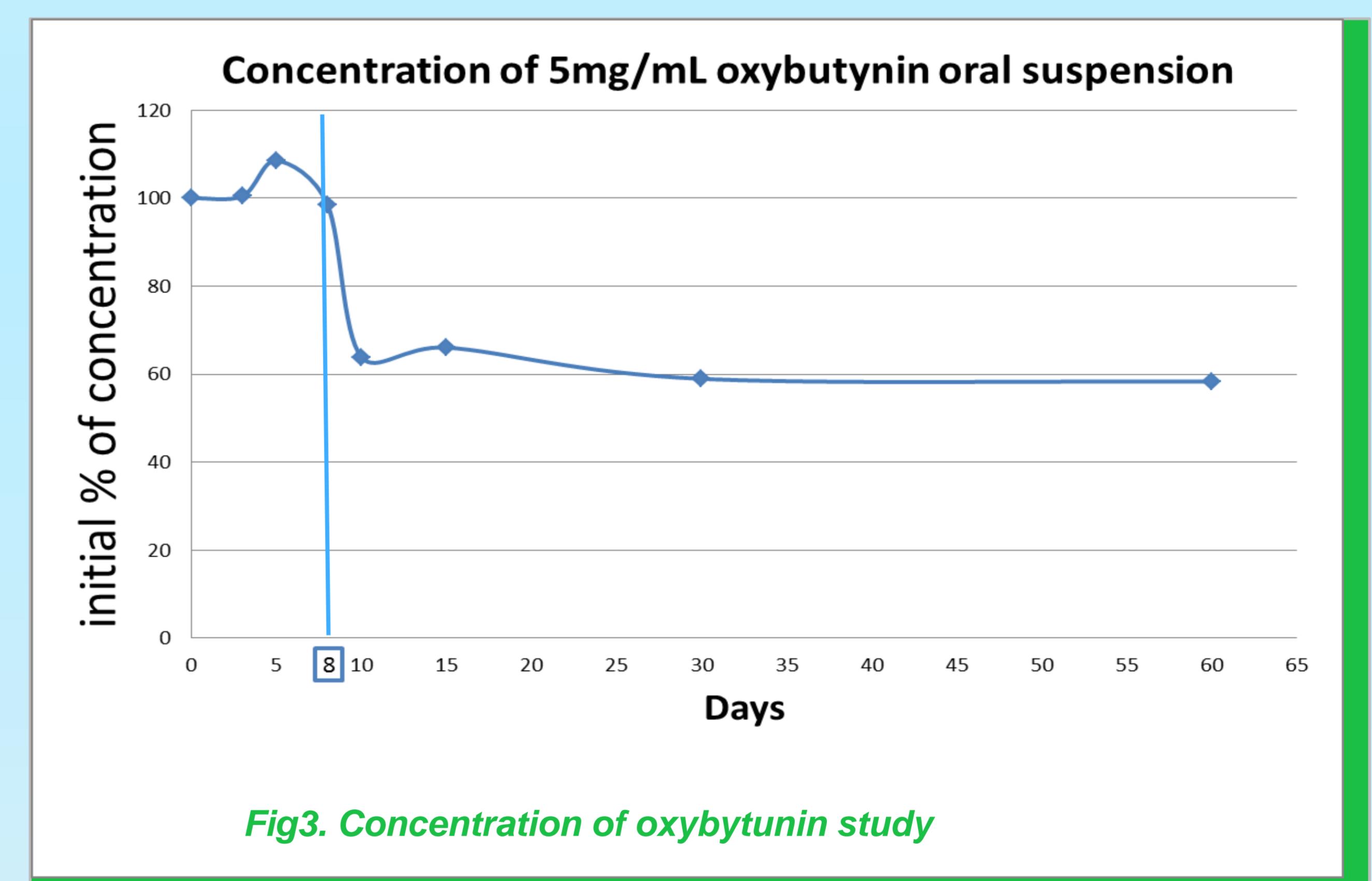


Fig3. Concentration of oxybutynin study

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 solvents of HPLC could influence stability of oxybutynin.

Further studies will be conducted such as forced degradation study.