

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

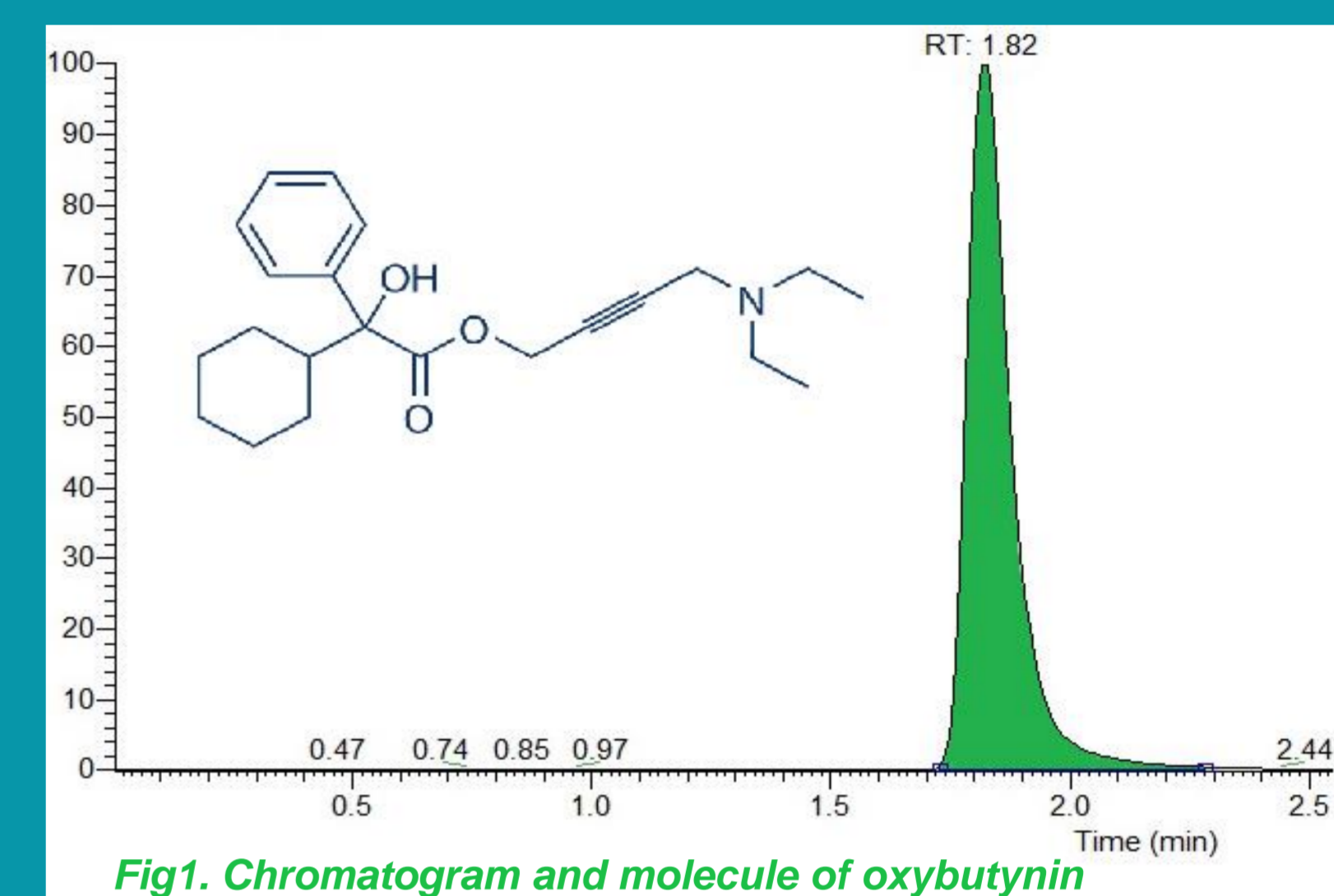
Accela pump with a Thermo Fisher C18 Accucore column (100 x 2.1 mm, 2.6µM)

Gradient of 10mM ammonium acetate buffer and 0.1% (v/v) acetonitrile with 0.1% (v/v) formic acid

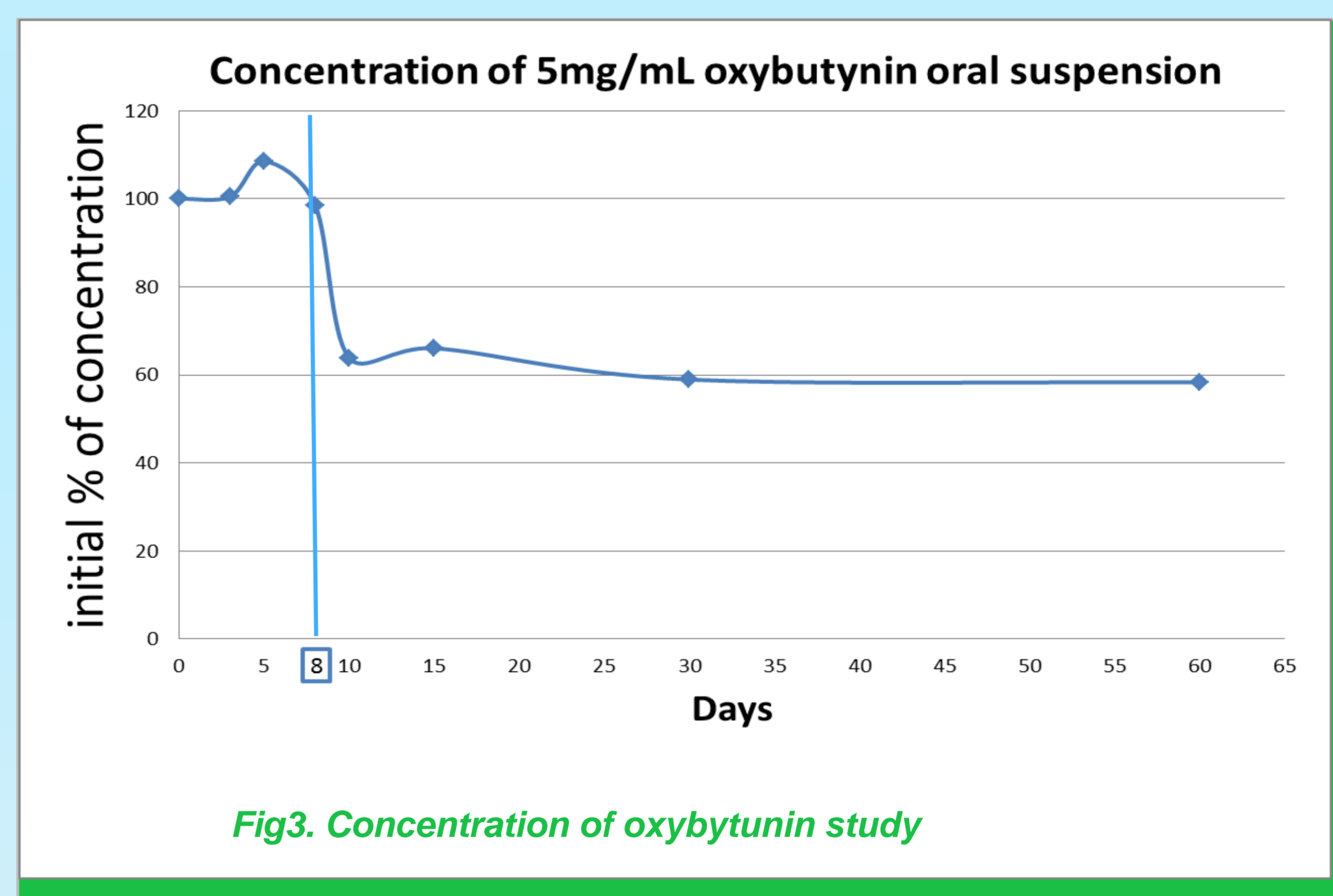
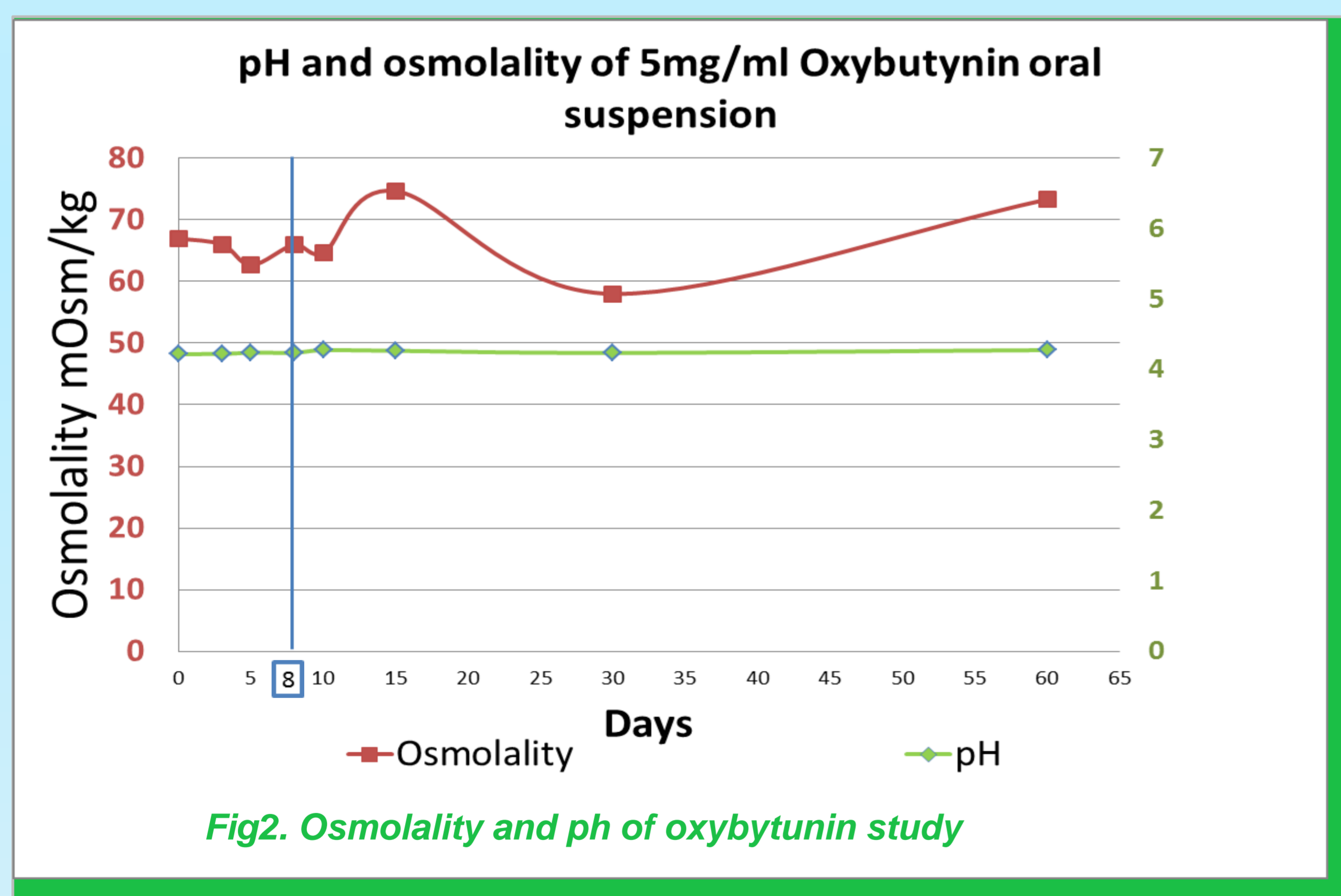
Data acquired in : Targeted Single Ion Monitoring (t-SIM) mode

Sample dilution ¹/_{1.000.000}

Measurement by extracting the mass value of protonated oxybutynin (358.2376 m/z) using 5 ppm mass window



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 solvents of HPLC could influence stability of oxybutynin.

Further studies will be conducted such as forced degradation study.