

# LONG-TERM STABILITY OF A READY-TO-USE TOPICAL ANAESTHETIC GEL KIT

E. DIJKERS<sup>1</sup>, H. POLONINI<sup>2</sup>, A. FERREIRA<sup>2</sup>, C. ZANDER<sup>3</sup>

<sup>1</sup>GLOBAL INNOVATION PROJECT MANAGER, FAGRON BV, ROTTERDAM, THE NETHERLANDS.

<sup>2</sup>ORTOFARMA ANALYTICAL SERVICES, MATIAS BARBOSA, BRAZIL.

<sup>3</sup>FAGRON INC, SAINT PAUL, USA.

## Conclusion

LETS GEL KIT™ showed excellent stability at both controlled refrigerated (2-8 °C) and room temperature (15-25 °C) for up to 150 days.

Prefilled compounded syringes using LETS GEL KIT™ can be a valuable alternative when commercial medication is not suitable or available.

## Introduction

Undergoing small surgery, aesthetic procedures or needle injections can be stressful, especially for paediatric patients.

Various local anaesthetics have therefore been developed to numb the skin, including commercially available medication.

Unfortunately, shortage of medicines, including for local anaesthetics remain a widespread and persistent problem.<sup>1</sup>

LETS - a solution of Lidocaine Hydrochloride, Epinephrine Bitartrate, Tetracaine Hydrochloride and Sodium Metabisulfite - has shown to be equal in providing and maintaining anaesthesia treating with up to 10-fold less systemic exposure.<sup>2,3</sup>

LETS GEL KIT™ is a ready-to-use kit developed by Fagron to compound a topical aesthetic gel to overcome this problem.

## Literature cited

1. WHO. WHO Drug Information. 2018;180-185.
2. Singer A. et al., LET versus EMLA for pre-treating lacerations: a randomized trial. Acad. Emerg. Med. 2001;223-230.
3. Oni G. et al., Comparison of Five Commonly-Available, Lidocaine-Containing Topical Anesthetics. J. Aesthetic Surg. 2012;495-450.

## Materials and methods

Aim of the study: to evaluate the chemical stability of the LETS GEL KIT™ when stored in syringes.

LETS GEL KIT™ contains lidocaine hydrochloride (4% w/w), epinephrine bitartrate (0.18% w/w), tetracaine hydrochloride (0.5% w/w) and sodium metabisulfite (0.075% w/w).

Samples were stored in plastic syringes (Comar, USA) at controlled refrigeration (2-8 °C) and controlled room temperature (20-25 °C).

Stability was assessed by assessing colour, odour and pH and by measuring the active content at varying time points (0, 30, 60, 90, 120 and 150 days) throughout a 150-day period.

API quantification was performed by validated, stability indicating, high-performance liquid chromatography (HPLC-UV).

## Results

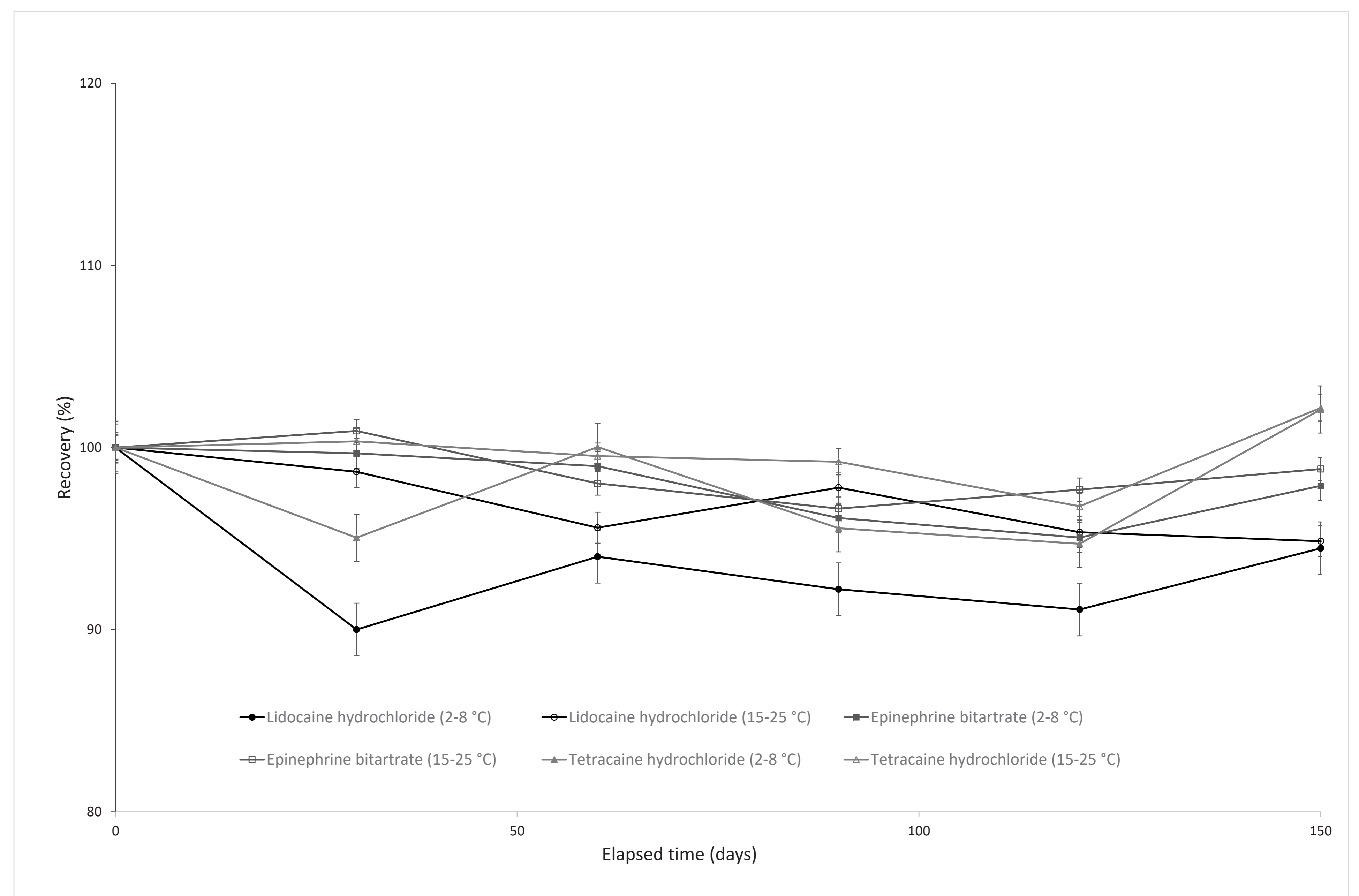
During validation of the HPLC method, all parameters were well within defined acceptance range.

Throughout the whole stability study, no phenomena as turbidity, macroscopically visible crystal growth or phase separation were observed.

Colour, odour and pH showed no significant change.

Drug content (in %) after 150 days were within the 90-110% of the declared content, for both refrigerated and room temperature

### LETS GEL kit stability



ATC N01 Anesthetics  
Abstract nr 3PC-027

### Further information

For further information, please contact  
eli.dijkers@fagron.com



**Fagron**  
personalizing  
medicine