Extended Application Note

Lidocaine

COGENT HPLC Columns™

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INTRODUCTION

Lidocaine is on the World Health Organization's List of Essential Medicines, as one of the most effective and safe medicines needed in a health system. It is used in the medical industry as a local numbing agent, treatment for heart arrhythmia and also for Epileptic seizures. An accurate and precise method is necessary in quantifying the API as well as verification for potential impurities in drug products. The current HPLC assay for the United States Pharmacopoeia uses a high percentage of an aqueous mobile phase with a pH adjusted to 3.4. This low pH can cause damages to the seals in HPLC instrumentation as well as a potential harmful solution to work with in laboratory settings. Also, the current sample solution of Lidocaine in the USP assay is a concentration of 1.7 mg/mL.

A customer used Cogent Diamond Hydride™ column for analyzing Lidocaine and had reported good retention of the compound, however the analyst noticed that peak height was below required 0.3 – 0.5 AU when 0.1 mg/mL lidocaine sample was injected, for both 2 µL and 10 µL injection volumes. In order to increase peak height the analyst prepared 0.5 mg/mL Lidocaine sample. When this sample was injected, peak distortion was observed.

In our lab we were able to solve both problems:

1. By changing the gradient profile we were able increase peak height for 0.1 mg/mL Lidocaine sample nearly 2-fold, achieving required 0.3 – 0.5 AU.

2. The analyst prepared 0.5 mg/mL sample in DI water. In our lab we prepared 0.5 mg/mL Lidocaine sample using in 80:20 Acetonitrile/DI water (recommended). This simple change in diluent for the sample was able to remedy peak distortion observed by customer.

Gradient 1:

A: DI H_2O + 0.1% TFA
B: Acetonitrile + 0.1% TFA

Time (min)	%B
0	95
5	10
6	10
7.2	95
10	95

Flow rate: 0.8 mL/min
Injection: 2 uL; 5 uL
Detection: UV 220 nm

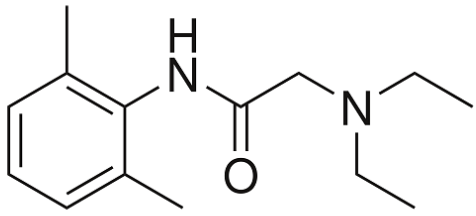
EXPERIMENTAL

Instrumentation

An Agilent (Little Falls, DE, USA) 1200SL Series LC system, including degasser, binary pump, temperature-controlled autosampler, and temperature-controlled column compartment was used.
A Cogent Diamond Hydride™ 4.6 x 75mm 4µm, 100Å column was used for this analysis.

Samples

Lidocaine samples were prepared from 1% Lidocaine HCl injection, USP 200 mg/20 mL (10 mg/mL, Lot: 92-073-DK, exp: 8/1/2020. Each mL contains lidocaine hydrochloride, anhydrous, 10 mg: sodium chloride 7mg: methylparaben 1 mg, pH: 6.5, Hospira Inc. Lake Forrest, IL 60045 USA.
A: 0.5 mg/mL Lidocaine* solution in 80:20 Acetonitrile/DI water
B: 0.5 mg/mL Lidocaine solution in DI water



Lidocaine

RESULTS AND DISCUSSION

By using the Cogent Diamond Hydride™ column, a rapid, sensitive, and reproducible method has been developed for analysis of this drug. The presented data (overlay of 5 injections) demonstrates how the compound can be effectively retained using ANP (Aqueous Normal Phase)-HPLC with both excellent peak shape, run-to-run repeatability, and great sensitivity using a simple gradient in ANP HPLC.

If longer analysis time is required, this can be achieved by a simple change in gradient profile.

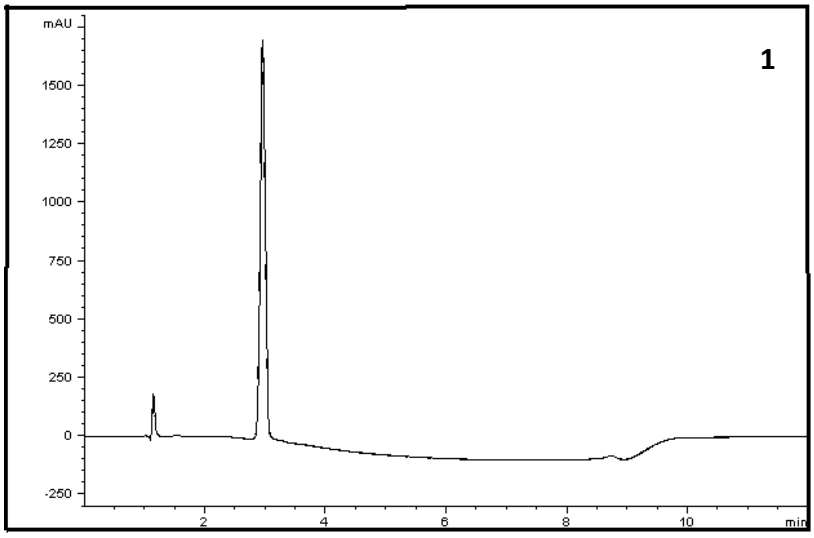


Figure 1:

Five overlaid 10 µL injections of 0.5 mg/ mL Lidocaine in ACN/ DI Water diluent.

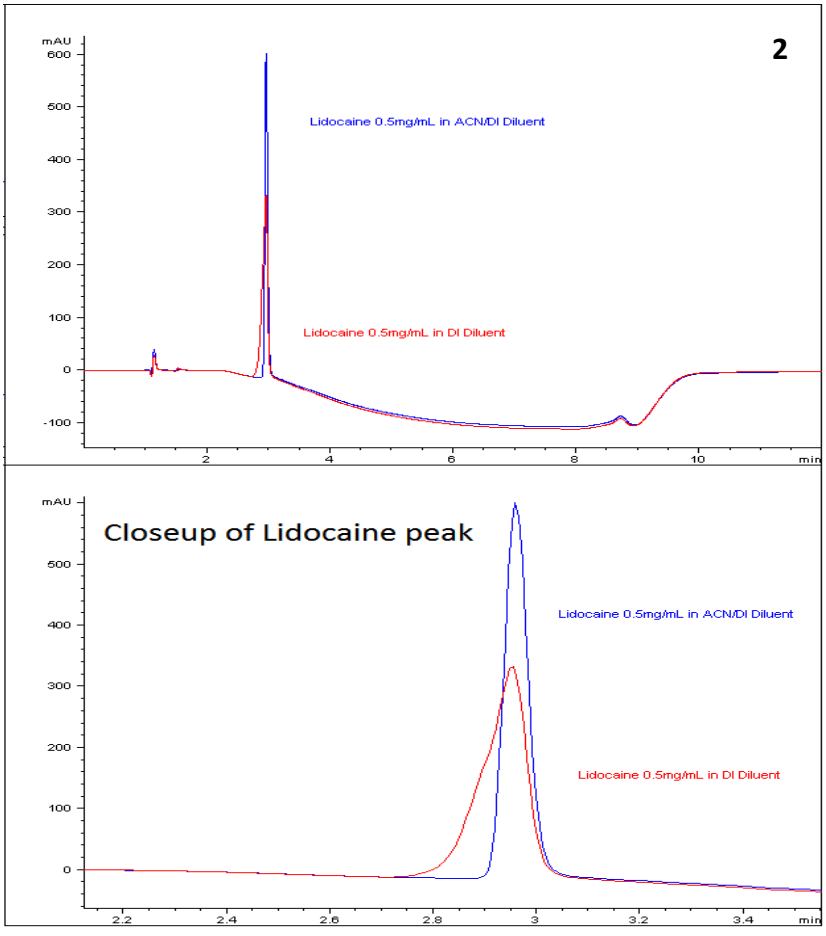


Figure 2:

Comparison of 2 µL injections of Lidocaine in DI Water diluent versus ACN/ DI Water Diluent.

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