An HPLC method to determine the stability of Lidocaine and Ketoprofen compounded individually, and in combination, with topical gel formulations.

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Introduction

- Drug self life is a regulatory requirement for pharmaceuticals and many other regulated consumer product.
- Self life of drug molecule is crucial to decide the dosing, potency uses and expiry of the specific drug.
- Here we choose lidocaine and ketoprofen formulated with PLO gel as a test drug (Provided by Maxima Pharmaceuticals Inc.), which is commonly used for pain management.
- Pluronic lecithin organogel (or PLO gel) cream base is used in compounding pharmacies to formulate various drug combinations, to meet patient-specific needs.

Methods

Sample Preparation

- PLO gel (Diffusimax and Diffusimax-10) mixed with Lidocaine and Diclofenac were measured out to approximately 100 mg in 50 mL tubes. To extract the drug molecules 1:1 mixture of acetonitrile and water added along with the internal standard. The tubes were then sonicated using a water bath sonicator for 15 minutes at room temp. The samples were vortexed for an additional 30 seconds and then centrifuged for 12 minutes at 1300 rpm. The supernatant was injected for HPLC analysis.

Analytical Methods

- Isocratic mobile phase of 50:50 acetonitrile: water at a flow rate of 2 ml/min were used. All the three drugs were detected using wave length of 210 nm with the oven temperature maintained at 30°C. Columns used were two C18 connected in series (Gemini 250 x 4.6 5 microns and Genesis 100 x 3.0 4 microns).

Results

- Fig 1: Representative HPLC chromatograms of Lidocaine and Ketoprofen with Diclofenac as a internal standard
- Fig 2: Standard calibration curve of Ketoprofen and Lidocaine ranging from 15 to 250 μg/ml in mobile phase
- Fig 3: Percentage recovery of Ketoprofen and Lidocaine ranging from pre mix PLO gel

Conclusions

Consistent absolute recovery of these drugs revealed the developed method is suitable to assay Lidocaine and Ketoprofen with PLO gel and may prove useful for other dosage forms, such as transdermal patches, ointments, etc.

References


Acknowledgment