

Probing characteristics of a controlled release delivery system on cardiac leads

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Introduction

Cardiac leads, which connect medical devices such as pacemakers and defibrillators to the heart, are used to monitor the heart's rhythm and provide therapy when needed. A drug delivery system is typically incorporated onto the distal end of cardiac leads to reduce inflammation and fibrosis at the lead-tissue interface and to enable optimal lead performance. Figure 1 depicts preclinical pacing threshold data with and without the incorporation of a steroid system. A detailed analysis of a dexamethasone acetate (DXA)/silicone rubber drug delivery system is reviewed.

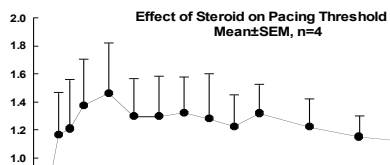


Figure 1. Anti-inflammatory controlled release system on distal end of cardiac leads can lower the acute and chronic pacing energy requirements

Methods

Drug release

In vitro drug elution is characterized at different time points using a release rate tester in combination with high performance liquid chromatography as shown in Figure 2.

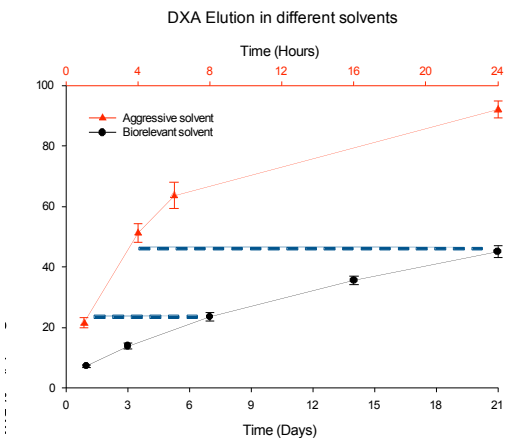


Figure 2. Steroid release profiles in different elution media.

Surface characterization

Confocal Raman microscopy is used to elucidate the spatial distribution of the steroid drug within the silicone rubber matrix as illustrated in Figure 3.

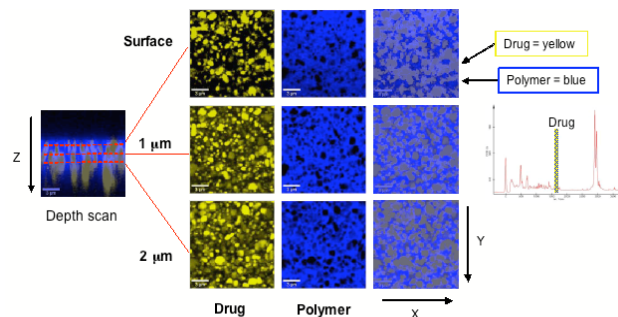


Figure 3. Confocal Raman microscopy reveals spatial drug distribution within a matrix.

Thermal analysis

Thermal analysis of the DXA active pharmaceutical ingredient from different vendors reveals information that correlate to observed release profile differences.

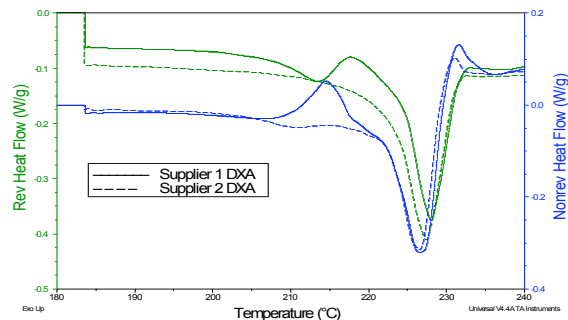


Figure 4. Modulated differential scanning calorimetry can reveal differences in raw drug characteristics that correlate to observed release profile differences.

Summary

The use of multiple techniques to assess drug delivery systems can provide insight into drug release mechanisms and related raw material properties to guide drug delivery design.