

# "RAPID METHOD FOR ASSESSING COMPOSITIONAL AND BATCH TO BATCH VARIABILITY OF HEPARIN" VCU# 08-02

## **Applications**

- Determines compos-itional differences in unfractionated heparin and LMWH
- Can be used at the point of manufacture or at the point of import entry
- Personalized anticoagulant treatments for patients

## **Advantages**

- · Fast and inexpensive method
- Does not require enzymatic deploymer-ization of heparin
- Fingerprints are highly reproducible

#### **Inventors**

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#### Contact

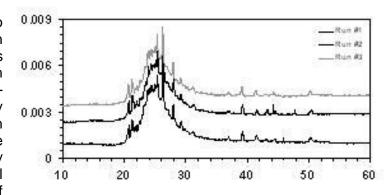
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#### **Market Need**

Heparin and other anticoagulation products have been plagued with significant quality control issues resulting in severe clinical problems including enhanced bleeding risk, adverse immunological reactions, patient-to-patient response variability, and frequent coagulation monitoring which all add to increase the cost to benefit ratio. Commonly used methods to fingerprint heparin such as size exclusion chromatography, mass spectrometry, and liquid chromatography are expensive and require extensive processing of the heparin. To decrease this cost to benefit ratio, an inexpensive and reproducible method for characterizing heparin products is needed.

## **Technology Summary**

This method is a simple and robust method to fingerprint both unfractionated heparin and LMWHs in the presence of optimized resolving reagents. This rapid method will directly address current problems in the heparin market of poly-dispersity, microheterogeneity, and method of preparation, by directly identifying an accurate fingerprint of the heparin product. Given the number of heparins that are currently approved by the FDA and the steady increase of foreign produced heparins this method will allow a quick and highly reproducible identification of



significant compositional differences, before any potential life-threatening product is introduced into a clinical setting.

## **Technology Status**

U.S. patent pending: 8,262,881Method has been validated on several commercially available forms of heparin.

This technology is available for licensing to industry for further development and commercialization.