



# FDA Update on Heparin Contamination

Ali Al-Hakim, Ph.D.

Branch Chief and Heparin Expert

**Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research  
Food and Drug Administration**

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# Quality of Heparin Sodium API

- All Heparin API batched should meet USP current specifications (absence of OSCS).
- Additional testing (beyond USP monograph) may be required to justify the presence of non-heparin peak/impurities in some heparin batches
- Implementation of Phase 2 testing on October 01 will improve the quality of heparin API.

# Inspection Activities

- cGMP Inspections of Heparin Manufacturing sites
  - Warning letters were issued to some manufacturers (*public information available on the Web*)

# Previous Progress

- Update of Heparin Monograph based on the constructive and successful collaboration between USP, FDA and other parties with respect to phase 1 and 2
- Updating the applications with respect to the revised USP Monograph
- Continue working with Heparin manufacturers regarding controlling the supplies and ensuring the safety, quality, purity and identity of the product

# Next stage

Further update of the Heparin Monograph to include:

- Modification and subsequent increase of the sensitivity of the H1-NMR method
- Modification of the impurities methods to improve the sensitivity of the detection limit for Proteins, Nucleic Acids and Lipids
- Introduce an Average Molecular Weight Method for heparin Sodium
- Labeling!

# Current/future Work

- Continue working to develop screening methods for other potential contaminants and/or impurities.
- Continue to work with international regulatory/licensing agencies and heparin manufacturers to assess quality throughout product life cycle and supply chains.
- Continue working with regulated industry to improve the quality of heparin drug product.