

# Application Note

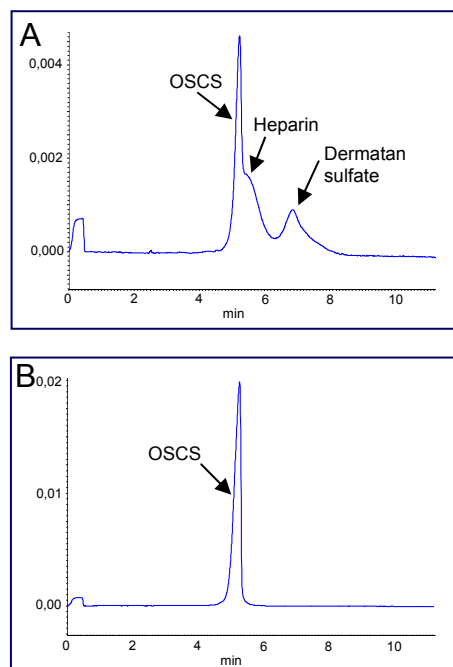
## Over Sulfated Chondroitin Sulfate (OSCS) Standard Identification of OSCS contamination in heparin

The occurrence of OSCS contaminated heparin sodium led to severe adverse events in the past. Ever since FDA and EDQM have asked companies manufacturing unfractionated and fractionated heparins containing drug substances to test these by capillary electrophoresis (CE) and  $^1\text{H}$  NMR spectroscopy. Nordmark GmbH & Co. KG as an established manufacturer of heparin sodium is also affected and developed an OSCS standard isolated from contaminated heparin sodium (SERVA Cat. No. 31254). This standard is suitable for identification of OSCS in unfractionated and fractionated heparins by CE,  $^1\text{H}$  NMR spectroscopy and other analytical methods.

### Features of SERVA OSCS Standard:

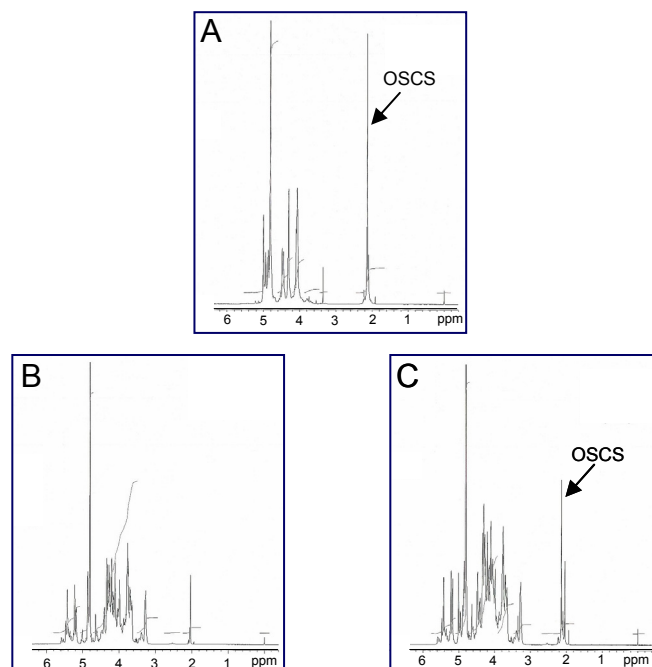
- Identification of OSCS impurity in unfractionated and fractionated heparin
- Highly purified from contaminated heparin sodium ( $\geq 95\%$ , based on CE)
- Applicable to Analytical Method Validation and System Suitability Test (SST)
- Bulk quantities for Process Validation available on request

### CE electropherogram of contaminated heparin sodium (A) and OSCS Standard (B)



**Fig. 1:** CE profiles of contaminated heparin sodium (A) and OSCS Standard isolated from contaminated heparin sodium (B). Sample volumes: 111 ng/run (A, B)

### $^1\text{H}$ NMR spectra of OSCS Standard (A), fractionated heparin (B) and fractionated heparin spiked with OSCS (C)



**Fig. 2:**  $^1\text{H}$  NMR spectra of OSCS Standard (A), non-contaminated fract. heparin (B) and non-contaminated fract. heparin spiked with OSCS Standard (C). Sample volumes: 6.2 mg/run (A); 20-25 mg/run (B, C)

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