

## Impurity Evaluation of Heparin Sodium by Capillary Electrophoresis

Instrument:	Hewlett Packard 3D-CE equipped with diode array detector or equivalent
Capillary:	Bare fused silica capillary, internal diameter 50 $\mu$ m 64.5cm-total length, 56cm-effective length
Column temp.:	25°C
Detection wavelength:	200nm (band width 10nm)
Polarity:	Negative
Voltage:	30 kV
Injection:	50 mbar pressure for 10 seconds
Filter:	Cellulose acetate membrane filters (0.22 $\mu$ m)
Separation Time:	15 minutes
Electrolyte:	36mM Phosphate buffer (pH 3.5): Transfer 1.0g of monobasic sodium phosphate, monohydrate to a beaker and add 195mL of Milli-Q water. Adjust pH with phosphoric acid to pH 3.5. Transfer the solution into 200 mL volumetric flask and dilute to the volume with Milli-Q water. Filter the buffer with a membrane filter. It recommended to degas buffer before use.
Test solution:	Prepare a Heparin sample concentration of approximately 10 mg/mL in Milli-Q water. Filter the sample solution.  Between each sample run, flush the capillary for 2 min. with filtered Milli-Q water and 2 min. with filtered electrolyte. Introduce the sample onto the capillary by hydrodynamic injection.
Specification:	The electropherogram of test solution does not exhibit a sharp distinguishable peak in front of the main heparin peak. The migration time of heparin in the test solution is about 5.7 min. See attached for examples.

### Reference:

1. Private communication, Baxter study number 41010
2. R.P. Patel, C. Narkowica, J.P. Hutchinson, E.F. Hilder, G.A. Jacobson, A simple CE method for the rapid separation and determination of intact low molecular weight and unfractionated heparins, *Journal of Pharmaceutical and Biomedical Analysis* 46 (2008) 30-35

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Figure 1: Electropherogram of a sample with an extra peak (“Fail”)

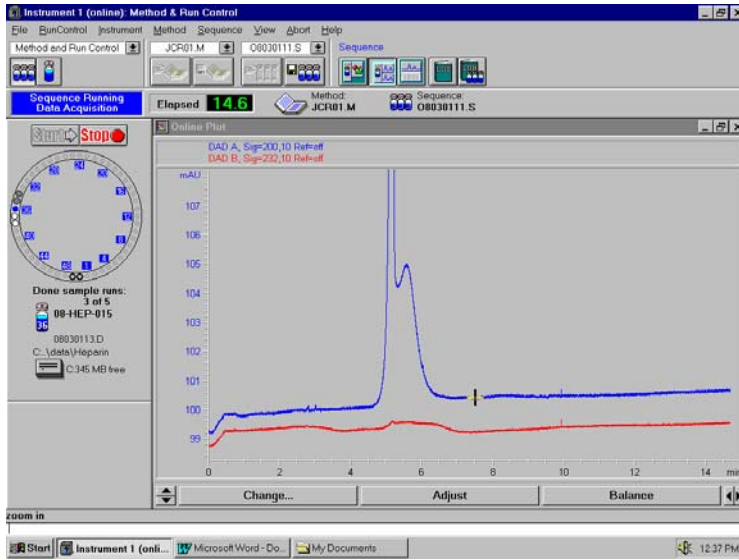
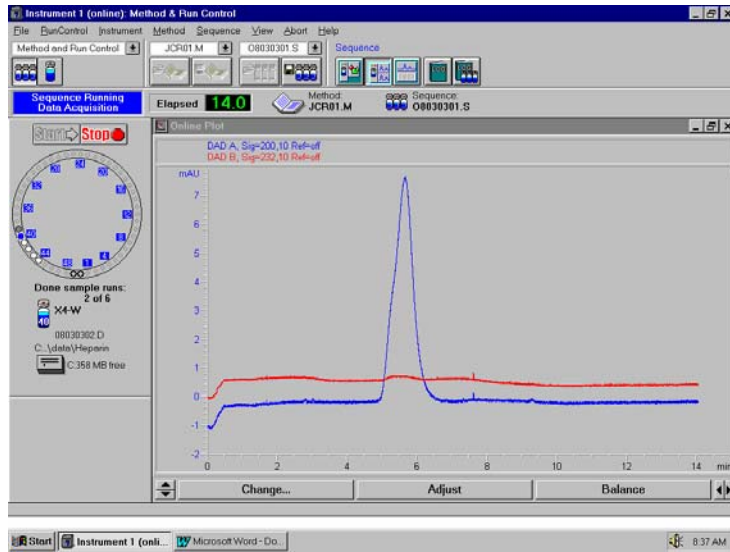


Figure 2: Electropherogram of control sample (“Pass”)



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