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A simple and rapid capillary zone electrophoresis method for determination of heparin in pharmaceutical products

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Background and Aims: The objective of the present study was development and validation of a simple and rapid method for determination of heparin in pharmaceutical products.
Methods: The separation was achieved by 50 µm i.d. 50 cm bare fused silica capillary with phosphate buffer 72 mM (pH = 3.5) at 35 °C. The applied voltage was set at -30 KV. Heparin was detected at 200 nm. The proposed method was validated in terms of linearity, accuracy, precision, limit of quantification (LOQ) and limit of detection (LOD).
Results: The results indicated that the method was linear in the range of 0.3 to 15 mg/ml, accurate (between 97.26% and 99.77%) and precise (RSD between 0.27% and 2.35%) with LOD of 78 microg/ml and LOQ of 312 microg/ml. The migration time of heparin was 2.39 ± 0.13 minutes. Heparin content in the pharmaceutical products was determined and the average assayed amount was 97.3 ± 2.3 % (n = 3), which is only 0.76 mg/ml deviated from the label claim.
Conclusions: In the present work, a rapid and simple capillary zone electrophoresis method, developed and validated in terms of linearity, precision and accuracy, for determination of heparin. The proposed method successfully used for quantification of heparin sodium in pharmaceutical samples and could be applied for quality control of heparin products in quality control laboratories.

Keywords: Heparin; Capillary zone electrophoresis; Pharmaceutical products