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Analytical and statistical comparability of generic enoxaparins from the US market with the originator product

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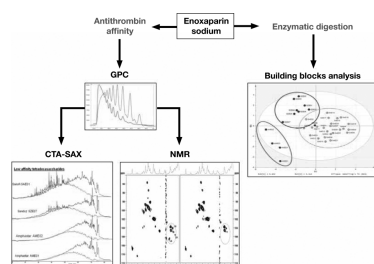
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Graphical abstract



Abbreviations

AT: antithrombin; ATIII: antithrombin III; BSA: bovine serum albumin; CNBr: cyanogen bromide; CTA: cetyltrimethylammonium; CZE: capillary zone electrophoresis; EMA: European Medicines Agency; FDA: US Food and Drug Administration; Gal: galactose; GlcA: glucuronic acid; GPC: gel permeation chromatography; HILIC: hydrophilic interaction liquid chromatography; HPLC: high-performance liquid chromatography; HSQC: heteronuclear single quantum correlation; LMWH: low-molecular-weight heparins; mAU: milliabsorbance units; MS: mass spectrometry; Mw: molecular weight; NIPALS: nonlinear iterative partial least squares; NMR: nuclear magnetic resonance; PLS-DA: partial least squares discriminant analysis; SAX: strong anion exchange; SD: standard deviation; Ser: serine; TPPI: time proportional phase incrementation; VIP: variable importance in the projection; Xyl: xylose.

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