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QUANTIFICATION OF TRANEXAMIC ACID IN HUMAN PLASMA: DEVELOPMENT AND VALIDATION OF UHPLC-MS/MS METHOD

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Tranexamic acid (TXA), an antifibrinolytic drug with the ability to inhibit lysine binding at plasminogen receptors, can be used in different settings such as trauma, cardiac surgery, major orthopedic surgery, obstetric when perioperative bleeding is concerned [1]. Effective methods for determination of TXA in biological samples are still required to understand the pharmacokinetics and pharmacodynamics of this drug in variable age groups undergoing surgeries with high blood loss [2].
The development and validation of a method based on ultra-high performance liquid chromatography coupled to triple quadrupole-tandem mass spectrometry (UHPLC-MS/MS) to quantify TXA in human plasma is described herein.
A simple, inexpensive and efficient sample treatment involving protein precipitation with acetonitrile containing 0.5% (v/v) formic acid was implemented using volumes within the microliter range. Separation was achieved using a hydrophilic interaction based stationary phase and ammonium bicarbonate in the mobile phase that permitted a more efficient separation of the analyte from the matrix interferences, thus reducing matrix effects and increasing method sensitivity.
The method was validated according to the European Medicines Agency guideline [3]. Excellent linearity was achieved (r^2 > 0.997) for TXA concentrations ranging from 30 to 600 ng mL^{-1} with LOD and LOQ of 3 and 6 ng mL^{-1} in plasma extracts, respectively. The developed method proved to be selective, sensitive, accurate (96.4-105.7% of nominal concentration values) and precise (RSD ≤ 4.5%).

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