METHOD DEVELOPMENT AND VALIDATION FOR QUANTIFICATION OF IMATINIB MESYLATE SPIKED *IN VITRO* SALIVA BY LC-MS/MS

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ABSTRACT

A novel, sensible, rapid, reliable and economical analytical hyphenated LC-MS/MS method has been developed as a key for the safety surveillance in chronic leukemia patients, and as a part of therapeutic drug monitoring of imatinib mesylate in human saliva. Imatinib mesylate or imatinib methane sulfonate is a tyrosine kinase inhibitor, apoptosis inducer and also known to be an anticoronaviral agent. Imatinib mesylate is a monomesylate salt of imatinib used for the treatment of gastrointestinal tumors and chronic myelogenous leukemia, and also in other complex malignancies. The λmax of imatinib mesylate was observed at 258 nm by UV spectrometry, establishing a very good linearity along with sensitivity. The detection limit (LOD) =0.2925 μg mL^{-1} and quantitation limit (LOQ)= 0.8977 μg mL^{-1} were obtained from the linear concentrations taken in the range of 2-12 μg mL^{-1}. The correlation coefficient (r^2) found was 0.999. The method validation parameters according to ICH Q2 (R1) were performed. The developed method described here, UPLC-MS/MS, was found to be novel, sensitive and rapid with improved results when successfully tested for human saliva samples without significant differences in the steady state imatinib mesylate concentrations. Current method could overcome the safety issues during therapeutic drug monitoring and pharmacokinetic behavior of the drug when tested clinically.