Submission Summary

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Paper Title
A SENSITIVE LC-MS/MS METHOD FOR QUANTITATIVE ESTIMATION OF DOLUTEGRAVIR IN HUMAN PLASMA

Abstract
A sensitive, precise Liquid chromatrography tandem mass spectroscopy method for quantitative estimation of Dolutegravir (DTG) in human plasma was developed and successfully validated. Dolutegravir belong to anti-retroviral class which is a integrase strand transfer inhibitor (INSTI) which blocks the functioning of HIV (Human Immuno Virus) integrase which is needed for viral replication. Dolutegravir and the Internal Standard Dolutegravir D6 was extracted from K3EDTA based Human Plasma samples by Solid Phase extraction procedure and processed samples were then subjected to analysis by Phenomenex Luna C18(2), 50×4.6 mm, 5µm column using Acetonitrile: Water (80:20 v/v) containing 0.1 mL of Formic Acid as Mobile Phase at a flow rate of 1.0000 ml/min with 80% flow splitting. The retention time of Dolutegravir and Dolutegravir D6 was found to be 0.60 minute and 0.59 minute respectively. The standard curve was linear (R2 > 0.99) over the concentration range of 28.44 ng/mL to 7054.37 ng/mL. All the bioanlaytical validation parameters were determined as per US FDA guidelines. The developed bioanalytical method was sensitive and reliable as sensitivity, selectivity, matrix effect and other method validation parameters were falls under the acceptance criteria as stated by guidelines. The peaks obtained for the Dolutegravir and Dolutegravir D6 were symmetrical in nature and well resolved from each other without any interferences from human plasma. The presented work provides a validated bioanalytical method for determination of Dolutegravir and it can be very useful for Bioavailability, and bioequivalence studies.

Keywords: LC-MS/MS, Dolutegravir, Solid phase extraction, Human plasma, etc.

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