Method Development and Validation of Methylprednisolone by LC-ESI-MS/MS in Human Plasma and its Application in BA/BE Studies

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Methylprednisolone is a synthetic glucocorticoid. It relieves inflammation. The present work is to develop an accurate, sensitive, rapid, precise and simple bioanalytical method for the estimation of Methylprednisolone in the human plasma. Used Internal Standard (IS) was Propranolol. The compound was identified and quantified using LC-ESI-MS/MS detection. The method was developed by gradient conditions using 0.1% Formic Acid in Milli-Q water and 0.1% Formic Acid in Methanol as mobile phase with 0.5 ml/min. flow rate. The Analyte and IS were separated by using a C18 Phenomenex Kinetex (50x3 mm, 5µ) column. The chromatographic run time 7.0 minutes. The plasma extraction is done by a simple protein precipitation technique (PPT). The method was very selective and sensitive. LOD was 6.25 ng/mL and LLOQ was 12.50 ng/mL. Linearity range between 12.25 ng/mL - 800 ng/Ml. Accuracy was between 86.42% to 109.16% and Precision was 1.89% to 9.78%. All stability data like Long term Stability, Short term Stability, Bench Top Stability, Autosampler Stability, Freeze thaw Stability, accuracy were between 85% to 115%. The developed method was found reproducible and very simple. The method was validated as per the EMA and USFDA guidelines. This method will be successfully applied for pharmacokinetic studies and as well as BA/BE studies

Key Words: Methylprednisolone, LC-ESI-MS/MS, Method Development and Validation, Application in BA/BE Studies.

Biography: I Mr. Dibya Das (M. Pharm), currently pursuing Ph.D. from JIS University, Kolkata, West Bengal, India. I have five years of research experience in the field of BA/BE studies at TAAB Biostudy Services Kolkata, West Bengal, India.