DEVELOPMENT AND VALIDATION OF BIOANALYTICAL METHOD FOR ESTIMATION OF LINEZOLID IN K3 EDTA HUMAN PLASMA BY USING HPLC-ESI-MS/MS.

Submitted By

Bhatt Manan Shailendra
Enrollment No. 112140813023

Supervised By

Ms. Jignasha Derasari

M. Pharm., Assistant Professor

Parul Institute of Pharmacy & Research
Parul Trust
Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

A rapid and sensitive liquid chromatography-tandem mass spectroscopy (LC-MS/MS) method for the determination of Linezolid in human plasma using Linezolid D8 as Internal Standard has been developed & validated, the analytical method consist of Solid Phase Extraction by using Orochem Cartridges. Samples were than analysed by HPLC on a column, Chromolith (5 µm, 100×4.6mm) using mobile phase consisting of Acetonitrile:5mM Ammonium Formate (85:15) delivered at 0.8mL/min with 85% of splitting. Detection was performed using an Applied Biosystem MDS SCIEX API 3000 mass spectrometer. Electron Spray Ionization was used for ion production. The assays were linear over the range 100 –24000 ng/mL with intra & inter day precision of 0.28 to 7.39%, accuracy in the range of 95.6 to 102.6% & mean recovery was 101.09%. The intended analyte is stable at below 10°C in all the preformed experiments and the stability experiments preformed are within the acceptance limits. This method can be used for quantification of Linezolid in human plasma for Bioequivalence studies.

Key words: Linezolid, HPLC-ESI-MS/MS, Bioanalytical Method Validation.