Purpose
To develop highly selective, sensitive, reproducible and rugged bioanalytical method for estimation of Linezolid, a "Reserve antibiotic" in human plasma and to validate the developed method according to US-FDA guideline.

Methods
Linezolid D8 was used as an Internal Standard for the determination of Linezolid in human plasma using a rapid and sensitive liquid chromatography-tandem mass spectroscopy (LC-MS/MS) method. The analytical method consists of Solid Phase Extraction by using Orochem Cartridges has been developed & validated. Samples were then analyzed 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. Mass spectrometry detection was carried out with an Applied Bio system MDS SCIEX API 3000 triple quadrupole mass spectrometer equipped with a Turbo Ion Spray as LC/MS interface. ESI mass spectra were acquired in positive ion mode with multiple reaction monitoring.

Results
There was no matrix interference across the elution windows, [% variability was 5.31% that was ≤15%] indicating the specificity of the method. Acceptable intraday and interday assay precision of 0.28 to 7.39% (<5% CV) and accuracy in the range of 95.6 to 102.6% (<10% diff.) were observed over a linear range of 100-24000 ng/mL. The mean (n=3) correlation coefficients was 0.9996 & mean recovery was 101.09%. The %CV of the area ratio was 1.50 %, retention time for drug was 0.11 % and for internal standard was 0.08% which indicated system suitability.

Conclusion
The intended analyte is stable at below 10°C in all the performed experiments and the stability experiments performed are within the acceptance limits. This method can be used for quantification of Linezolid in human plasma for Bioequivalence studies.