

d. Long Term Stability at -30° C

The storage time in a long-term stability evaluation should exceed the time between the date of first sample collection and the date of last sample analysis. Long-term stability was determined by storing three samples with concentrations {(QC Low: 150, QC Mid: 4000, and QC High: 6000) ng/ml} at -30 °C.

The concentrations of all the stability samples were compared to the mean of back-calculated values for the standards from the first day of long-term stability testing.

There should be not more than 15% decrease in the analytical results.

e. Drug and Internal Standard Stock Solution Stability:

The stock solutions stability of drug and the internal standard were evaluated at zero time, then at room temperature after 24 hours, then in refrigerator for 4 weeks. Stability was tested by comparing the instrument response with that of freshly prepared solutions. All analysis was done in six samples. The Stock solution sample was diluted before analysis to eventually have 800 ng /ml for the drug and 24000 ng /ml for the internal standard.