



RESIDUAL SOLVENTS METHOD LIMIT OF QUANTIFICATION – METHANOL IN HEPES

BSI-PRL-0353, Analytical Method Validation Protocol: Residual Solvents USP 1467 HEPES – Methanol, was executed and is still pending the completion of the method validation report. This memo will serve as an interim report to document the Method Limit of Quantitation to support batch release for the HEPE-3250 product code. The manufacturing process for HEPES does not utilize Methanol as the solvent in the process. The Method limit of Quantitation was found to be 1,500 ppm based on the data from the protocol execution. All results, until the report is completed, will be reported as <3,000ppm.