APPENDIX 16.1.9

DOCUMENTATION OF STATISTICAL METHODS

STATISTICAL ANALYSIS

Primaquine

The statistical analysis was performed using SAS® statistical software (Version: 9.4; SAS Institute Inc., USA). The SAS PROC GLM procedure was used for the analysis of variance. The study power calculations and the 90% confidence interval calculations were based on the least-squares means values generated by the SAS LSMEANS option to the SAS PROC GLM procedure and the standard error of the estimate as given by the PROC GLM procedure.

Ln-transformed data of Cmax, AUC72 and AUCt were evaluated statistically using the PROC GLM from SAS® for difference due to treatment, period, sequence and subject(sequence) as fixed effects.

Treatment and period were tested using Mean Square Error and Sequence was tested using Subject (sequence) as the error term at 5% level of significance.

Bioequivalence criteria: The 90% confidence interval of the relative mean (geometric least square mean) of the test to reference product for Ln-transformed Pharmacokinetic parameters Cmax, and AUCt was to be within 80.00% to 125.00% to establish bioequivalence for Primaquine.

Data of inactive metabolite of Carboxyprimaquine was to be provided as supportive data.

Please refer Appendix 16.2.6 for,

16.2.6.1 Statistical analysis results of individual subject's pharmacokinetic data with descriptive statistics, ANOVA tables, LS means, Geometric means, ratio and confidence interval for Primaquine.

16.2.6.2 Statistical analysis results of individual subject's pharmacokinetic data with descriptive statistics, ANOVA tables, LS means, Geometric means, ratio and confidence interval for Carboxyprimaquine.

16.2.6.3 Concentration vs. time Linear and Semi-logarithmic Plots of Mean and Individual Subjects for Primaquine.

16.2.6.4 Concentration vs. time Linear and Semi-logarithmic Plots of Mean and Individual Subjects for Carboxyprimaquine.