Safety Evaluation

Screening subject No. 6 had abnormal value for laboratory serum glutamic pyruvic transaminase (SGPT) liver enzyme of 60 U/L where the normal value is up to 40 U/L

Brief summary of adverse events experienced during the study:

- Subject No. 4 experienced nausea post drug administration but fully recovered after 35 minutes, no action was needed.
- Subject No. 6 experienced abdominal pain post drug administration but fully recovered after 55 minutes, no action was needed.

Method of Analysis Validation Data

Validation of the analytical method was performed in order to evaluate the method in terms of recovery, linearity of response, accuracy, precision, sensitivity, stability and specificity. The validation was performed on three separate days with a seven point standard line (not including zero) on each day. Each day of validation included plasma samples representing ten Q.C.s of each level {(QC Low: 150, QC Mid: 4000, and QC High: 6000) ng/ml}.

Recovery

The extent of recovery for rhein plasma concentrations of {(QC Low: 150, QC Mid: 4000, and QC High: 6000) ng/ml} prepared in triplicate and candesartan cilexetil were consistent, precise, and reproducible.