6.0 SUMMARY AND CONCLUSION

The present study was undertaken to establish the bioequivalence between Esomeprazole magnesium for delayed release oral suspension (containing Esomeprazole 40 mg) of Ranbaxy Laboratories Limited and NEXIUM® 40 mg (esomeprazole magnesium) for delayed-release oral suspension (containing esomeprazole 40 mg) of AstraZeneca LP. The study was conducted as an open label, balanced, randomized, two-treatment, two-period, two-sequence, single dose, crossover, bioavailability study in healthy, adult, human male subjects under fasting condition.

The protocol and the corresponding informed consent form (ICF) used to obtain informed consent of study subjects were reviewed by the Jamia Hamdard Institutional Review Board. This research was carried out in accordance with the Basic Principles defined in US 21 CFR Part 320, the ICH (62FR 25692) 'Guidance for Good Clinical Practice', ICMR 'ethical guidelines for biomedical research on human participants (2006)', CDSCO 'Guidance on Good Clinical Practices for Clinical Research in India' and the principles enunciated in the Declaration of Helsinki (WMA General Assembly, Seoul 2008) respectively. The standard SOP’s of the clinical pharmacology unit (CPU) and Clinical Pharmacology and Pharmacokinetics (CPP), Ranbaxy have been adhered to in the clinical, analytical, pharmacokinetic and statistical analysis.

A high performance liquid chromatographic method, validated in terms of selectivity, linearity, sensitivity, accuracy and precision, was used for the estimation of Esomeprazole in plasma. The standard curve was linear & coefficient of co-relation was found to be greater than 0.99 throughout the study.

The clinical phase was conducted as an open label, balanced, randomized, two treatment, two period, single dose crossover study in eighteen (18) healthy, adult, human, male subjects under fasting condition. Both the test and reference formulations were well tolerated by the study subjects. No adverse event was reported during the course of study.

Bioequivalence was assessed by measuring the pharmacokinetic parameters
namely $C_{\text{max}}$, $AUC_{0-t}$, $AUC_{0-24}$ and $AUC_{0-\infty}$ as laid down by the USFDA and DCGI guidelines.

The 90% confidence intervals for log transformed data for $C_{\text{max}}$, $AUC_{0-t}$, $AUC_{0-24}$ and $AUC_{0-\infty}$ for the test product vs. reference (T/R) were 102.58% (90.97%–115.67%), 96.86% (87.20%–107.60%), 96.94% (87.31%–107.63%) and 96.88% (87.29%–107.54%) respectively, which were within the FDA limits for establishing bioequivalence. Power of the test for $C_{\text{max}}$, $AUC_{0-t}$, and $AUC_{0-\infty}$ was found to be 86.11%, 93.41%, 93.58% and 93.70% respectively.

It can be concluded that BE studies can be used to demonstrate the systemic exposures and the concentration between two drugs and ensure comparable clinical outcomes.