4.0 SUMMARY AND CONCLUSION

4.1 Summary of Results

- For the log transformed Gabapentin data, the ratio and 90% confidence intervals around the least square mean ratio of the test to reference product were within the bioequivalence limit of 80% to 125% for primary pharmacokinetic parameters \( C_{\text{max}} \), \( \text{AUC}_{0-t} \) and \( \text{AUC}_{0-\infty} \) under both fasting and fed study.
- No Pre-dose concentration was detected for subjects in period I and II of both fasting and fed study.
- The drug was detected in plasma for 48.0 hours post dose. There were no sequence, period and formulation effect was observed for \( C_{\text{max}} \), \( \text{AUC}_{0-t} \) and \( \text{AUC}_{0-\infty} \) under both fasting and fed study.

4.2 Results of Gabapentin Fasting study

After oral administration;

- \( C_{\text{max}} \): The mean \( C_{\text{max}} \) obtained for Gabapentin in reference and test product was 3379.8912 ng/mL and 3423.3817 ng/mL respectively.
- \( \text{AUC}_{0-t} \): The mean area under the curve from zero to last measurable concentration for Gabapentin in reference and test product was 34305.2370 (ng/mL).hr and 34688.1346 (ng/mL).hr respectively.
- \( \text{AUC}_{0-\infty} \): The mean area under the curve from zero to infinity for Gabapentin in reference and test product was 35418.7432 (ng/mL).hr and 35904.6993 (ng/mL).hr respectively.
- The mean \( T_{1/2} \) for Gabapentin was 5.6396 hours for reference product and 5.7157 hours for test product.
- The mean \( K_e \) for Gabapentin was 0.1261 hrs\(^{-1}\) for reference product and 0.1232 hrs\(^{-1}\) for test product.
- The \( T_{\text{max}} \) was attained for Gabapentin at 3.2826 hour for reference product and at 3.0870 hour for test product.
- The \( T/R \) ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for \( C_{\text{max}} \) (as a measure of rate of absorption) for Gabapentin was found 101.38 %
(95.23-107.93%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

- The T/R ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for AUC$_{0-t}$ (as a measure of extent of absorption) for Gabapentin was found 101.57% (93.42-110.42%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

- The T/R ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for AUC$_{0-\infty}$ (as a measure of extent of absorption) for Gabapentin was found 101.67% (94.34-109.58%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

4.3 Results of Gabapentin Fed study

After oral administration,

- C$_{\text{max}}$: The mean C$_{\text{max}}$ obtained for Gabapentin in reference and test product was 3753.7626 ng/mL and 3836.5818 ng/mL respectively.

- AUC$_{0-t}$: The mean area under the curve from zero to last measurable concentration for Gabapentin in reference and test product was 39154.5004 (ng/mL).hr and 39987.1434 (ng/mL).hr respectively.

- AUC$_{0-\infty}$: The mean area under the curve from zero to infinity for Gabapentin in reference and test product was 40291.8999 (ng/mL).hr and 41170.0440 (ng/mL).hr respectively.

- The mean T$_{1/2}$ for Gabapentin was 5.7406 hours for reference product and 5.8595 hours for test product.

- The mean K$_{el}$ for Gabapentin was 0.1223 hrs$^{-1}$ for reference product and 0.1208 hrs$^{-1}$ for test product.

- The T$_{\text{max}}$ was attained for Gabapentin at 3.9891 hour for reference product and at 3.9239 hour for test product.

- The T/R ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for C$_{\text{max}}$ (as a measure of rate of absorption) for Gabapentin was found 102.93%
(99.86-106.09%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

- The T/R ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for $\text{AUC}_{0-t}$ (as a measure of extent of absorption) for Gabapentin was found 101.77% (98.31-105.35%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

- The T/R ratio of Least square geometric mean and the 90% confidence interval for Log (natural) transformed data for $\text{AUC}_{0-\infty}$ (as a measure of extent of absorption) for Gabapentin was found 101.78% (98.44-105.23%) which is within the bioequivalence range of 80%-125% for the log transformed data values.

4.4 Conclusion

The result of this study indicates that the test product Gabapentin capsules USP 400 mg of Alkem Laboratories Limited is bioequivalent to the reference product Neurontin® (Gabapentin Capsules USP 400 mg) of Pfizer, USA with respect to the rate and extent of absorption under both Fasting and Fed condition. Both the study formulations were found safe and well tolerated by all subjects in both the study. No AE and SAE were observed during the study.