A Comparative Bioavailability Study of
Two Ibuprofen Formulations after Single-dose Administration in Healthy Volunteers

This study was aimed to investigate the bioequivalence of ibuprofen 125 mg suppository formulation (Ibukal®, test formulation from PT. Kalbe Farma, Tbk., Jakarta) and the ibuprofen suppository comparative formulation (Proris®, from PT. Pharos Indonesia, Jakarta) in 12 healthy volunteers. The pharmacokinetic parameters used in this study were the area under the concentration-time curve from time zero to hour 10 (AUC0-10), the area under the concentration-time curve from time zero to infinite (AUC0-inf), the maximum concentration (Cmax), and the time needed to reach the maximum concentration (tmax). The study was designed as a random cross-over fashion, single-blinded which included 12 healthy adult volunteers. The volunteers were fasted overnight and in the morning they received a suppository of the test drug (Ibukal®) or a suppository of the comparative drug (Proris®). Blood samples were withdrawn on hour 0 (control), 20 min; 40 min; 1; 1.5; 2; 2.5; 3; 4; 6; 8; and 10 time points after the administration of the drug. Following a wash-out period of 1 week, this procedure was repeated using the other drug. The serum concentration of the drug was determined by means of high-performance liquid chromatography with ultraviolet detection. The results of the study showed that, the mean (SD) of AUCo-1 AUCO-inf Cmax and tmax of the test drug were, respectively, 28.59(3.37) ug.h.mL⁻¹, 30.47(3.56) ug.h.mL⁻¹, 8.24(1.44)ug/mL, and 1.33(0.44) h. The mean (SD) of AUCo-1, AUC-inf Cmaxr and tmax of the comparative drug were, respectively, 28.13(8.14) ug.h.mL⁻¹, 30.56(8.05) ug.h.mL⁻¹, 8.27(2.88) ug/mL, and 1.79(0.33) h. The geometric means ratio of the test to the comparative drug were 104.38% (CI 90%: 90.38-120.54 %) for AUC0-1, 101.97% (CI 90%: 89.51-116.16%) for AUC0-inf and 104.02% (CI 90%: 85.73-126.16%) for Cmax. There was no side effect of the drug detected in this study. From the results we can conclude that the 125 mg of ibuprofen suppository of PT Kalbe Farina, Tbk. (Ibukal®) is bioequivalent to that of the comparative drug(Proris®).

Keywords: ibuprofen suppository, high-performance liquid chromatography, bioequivalence