Thesis Title	Pharmacokinetics of Betacarotene in Healthy Thai Volunteers
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ABSTRACT

Betacarotene, a major source of vitamin A, was recently introduced in the market but there has been no report of clinical trial for evaluation of its pharmacokinetics in Thai people. The present study was performed to investigate for one-day and ten-day serum level and pharmacokinetic parameters in healthy Thai volunteers after single oral administration of 15- and 30-mg betacarotene.

Twenty healthy Thai volunteers, 11 males and 9 females, participated in the study. The amount and type of food taken during 7 days before drug administration were recorded. On the study day, after fasting for a minimum of 8 hours, a single dose of betacarotene, 15 or 30 mg, was orally administered to subjects followed by 200 mL of water and prepared breakfast containing 45% of fat. Five mL of blood were drawn at 0, 0.5, 1.0, 1.5, 3.0, 4.5, 6.0, 7.5, 9.0, 12.0 and 24.0 hours after betacarotene administration for the one-day study. Only 6 subjects (3 males, 3 females) re-participated in the study in which blood samples were taken at 0, 6 hours and every 24 hours until 10 days after betacarotene administration. All serum samples were analysed for betacarotene by high performance liquid chromatography.

The results showed mean ± SEM baseline betacarotene serum concentration of 20 subjects to be 256.03 ± 18.72 ng/mL after habitual diet and daily betacarotene intake to be 3.31± 0.45 mg. The one-day study showed the mean ± SEM $AUC_{0\text{-}24hr}$ to be 794.36 ± 230.34 and 1,402.11 ± 257.41 ng·hr/mL for 15- and 30-mg dose, respectively. The ten-day study of betacarotene serum level after the administration of single dose of 15-mg betacarotene revealed the mean ± SEM values of adjusted C_{max} was 40.39 ± 7.46 ng/mL, T_{max} was 41.13 ± 4.18 hr, $AUC_{0\text{-}96hr}$ was 2,262.00 ± 523.44 ng·hr/mL, $T_{1/2}$ was 131.20 ± 41.44 hr, K_a was 0.0233 ± 0.0044 hr^{-1}, K_e was 0.0074 ± 0.0017 hr^{-1} and $T_{\rightarrow Co}$ was 112.14 ± 11.99 hr. The 30-mg betacarotene single dose with 10 days of follow-up of the betacarotene serum level resulted in the mean ± SEM values of adjusted C_{max} was 81.61 ± 21.44 ng/mL, T_{max} was 45.57 ± 8.53 hr, $AUC_{0\text{-}96hr}$ was 5,724.02 ± 1,688.98 ng·hr/mL, $AUC_{0\text{-}240hr}$ was 9,833.97 ± 3,812.83 ng·hr/mL, $T_{1/2}$ 230.40 ± 80.91 hr, K_a was 0.0531 ± 0.0118 hr^{-1}, K_e was 0.0047 ± 0.0011 hr^{-1} and $T_{\rightarrow Co}$ was 191.06 ± 29.03 hr. The differences in these pharmacokinetic parameters were not significantly different according to different doses, except for $AUC_{0\text{-}24hr}$ and $T_{\rightarrow Co}$.

It was concluded that 15-mg betacarotene gave nonsignificant difference in betacarotene serum level and most of pharmacokinetic values when compared to 30-mg dose.