

# Formulasi sediaan transdermal gel glukosamin menggunakan enhancer serta uji penetrasi perkutan *in vitro* dan uji ketersediaan hayati *in vivo* pendahuluan pada manusia = Transdermal formulation of glucosamine gel using skin penetration enhancer and *in vitro* penetration study and *in vivo* preliminary bioavailability study in human

Zuliar Permana, author

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## Abstrak

Telah dikembangkan formulasi sediaan transdermal gel glukosamin yang menggunakan senyawa *enhancer*: etanol, propilen glikol, dan gliserin. Kemampuan penetrasi perkutan formulasi sediaan tersebut dievaluasi dengan uji penetrasi perkutan *in vitro* menggunakan sel difusi Franz melalui penambahan 1 g sediaan gel glukosamin 1% ke dalam kompartemen donor dan uji ketersediaan hayati *in vivo* pendahuluan menggunakan seorang subyek manusia sehat melalui aplikasi selama 10 jam dosis tunggal 10 g sediaan gel glukosamin 1% di kedua lututnya. Jumlah kumulatif glukosamin yang terpenetrasi dari formula kontrol, formula I (etanol 3%), formula II (etanol 5%), formula III (propilen glikol 1%), formula IV (propilen glikol 3%), formula V (gliserin 1%), dan formula VI (gliserin 3%) setelah 180 menit secara berturut-turut adalah sebanyak  $76,4836 \pm 2,3479$ ;  $417,8439 \pm 18,9042$ ;  $583,1494 \pm 5,9162$ ;  $152,1894 \pm 1,5184$ ;  $515,1065 \pm 14,0069$ ;  $83,0822 \pm 0,0364$ ; dan  $478,6089 \pm 3,7406$   $\mu\text{g.cm}^{-2}$ . Laju penetrasi atau fluks rata-rata glukosamin dari formula kontrol, formula I, formula II, formula III, formula IV, formula V, dan formula VI selama 180 menit secara berturut-turut adalah  $24,4453$ ;  $123,608$ ;  $167,5478$ ;  $47,0377$ ;  $164,603$ ;  $28,7548$ ; dan  $139,3895$   $\mu\text{g.cm}^{-2}.\text{jam}^{-1}$ . Waktu laten dari formula kontrol, formula I, formula II, formula III, formula IV, formula V, dan formula VI secara berturut-turut adalah 13,89; 10,24; 9,75; 13,05; 10,04; 13,51 menit, dan tidak dapat diekstrapolasikan. Profil ketersediaan hayati menunjukkan  $C_{\text{maks}}$ ,  $t_{\text{maks}}$ , dan  $\text{AUC}_{0-10}$  dari formula II dan formula kontrol secara berturut-turut adalah  $310,56$   $\text{ng.mL}^{-1}.\text{jam}$ , jam ke-5, dan  $2079,85$   $\text{ng.mL}^{-1}.\text{jam}$ ;  $285,79$   $\text{ng.mL}^{-1}.\text{jam}$ , jam ke-5, dan  $1921,65$   $\text{ng.mL}^{-1}.\text{jam}$ .

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A transdermal formulation of glucosamine gel using skin penetration enhancers, i.e. ethanol, propylene glycol, and glycerin had been developed. Penetration ability of the formulation was evaluated by *in vitro* penetration study using Franz diffusion cell with 1 g glucosamine gel 1% applied into the donor compartment and *in vivo* preliminary bioavailability study of a healthy male subject received a single dose of 10 g glucosamine gel 1% on both knees as long as 10-hour applications. Cumulative amount of glucosamine penetrated from control, formula I (ethanol 3%), formula II (ethanol 5%), formula III (propylene glycol 1%), formula IV (propylene glycol 3%), formula V (glycerin 1%), and formula VI (glycerin 3%) after 180 minutes penetration study were  $76.4836 \pm 2.3479$ ;  $417.8439 \pm 18.9042$ ;  $583.1494 \pm 5.9162$ ;  $152.1894 \pm 1.5184$ ;  $515.1065 \pm 14.0069$ ;  $83.0822 \pm 0.0364$ ; and  $478.6089 \pm 3.7406$   $\mu\text{g.cm}^{-2}$  respectively. Mean flux of glucosamine from control, formula I, formula II, formula III, formula IV, formula V, and formula VI within 180 minutes were  $24.4453$ ;  $123.608$ ;  $167.5478$ ;  $47.0377$ ;  $164.603$ ;  $28.7548$ ; and  $139.3895$   $\mu\text{g.cm}^{-2}.\text{hour}^{-1}$  respectively. Lag time for steady-state of

control, formula I, formula II, formula III, formula IV, formula V, and formula VI were 13.89; 10.24; 9.75; 13.05; 10.04; 13.51 minutes, and unextrapolated one, respectively. The bioavailability profile showed the  $C_{max}$ ,  $t_{max}$ , and  $AUC_{0-10}$  of formula II and control were 310.56 ng.mL<sup>-1</sup>, 5 hours, and 2079.85 ng.mL<sup>-1</sup>.hour; 285.79 ng.mL<sup>-1</sup>, 5 hours, and 1921.65 ng.mL<sup>-1</sup>.hour respectively.