

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

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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_{maks} , t_{maks} , dan AUC_{0-10} dari formula II dan formula kontrol secara berturut-turut adalah $310,56$ $\text{ng.mL}^{-1}.\text{jam}$, $2079,85$ $\text{ng.mL}^{-1}.\text{jam}$; $285,79$ $\text{ng.mL}^{-1}.\text{jam}$, $285,79$ $\text{ng.mL}^{-1}.\text{jam}$, 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 ± 2.3479 ; 417.8439 ± 18.9042 ; 583.1494 ± 5.9162 ; 152.1894 ± 1.5184 ; 515.1065 ± 14.0069 ; 83.0822 ± 0.0364 ; and 478.6089 ± 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⁻¹, 5 hours, and 2079.85 ng.mL⁻¹.hour; 285.79 ng.mL⁻¹, 5 hours, and 1921.65 ng.mL⁻¹.hour respectively.