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

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 ± 2,3479; 417,8439 ± 18,9042; 583,1494 ± 5,9162; 152,1894 ± 1,5184; 515,1065 ± 14,0069; 83,0822 ± 0,0364; dan 478,6089 ± 3,7406 µg.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 µg.cm⁻².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 AUC₀₋₁₀ dari formula II dan formula kontrol secara berturut-turut adalah 310,56 ng.mL⁻¹, jam ke-5, dan 2079,85 ng.mL⁻¹.jam; 285,79 ng.mL⁻¹, jam ke-5, dan 1921,65 ng.mL⁻¹.jam.

.....

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 µg.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 µg.cm⁻².hour⁻¹respectively. 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_{ma}_x, t_{ma}_x, and AUC₀₋₁₀ 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.