

Pengembangan eksipien koproses amilosa tersambungsilang12 xanthan gum sebagai matriks dalam sediaan transdermal serta uji penetrasi in vitro dan in vivo = Development of co processed excipient of 12 crosslinked amylose xanthan gum as transdermal hidrogel matrix and the in vitro in vivo penetration studies

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Abstrak

Eksipien koproses amilosa tersambungsilang12- xanthan gum (Ko-CLA12-XG) 1:2 merupakan eksipien baru yang dimanfaatkan sebagai matriks dalam sediaan hidrogel transdermal. Rute transdermal mengantarkan obat melalui kulit dan masuk kedalam sirkulasi sistemik. Pada penelitian sebelumnya eksipien Ko- CLA12-XG 1:2 telah dikarakterisasi memiliki kekuatan gel yang besar.

Penelitian ini bertujuan untuk memformulasikan eksipien Ko-CLA12-XG 1:2 sebagai matriks dalam sediaan transdermal dan dievaluasi kemampuan penetrasinya secara in vitro dan in vivo. Uji penetrasi secara in vitro dilakukan dengan alat sel difusi Franz dengan menggunakan kulit abdomen tikus galur sprague-dawley selama 12 jam. Uji penetrasi in vivo dilakukan dengan mengaplikasikan sediaan pada abdomen tikus jantan galur sprague-dawley selama 12 jam kemudian plasma darah tikus dianalisis menggunakan kromatografi cair kinerja tinggi (KCKT).

Hasil uji penetrasi in vitro menunjukkan jumlah kumulatif dan persentase natrium diklofenak yang terpenetrasi adalah 6842 ± 467 g.cm⁻² dan $20,83 \pm 2,18\%$, serta didapatkan nilai fluks sebesar 569 ± 27 g.cm⁻².jam⁻¹. Selain itu hasil uji penetrasi in vivo menunjukkan kadar tertinggi natrium diklofenak dalam plasma adalah $4,87 \pm 1,06$ g.ml⁻¹ dan dicapai dalam waktu 1 jam serta AUC_{0-t} diperoleh sebesar $53,52 \pm 11,04$ g jam.ml⁻¹. Dari hasil keseluruhan dapat disimpulkan bahwa eksipien Ko-CLA12-XG dapat membentuk matriks pada sediaan hidrogel transdermal dan mampu menghantarkan natrium diklofenak masuk kedalam sirkulasi sistemik.

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In the previous study, it was reported that Co-CLA12-XG 1:2 excipient had good gel strength and had good swelling ability. Therefore, it could be used as matrix controlling drug delivery, such as on transdermal hydrogel formulation. Transdermal is a route of administration, which is designed to deliver drug through the skin to systemic circulation.

The aims of this study were to formulate Co-CLA12-XG 1:2 excipient as matrix on transdermal dosage forms and to study In vitro In vivo penetration abilities on delivering drug substances. In vitro penetration evaluation was carried on using Franz diffusion cell and the abdominal membrane rats for 12 hours. In vivo penetration evaluation was conducted on Sprague-Dawley strain male rats for 12 hours, then drug concentrations on plasma were analysed by high performance liquid chromatography.

The results showed that cummulative penetrated-drug was 6842 ± 467 g.cm⁻² or $20,83 \pm 2,18\%$, and

the flux of sodium diclofenac was $569 \pm 27 \text{ } \mu\text{g}\cdot\text{cm}^{-2}\cdot\text{hour}^{-1}$. The results of the in vivo studies showed that maximum plasma level and area under curve (AUC_{0-t}) of sodium diclofenac were $4,87 \pm 1,06 \text{ } \mu\text{g}\cdot\text{ml}^{-1}$ and $53,52 \pm 11,04 \text{ } \mu\text{g}\cdot\text{hour}\cdot\text{ml}^{-1}$, respectively. Based on the results, it can be concluded that Co-CLA12-XG 1:2 excipient could be applied as matrix on transdermal hydrogel formulation and deliver sodium diclofenac in to systemic circulation.