

Pengembangan Nanostructured Lipid Carrier Kalsitonin Salmon untuk Penghantaran Transdermal = Development of Nanostructured Lipid Carrier in Salmon Calcitonin for Transdermal Delivery

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Abstrak

Kemajuan pada bidang bioteknologi saat ini telah banyak memanfaatkan protein dan peptida sebagai agen terapeutik untuk berbagai macam penyakit. Salah satu protein peptida terapeutik yaitu kalsitonin salmon yang digunakan untuk mengobati hiperkalsemia pada penderita hiperparatiroid. Namun, dalam penghantarannya kalsitonin salmon masih memiliki kekurangan, seperti mudah terdegradasi oleh enzim pencernaan saat diberikan secara peroral dan ketidaknyamanan saat menggunakan kalsitonin injeksi maupun intranasal. Penghantaran transdermal menjadi salah satu alternatif yang dapat digunakan untuk menghantarkan kalsitonin salmon secara efektif. Pada penghantaran transdermal, kalsitonin salmon memiliki hambatan penetrasi seperti bobot molekul yang besar dan sifatnya yang hidrofilik, sehingga diperlukan formula yang tepat untuk menghantarkan kalsitonin salmon melalui rute transdermal seperti memformulasikannya dalam pembawa Nanostructured Lipid Carrier (NLC). Tujuan penelitian ini adalah untuk menghasilkan sediaan transdermal kalsitonin dalam pembawa NLC yang dapat meningkatkan penetrasi kalsitonin dan memenuhi persyaratan stabilitas. Enam formula NLC (F1-F6) dibuat dengan metode emulsi ganda dengan penguapan. Formula dikarakterisasi pada ukuran partikel, indeks polidispersitas, zeta potensial, efisiensi penjerapan, dan morfologi partikel. Kemudian, NLC kalsitonin salmon diformulasikan dalam pembawa emulgel. Emulgel NLC kalsitonin salmon dilakukan uji penetrasi in vitro dan studi stabilitas. Hasil penelitian ini menunjukkan formula NLC rasio 75:25 lipid padat dan lipid cair dengan konsentrasi kalsitonin salmon 0,04% (F3) merupakan formula optimal, dengan karakteristik ukuran partikel 135,6 nm, indeks polidispersitas 0,1, potensial zeta 34,7 mV, efisiensi penjerapan 99,6%, dan morfologi menunjukkan vesikel berbentuk speris. Berdasarkan hasil uji penetrasi, emulgel NLC kalsitonin menghasilkan peningkatan lima kali lipat dibandingkan dengan emulgel kalsitonin non-NLC. Selain itu, studi stabilitas menggambarkan kadar kalsitonin setelah enam bulan masing-masing 46,09-68,59% dan 43,45-60,59% pada kondisi penyimpanan $5^{\circ}\pm 3^{\circ}\text{C}$ dan $25^{\circ}\pm 2^{\circ}\text{C}$ dengan kelembaban relatif $60\%\pm 5\%$.

.....Currently advances in biotechnology has been using proteins and peptides as therapeutic agents. One of therapeutics protein peptide is salmon calcitonin that is used to treat hypercalcemia in hyperparathyroid. However, calcitonin still has limitations in its delivery, such as being easily degraded by digestive enzymes when using perorally, and causing discomfort when using injectable or intranasal. Transdermal delivery is one of the alternative methods that can effectively deliver salmon calcitonin. In transdermal delivery, salmon calcitonin has obstacles to penetration such as hydrophilic and large molecular weight, thus an appropriate formula is needed to deliver through the transdermal route such as formulating in a Nanostructured Lipid Carrier (NLC) carrier system. The aim of this study was to produce calcitonin transdermal in NLC system that can increase the penetration and met the stability requirements. Six formulas of calcitonin NLC were prepared by the double emulsion-evaporation method, then all formulas were characterized in terms of particle size, polydispersity index, zeta potential, entrapment efficiency, and morphology. Salmon Calcitonin NLC were then formulated into NLC-based emulgel. Further, in vitro

penetration and stability of NLC calcitonin emulgel studies were conducted. The result showed that formula NLC using 75:25 ratio of solid lipid to liquid lipid with 0.04% drug concentration (F3) was optimal, with a particle size of 135.6 nm, an polydispersity index 0.1, the zeta potential of -34.7 mV, entrapment efficiency of 99.6%, and spherical vesicle morphology. According to the percutaneous penetration study, the NLC salmon calcitonin emulgel resulted in a fivefold enhancement compared to the non-NLC salmon calcitonin emulgel. Moreover, the stability study illustrated salmon calcitonin levels after six months were 46.09-60.95% and 43.45-68.59% at storage conditions of $5^{\circ}\pm 3^{\circ}\text{C}$ and $25^{\circ}\pm 2^{\circ}\text{C}$ with relative humidity $60\%\pm 5\%$, respectively.