Uji Stabilitas Fisik Sediaan Gel dan Emulgel yang Mengandung Zoledronat = Physical Stability Test of Zoledronate Gel and Emulgel

Eva Gracia Dameirisca, author

Abstrak

Latar Belakang: Zoledronat merupakan jenis obat bisfosfonat yang paling kuat dalam menghambat resorpsi tulang. Zoledronat terbukti dapat menghambat pergerakan gigi ortodonti dan memperkuat penjangkaran maksimum, pada studi hewan. Sebagian besar studi masih menggunakan obat zoledronat dalam bentuk injeksi. Sediaan topikal mulai dikembangkan untuk mengatasi permasalahan yang ditimbulkan melalui pemberian obat secara injeksi Gel dan emulsi gel (emulgel) merupakan jenis sediaan obat topikal semi padat. Uji stabilitas suatu produk farmasi perlu dilakukan untuk menilai kemampuan suatu formulasi dalam mempertahankan sifat dan karakteristiknya saat pengemasan selama periode penyimpanan dan penggunaan. Penelitian ini bertujuan untuk membandingkan stabilitas fisik gel dan emulgel zoledronat yang disimpan pada suhu ruang (28±2°C) dan akselerasi (40°C) selama 8 minggu pengamatan. Metode penelitian: Gel dan emulgel disimpan selama 8 minggu pada suhu 28±2°C dan 40°C. Parameter stabilitas fisik yang dilihat antara lain organoleptis, pH, daya sebar, viskositas dan ukuran globul emulgel. Evaluasi dilakukan pada hari pertama, minggu ke-2,4,6 dan 8. Hasil: Terdapat perbedaan bermakna secara statistik pada seluruh parameter antar sediaan gel dan emulgel pada setiap waktu pengamatan. Pada sediaan emulgel yang disimpan di suhu 28±2°C, tidak terdapat perbedaan bermakna pada parameter viskositas, daya sebar dan ukuran globul selama 8 minggu pengamatan. Pada sediaan gel yang disimpan pada suhu 28±2°C, terdapat perbedaan bermakna pada seluruh parameter selama 8 minggu pengamatan. Kesimpulan: Emulgel zoledronat yang disimpan pada suhu 28±2°C selama 8 minggu stabil menurut semua parameter-parameter fisik yang diuji, kecuali pH. Perubahan pada nilai pH masih dekat dengan kisaran normal pH pada rongga mulut. Selain itu, gel zoledronat yang disimpan pada suhu 28±2°C selama 8 minggu dapat disimpulkan tidak stabil.

.....Introduction: Zoledronate is the most potent bisphosphonate at inhibiting bone resorption. Zoledronate has been shown to inhibit orthodontic tooth movement and increase maximum anchorage in animal studies. Most studies are still using zoledronate in injectable form. The strategy to overcome problems associated with drug administration by injection is to develop zoledonate that can be administered topically. Gel and emulsion gel (emulgel) are a semi-solid drug preparation. Stability testing of pharmaceutical product must be done to evaluate the capability of a particular formulation to retain its properties and characteristics at the time of packaging throughout its period of storage and use. This study aims to compare the physical stability of zoledronat gel and emulgel stored in room temperature (28±2°C) and accelerated temperature (40°C) for eight weeks. Methods: Gel and emulgel were stored in room temperature (28±2°C) and accelerated temperature (40°C) for eight weeks. The physical stability parameters that were used in this study is organoleptic, pH, spreadability, viscosity and globule size diameter for emulgel preparation. Gel and emulgel were evaluated on the first day, 2nd week, 4th week, 6th week and 8th week. Results: There were statistically significant differences in all stability parameters, except pH, between gel and emulgel prepatations. For emulgel preparations that was stored in room temperature, there was no statistically

significant differences in viscosity, spreadability and globule size diameter during eight weeks of observation. For gel preparations that was stored in room temperature, there were significant differences in all stability parameters during eight week of observation. Conclusion: According to the parameters in physical stability test, except pH, zoledronate emulgel stable in room temperature (28±2°C) storage for eight week observation. The changes in pH values was near from normal pH range in oral cavity. Other than that, zoledronate gel was not stable in room temperature (28±2°C) storage for eight week observation.