Uji stabilitas fisik dan kadar obat sediaan gel emulsi zoledronate bisphosphonates dalam virgin coconut oil sebagai fase minyak = stability test of zoledronate bisphosphonate (ZOL) gel emulsion in virgin coconut oil (VCO) as an oil phase

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Abstrak

Pendahuluan: Hilangnya penjangkaran dan relaps pada perawatan ortodontik menjadi hal yang dapat menyebabkan kegagalan perawatan ortodonti dalam jangka panjang. Pemberian gel emulsi berbahan dasar minyak Zoledronate Bisphosphonate (ZOL) dan campuran Virgin Coconut Oil (VCO) secara topikal memiliki potensi meningkatkan apoptosis osteoklas sehingga dapat dipertimbangkan sebagai alternatif penjangkaran dan pencegahan relaps. Tujuan penelitian ini ialah mengetahui stabilitas fisik dan kadar obat gel emulsi ZOL dengan VCO sebagai syarat suatu sediaan dan pengembangan obat baru pada penyimpanan suhu ruangan (25°C) dan suhu pengiriman (40°C).
Metode: Gel emulsi disimpan selama 1 bulan pada suhu 25°C dan 40°C. Parameter pengukuran stabilitas, antara lain pH, viskositas, daya sebar, daya lekat, dan kadar obat. Evaluasi dilakukan pada hari pertama, 7, 14, dan 28.
Hasil: Uji repeated measure ANOVA pada penyimpanan suhu 25°C dan 40°C menunjukkan terdapat perbedaan bermakna secara statistik pada parameter pH, viskositas, daya lekat, dan kadar obat antar waktu penyimpanan ($p<0,05$). Pada parameter kadar obat pada penyimpanan suhu 25°C dan 40°C tidak terdapat perbedaan bermakna antar waktu penyimpanan ($p>0,05$). Sementara, pada penyimpanan gel emulsi ZOL antara suhu 25°C dan 40°C dengan uji t-test independent menunjukkan bahwa nilai pH pada hari ke-7 dan 14, nilai viskositas pada hari ke-14, nilai daya lekat pada hari ke-7, dan nilai kadar pada hari ke-7 dan 14 berbeda bermakna ($p>0.05$). Sebaliknya, nilai viskositas pada hari ke-7, daya sebar, dan daya lekat pada hari ke- 14 tidak terdapat perbedaan bermakna secara statistik ($p>0.05$).
Kesimpulan: Gel emulsi zoledronate dengan VCO yang disimpan pada suhu 25°C selama 28 hari relatif stabil. Namun perubahan pada nilai pada uji stabilitas relatif konstan dan dalam batas normal mukosa rongga mulut. Gel emulsi zoledronate yang disimpan pada suhu 40°C selama 28 hari disimpulkan tidak stabil.
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Introduction: Loss of anchorage and relapse during and after orthodontic treatment could be the leading causes of an unsuccessful result of orthodontic treatment. Various intra and extra oral application have been used to prevent anchorage loss and relapse in orthodontics with some risks and patient dependent compliance. Topical application of gel emulsion Zoledronate Bisphosphonate (ZOL) with Virgin Coconut Oil (VCO) has a potential to increase the apoptosis of osteoclast to prevent undesirable tooth movement. This study aims to analyze and evaluate the physical stability and drug content of gel emulsion zoledronate, VCO, and preservative agent as a new pharmaceutical drug for one month, stored in a room temperature (25°C) and distribution temperature (40°C). The parameters used for evaluation of ZOL gel emulsion are pH value, viscosity, spread ability, adhesive strength, and drug content.
Methods: The ingredients of ZOL gel emulsion consisted of ZOL powder, carboxyl methyl cellulose

(CMC), VCO, sodium benzoate, antioxidant butylated hydroxytoluene (BHT), and distilled water. The gel emulsions stored for one month at 25°C and 40°C. The parameters used for stability tests were pH, viscosity, spreadability, adhesive strength, and drug content. The ZOL gel emulsion was evaluated on the 1st day, 7th day, 14th day, and 28th day.
Results: The result of this study showed that ZOL gel emulsion was clinically stable over 28 days of storage at 25°C. As for the ZOL gel emulsion that stored at 40°C on the 28th day the gel was not stable. Also, there was no significant difference between ZOL gel emulsion at 25°C and 40°C storage.
Conclusion: According to the physical stability and drug content test of ZOL gel emulsion, this study concluded that the ZOL gel emulsion stable in the room temperature (25°C) storage. Organoleptic, pH, viscosity, spreadability, adhesive strength value was also stable and the degradation was constant. It is recommended that the storage of ZOL gel emulsion is in room temperature and also well tightly packed.