

Formulasi dan uji stabilitas fisik serta kimia sediaan obat tetes mikroemulsi ekstrak etanol temulawak 15% sebagai agen anti C. albicans = Formulation and stability in physical and chemical of microemulsion oromucosal drops containing 15% curcuma xanthorrhiza ethanoic extract as agent of anti C. albicans

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Abstrak

Latar Belakang: C. albicans rongga mulut adalah flora normal yang dapat berubah menjadi patogen sehingga menyebabkan kandidiasis oral. Ekstrak etanol temulawak dengan kandungan utama xanthorrhizol dilaporkan dapat menginhibisi dan mengeradikasi biofilm C. albicans pada konsentrasi 15%, serta menurunkan aktifitas enzim fosfolipase dan proteinase C. albicans. Selanjutnya, ekstrak etanol temulawak diformulasikan dan dikembangkan menjadi bentuk sediaan obat tetes mikroemulsi. Dalam pengembangan bentuk sediaan obat, maka diperlukan penetapan formulasi dan uji stabilitas biologis, fisik, dan kimia. Tujuan: Menetapkan formulasi dan mengevaluasi stabilitas fisik dan kimia obat tetes mikroemulsi ekstrak etanol temulawak
Metode: Ekstrak etanol temulawak 15% diformulasikan menjadi sediaan obat tetes mikroemulsi. Kemudian stabilitas fisik dan kimia dievaluasi 2-4 minggu pada 3 suhu penyimpanan yang berbeda yaitu $4\pm2^{\circ}\text{C}$; $28\pm2^{\circ}\text{C}$; dan $40\pm2^{\circ}\text{C}$. Selanjutnya stabilitas fisik berupa organoleptis, homogenitas, pH, viskositas, dan tipe aliran dievaluasi. Pada stabilitas kimia dievaluasi perubahan kadar xanthorrhizol setelah 2 dan 4 minggu, menggunakan metode GC-MS. Hasil: Formulasi obat tetes mikroemulsi mengandung ekstrak etanol temulawak 15% memiliki organoleptik; larutan kuning kecoklatan, rasa pahit, dan berbau khas jamu, homogenitas; terjadi pemisahan antara komponen minyak dan air, pH berkisar 6,3-6,9, dan tipe alir pseudoplastis pada 2-4 minggu dengan 3 suhu penyimpanan. Viskositas menurun seiring dengan peningkatan suhu penyimpanan. Kadar xanthorrhizol menurun setelah 2-4 minggu pada ketiga suhu penyimpanan. Kesimpulan: Adanya pemisahan komponen minyak dan air serta penurunan kadar zat aktif dalam kurun 2-4 minggu mendasari kesimpulan bahwa formulasi obat tetes ekstrak etanol temulawak 15% tidak stabil secara fisik dan kimia setelah disimpan selama 2 dan 4 minggu sehingga masih diperlukan reformulasi.

.....**Introduction:** C. albicans is a normal flora in oral cavity that can be pathogenic that causing oral candidiasis. Curcuma xanthorrhiza ethanoic extract has a main component, xanthorrhizol that was reported to be able to inhibit and eradicate C. albicans biofilms at a 15% concentration and reduce the activity of phospholipase and proteinase enzymes of C. albicans. Furthermore, curcuma xanthorrhiza ethanoic extract is formulated and developed into microemulsion oromucosal drops. In the development of the drug, it is necessary to determine the formulation and test the stability in biological, physical, and chemical. **Objective:** Determining the formulation and

evaluating the physical and chemical stability of microemulsion oromucosal drops containing 15% curcuma xanthorrhiza ethanoic extract. Methods: Curcuma xanthorrhiza ethanoic extract is formulated into microemulsion oromucosal drops containing 15% curcuma xanthorrhiza ethanoic extract. Then, the physical and chemical stability are evaluated for 2-4 weeks in 3 different temperature, that is $4 \pm 2^{\circ}\text{C}$; $28 \pm 2^{\circ}\text{C}$; and $40 \pm 2^{\circ}\text{C}$. Furthermore, the physical stability in the form of organoleptic, homogeneity, pH, viscosity, and flowing type are evaluated. Chemical stability is evaluated the xanthorrhizol level using the GC-MS method. Results: Microemulsio oromucosal drops containing 15% curcuma xanthorrhiza ethanoic extract have organoleptic; brownish-yellow solution, bitter taste, and smells like herb, homogeneity; there is a separation between the oil and water phase, pH ranges from 6,3-6,9, and flowing type are pseudoplastic. The viscosity value decreases with the increasing of storage temperature. Xanthorrhizol level are decreasing after 2-4 weeks of storage in the 3 different temperature. Conclusion: The separation between the oil and water phase and degradation of xanthorrhizol level after stored 2-4 weeks are the underlying conclusion that formulation of oromucosal drops containing curcuma xanthorrhiza ethanoic extract are not stabile in physical and chemical after stored for 2 and 4 weeks so that the drugs need to be reformulated.