

INTISARI

Proses peracikan dapat menyebabkan perubahan bentuk dan stabilitas obat terutama pada peracikan salep asam salisilat. Stabilitas sediaan racikan dapat ditentukan melalui *beyond use date* (BUD). Sediaan racikan salep memiliki BUD selama 1 bulan menurut USP edisi 37. Tujuan penelitian ini untuk mengevaluasi stabilitas fisika dan kimia sediaan racikan salep asam salisilat yang disimpan selama 1 bulan pada suhu ruang.

Uji stabilitas fisika meliputi uji organoleptis, homogenitas, daya sebar, viskositas dan profil tekstur. Uji stabilitas kimia sediaan meliputi perubahan kadar zat aktif dan pH salep. Data penelitian dianalisis menggunakan uji *Shapiro-Wilk* (SW) dilanjutkan dengan uji t berpasangan antara data hari ke-7, 14, 21 dan 30 terhadap data hari ke-0 dengan tingkat kepercayaan 95% untuk mengetahui stabilitas sediaan.

Berdasarkan penelitian yang telah dilakukan, hasil menunjukkan bahwa sediaan racikan salep asam salisilat tidak stabil pada penyimpanan 1 bulan baik secara fisika maupun kimia. Hal ini berbeda dengan ketentuan BUD menurut USP edisi 37 yang seharusnya stabil selama 1 bulan. Ketidakstabilan secara kimia berdasarkan pH terjadi pada hari ke-7 sedangkan berdasarkan kadar terjadi pada hari ke-21. Berdasarkan sifat fisika berupa organoleptis, daya sebar, viskositas, ketidakstabilan terjadi pada hari ke-14 sedangkan berdasarkan profil *adhesiveness* terjadi pada hari ke-21 dan *cohesiveness* terjadi pada hari ke-7.

Kata kunci: stabilitas, salep, asam salisilat, *beyond use date*

ABSTRACT

The compounding process may cause changes the shape and stability of the drug, especially in the compounding of salicylic acid ointment. The stability of dosage form with compounding can be determined through a beyond-use date (BUD). The ointment formulated with compounding has BUD for 1 month according to USP 37th edition. The objectives of this study was to evaluate the stability physics and chemical of salicylic acid ointment formulated with compounding stored for 1 month at room temperature.

Physical stability tests included organoleptic, homogeneity, dispersion, viscosity and texture profiles. Chemical stability tests included changes in active substance and pH ointment. The data were analyzed using Shapiro-Wilk (SW) test then continued with paired t-test between data day 7th, 14th, 21st and 30th towards day zero data with a 95% confidence level to knowing the stability of ointment.

Based on research that has been done, the results showed that the salicylic acid ointment formulated with compounding is unstable at 1 month storage both physically and chemically. This is different from the terms of BUD according to USP 37 edition which should be stable for 1 month. Chemical instability based on pH occurs on the 7th day while based on the levels of active substances occurs on the 21st day. Based on the physical properties of organoleptic, dispersion, viscosity, instability occurs on day 14 while based on adhesiveness occurs on day 21 and cohesiveness occurs on day 7.

Keyword: stability, ointment, salicylic acid, beyond use date