Formulasi pembawa sediaan suspensi siap pakai untuk pembuatan obat racikan mengandung diltiazem hidroklorida sebagai model obat = Formulation of suspending vehicle for extemporaneous oral liquid compounding containing diltiazem hydrochloride as a drug model

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Abstrak

Di Australia, Eropa dan Amerika Serikat, pembawa suspensi untuk pembuatan obat racikan yang diberikan secara oral telah beredar di pasaran dan dikenal dengan nama dagang Ora-Plus. Namun, sediaan Ora-Plus ini belum beredar di Indonesia sehingga perlu dibuat formulasi pembawa sediaan suspensi untuk pembuatan obat racikan.
Penelitian ini bertujuan untuk memperoleh formula pembawa sediaan suspensi yang stabil secara fisik dan kimia setelah penambahan zat aktif berupa tablet diltiazem hidroklorida sebagai model obat. Uji stabilitas dilakukan selama 30 hari pada formula pembawa suspensi terpilih, yaitu formula A dan E. Uji stabilitas fisik dilakukan pada suhu kamar dengan pengujian terhadap bau, warna serta pH sediaan.
Hasil menunjukkan bahwa suspensi oral diltiazem hidroklorida berwarna putih dan memiliki bau seperti obat, serta pH yang dihasilkan mengalami penurunan yang tidak terlalu jauh selama masa penyimpanan. Uji stabilitas kimia dilakukan pada dua kondisi yang berbeda, yaitu suhu kamar dan suhu 4±2ºC untuk selanjutnya dilakukan penetapan kadar menggunakan spektrofotometer UV-Vis. Kadar suspensi oral diltiazem hidroklorida mengalami kenaikan dan penurunan selama masa penyimpanan sehingga dapat dikatakan bahwa suspensi oral diltiazem hidroklorida stabil secara fisik namun tidak stabil secara kimia.
<hr>In Australia, Europe and the United States, suspending vehicle which is made by the manufactures for extemporaneous compounding in oral medications are known under the Ora-Plus trade name. However, Ora-Plus has not distributed in Indonesia, therefore a suspending vehicle formulation for extemporaneous oral liquid compounding should be formulated.
The objective of this research was to obtain the optimum concentration of suspending vehicle and to obtain a physically and chemically stable formulation of diltiazem hydrochloride suspension. Stability test of suspension had been carried out for 30 days in the selected suspending vehicle formulas (Formula A and E). Physical stability test was performed at room temperature and physical properties (odor and color) and pH of suspension was evaluated.
The results showed that the oral suspension of diltiazem hydrochloride possessed white and drug-like odor, and the resulting pH decreased less significantly during storage. Chemical stability test was carried out in two different conditions, at room temperature and at 4±2ºC for chemical stability test in suspension using spectrophotometer UV-Vis. Concentration of diltiazem hydrochloride in the oral suspension showed fluctuation during storage period. Based on those results, it can be concluded that the oral suspension of diltiazem hydrochloride was physically stable but not chemically stable during the storage period.