Formulasi dan Uji Stabilitas Pembawa Sediaan Suspensi untuk Anak dengan Rifampisin sebagai Model Obat = Formulation and Stability Testing of Oral Suspending Vehicle for Children with Rifampicin as a Model Drug

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Abstrak

Terdapat zat aktif yang kurang stabil dalam waktu lama jika dibuat dalam sediaan suspensi yang mengandung banyak air seperti rifampisin. Di Indonesia belum tersedia suatu pembawa sediaan suspensi yang dapat digunakan untuk mengatasi masalah kestabilan tersebut. Penelitian ini bertujuan untuk mengembangkan formula pembawa suspensi yang stabil secara fisik dan kimia setelah penambahan isi kapsul rifampisin sebagai zat aktif. Formulasi dibuat sebanyak 4 formula dengan variasi jenis dan konsentrasi bahan pensuspensi. Formula pembawa terbaik dari hasil evaluasi volume sedimentasi, redispersi, dan pH dipilih, lalu ditambahkan kapsul rifampisin dan dilakukan pengujian stabilitas. Uji stabilitas fisik pada suhu kamar 25Ë± 2ËC, suhu dingin 4Ë± 2ËC, dan suhu tinggi 40Ë± 2ËC selama 28 hari meliputi pengujian terhadap organoleptis (bau, bentuk, warna) dan pH menunjukkan bahwa suspensi rifampisin mengalami perubahan warna menjadi merah agak kehitaman setelah 7 hari penyimpanan, bau seperti obat, peningkatan pH, serta perubahan konsistensi. Uji stabilitas kimia dilakukan pada kondisi suhu kamar dengan menetapkan kadar rifampisin dalam suspensi menggunakan KCKT. Kadar suspensi rifampisin mengalami penurunan hingga 0,82% selama masa penyimpanan 14 hari pada suhu kamar. Dalam penelitian ini, suspensi rifampisin stabil secara fisik selama 7 hari, namun sangat tidak stabil secara kimia.
.....Active ingredients in suspending vehicles with high water content, such as rifampicin, can degrade over time due to their instability. In Indonesia, there is no available suspending vehicle that can effectively address this stability issue. This research aimed to develop a stable suspending vehicle after the addition of rifampicin capsule contents as the active ingredient. Four formulations were prepared with variations in the type and concentration of suspending agents. The best suspending vehicle based on the evaluation of sedimentation volume, redispersion, and pH was selected, and then rifampicin capsules were added and stability testing was performed. Physical stability testing conducted at room temperature of 25Ë± 2ËC, refrigerated temperature of 4Ë± 2ËC, and elevated temperature of 40Ë± 2ËC for 28 days, including organoleptic (smell, form, and color) and pH testing, revealed a color change of the rifampicin suspension to a reddish-black color after 7 days of storage, along with a medicinal odor, increased pH, and consistency change. Chemical stability testing was conducted at room temperature conditions by determining the rifampicin content in the suspension using HPLC. The rifampicin suspension concentration decreased by up to 0,82% during the 14-day storage period at room temperature. In this research, the rifampicin suspension was found to be physically stable for 7 days, but chemically very unstable.