Pengembangan Formula Sediaan Cair Oral Omeprazol untuk Pasien Pediatri = Development of Oral Liquid Formulation of Omeprazole for Pediatric Patients

Natasya Fathania Rizkillah, author

Abstrak

Omeprazol merupakan obat golongan proton pump inhibitor yang berfungsi menekan produksi asam dengan menghambat pompa proton di sel parietal lambung. Pada beberapa kasus, omeprazol sering diresepkan pada pasien pediatri, namun omeprazol hanya tersedia dalam bentuk kapsul lepas tunda atau serbuk injeksi steril. Oleh karena itu, penelitian ini dilakukan untuk mengembangkan formula sediaan cair oral omeprazol yang stabil dan mudah disiapkan di instalasi farmasi rumah sakit. Sirup pembawa dan sirup oral omeprazol dibuat dengan variasi zat pensuspensi dan pendapar, kemudian dikarakterisasi pH, viskositas dan kadarnya. Stabilitas sirup pembawa dan sediaan cair oral omeprazol dievaluasi setelah produk disimpan selama 35 hari pada suhu dingin (4o ± 2oC) dan suhu ruang (25o ± 2oC). Sirup pembawa menunjukkan stabilitas yang baik dengan menunjukkan pH dan viskositas yang relatif stabil pada dua kondisi penyimpanan. Pada sirup oral omeprazol terjadi perubahan warna menjadi kecokelatan serta penurunan viskositas yang lebih cepat pada penyimpanan di suhu ruang. Akan tetapi, pH kelima formula pada dua kondisi penyimpanan relatif stabil dan memenuhi persyaratan yaitu di atas 7,4 untuk memperlambat degradasi omeprazole. Hasil penetapan kadar menggunakan spektrofotometer UV-Vis menunjukkan adanya penurunan kadar pada kelima formula. Akan tetapi, formula F2 menunjukkan stabilitas kadar yang paling baik dengan penurunan kadar kurang dari 5% hingga hari ke-35 baik pada penyimpanan baik di suhu dingin maupun suhu ruang. Berdasarkan hasil penelitian, disimpulkan bahwa penambahan suspending agent berupa HPMC dengan konsentrasi yang optimum dapat meningkatkan stabilitas sirup oral omeprazol. Akan tetapi, penambahan dapar tidak secara signifikan meningkatkan stabilitas sediaan.

.....Omeprazole is a drug belonging to the proton pump inhibitor, which functions to suppress acid production by inhibiting the proton pump in the gastric parietal cells. Omeprazole is commonly prescribed for pediatric patients, however it is only available in delayed-release capsule or sterile injection powder forms. Therefore, this research was conducted to develop a stable and easily prepared oral liquid formulation of omeprazole in the hospital pharmacy installation. Carrier syrup and oral omeprazole syrup were formulated with variations in suspending and buffering agents, and then their pH, viscosity, and content were characterized. The stability of these formulation was evaluated after storage for 35 days at cold (4°C±2°C) and room (25°C±2°C) temperature. The carrier syrup stored demonstrated good stability, indicated by relatively stable pH and viscosity under both storage conditions. However, the oral omeprazole syrup showed color changes to brownish and a faster decrease in viscosity during storage at room temperature. Nevertheless, the pH of both formulations under the two storage conditions relatively stable and met the requirements of being above 7.4 to slow down omeprazole degradation. Content determination using UV-Vis spectrophotometer showed a decrease in content in all formulations. However, F2 exhibited the best content stability, with a decrease of less than 5% until day 35, under both storage conditions. Based on the research findings, it is concluded that adding HPMC as a suspending agent at the optimum concentration can improve the stability of oral omeprazole syrup. However, the addition of buffering agents

did not significantly enhance the formulation's stability.