ABSTRAK

Judul : Pengaruh Penyimpanan Terhadap Stabilitas Fisik dan Kadar Ambroxol Hidroklorida Sediaan Sirup yang Diperoleh di Pasar Pramuka dan Apotek dengan Menggunakan Spektrofotometri Uv-Vis

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Ambroxol HCl sirup merupakan terapi batuk yang sering digunakan pasien anak. Sediaan sirup disimpan dalam wadah tertutup rapat dan di tempat sejuk atau pada suhu kamar agar stabil. Sehingga perlu dilakukan penelitian terkait pengaruh lama dan suhu penyimpanan sirup terhadap kadar dan stabilitas. Penentuan kadar Ambroxol HCl dalam sirup menggunakan metode spektrofotometri UV-Vis. Penelitian dilakukan untuk mengetahui metode yang digunakan memenuhi persyaratan parameter validasi meliputi akurasi, presisi, linearitas, LOD dan LOQ serta untuk menentukan kadar dan stabilitas sediaan sirup dalam penyimpanan. Hasil optimasi panjang gelombang sebesar 247 nm. Hasil uji linearitas dengan persamaan regresi y = 0,0265x - 0,0023, memiliki koefisien korelasi sebesar 0,9991. Hasil uji akurasi (%*recovery*) 98,05-100.15% dan presisi (RSD) 0,23 – 0,66 %. Hasil LOD 0,8059 dan LOQ 2,4420. Penentuan kadar dilakukan berdasarkan lama penyimpanan yang dilakukan pengukuran setiap satu minggu dalam 3 minggu (minggu ke-0, ke-1, ke-2, dan ke-3) terhadap sirup yang disimpan dalam suhu dingin (2-8º C), suhu ruang (15-30º C), dan suhu mobil (30- 49º C). Hasil yang didapatkan selama penyimpanan dan pada suhu yang ditentukan mengalami penurunan kadar yang stabil dengan nilai signifikansi. Uji stabilitas sirup Ambroxol HCl dengan melakukan uji organoleptik, uji kejernihan, uji pH, dan uji viskositas. Hasil uji organoleptik menunjukkan semua sampel memiliki bentuk, bau, warna dan rasa yang sama dengan saat sirup dibuka, serta hasil uji kejernihan menunjukkan larutan bersifat jernih. Berdasarkan uji pH sirup memiliki pH 4,23-4,32. Dapat disimpulkan metode spektrofotometri UV-Vis untuk penentuan kadar Ambroxol HCl memenuhi persyaratan parameter validasi dan kadar Ambroxol HCl mengalami penurunan yang stabil serta stabilitas fisik yang memenuhi persyaratan (Depkes RI, 2007).

Kata kunci : Ambroxol HCl, validasi metode, penetapan kadar, lama dan suhu penyimpanan, stabilitas.

ABTRACT

Title	:	Effect of Storage on Physical Stability and Levels of Ambroxol Hydrochloride Syrup Obtained at Pramuka Market and Pharmacies Using Spectrophotometry UV-Vis
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Ambroxol HCl syrup is a cough therapy that is often used by pediatric patients. Syrup preparations are stored in tightly closed containers in a cool place or at room temperature so that they are stable. So it is necessary to do research related to the effect of syrup storage time and temperature on levels and stability. Determination of ambroxol HCl content in syrup using the spectrophotometry UV-Vis method The research was conducted to determine the method used to meet the requirements for validation parameters, including accuracy, precision, linearity, LOD, and LOQ, as well as to determine the level and stability of syrup preparations in storage. The optimization results for a wavelength of 247 nm The results of the linearity test with the regression equation y = 0.0265x - 0.0023 have a correlation coefficient of 0.9991. Accuracy test results (% recovery) were 98.05–100.15% and precision (RSD) was 0.23–0.66%. The results of LOD 0.8059 and LOQ 2.4420 Determination of the content is carried out based on the length of storage, which is measured every one week for 3 weeks (weeks 0, 1, 2, and 3) for syrup stored at a cold temperature (2–8 ºC), a temperature room (15–30 ºC), and a car temperature (<40 ºC). The results obtained during storage and at the specified temperature experienced a steady decrease in levels with a significant value. Stability test of ambroxol HCl syrup by conducting organoleptic tests, clarity tests, pH tests, and viscosity tests The results of the organoleptic test showed that all samples had the same shape, smell, color, and taste as when the syrup was opened, and the results of the clarity test showed that the solution was clear. Based on the pH test, the syrup has a pH of 4,23-4,32. It can be concluded that the UV-Vis spectrophotometric method for determining ambroxol HCl levels met the requirements for validation parameters, ambroxol HCl levels experienced a steady decrease, and physical stability met the requirements (Depkes RI, 2007).

Key words: ambroxol HCl, method validation, assay, storage time and temperature, stability.