ABSTRAK

Kombinasi parasetamol, tramadol HCl, dan tiamin HCl dibuat dalam bentuk sediaan racikan pulveres sebagai terapi nyeri. Namun, kandungan garam tramadol HCl dan tiamin HCl menyebabkan keduanya cenderung bersifat higroskopis yang memicu penurunan stabilitas sediaan. Penelitian ini bertujuan untuk mengetahui stabilitas fisika dan kimia sediaan racikan pulveres kombinasi parasetamol, tramadol HCl dan tiamin HCl selama penyimpanan 28 hari.

Penelitian ini termasuk jenis penelitian eksperimental murni. Parameter yang digunakan dalam uji stabilitas pulveres adalah uji stabilitas fisika dengan pengamatan organoleptis seperti warna, bau dan bentuk sediaan, sedangkan uji stabilitas kimia dilakukan dengan menghitung penurunan kadar sampel menggunakan seperangkat alat spektrofotometri UV. Pengujian stabilitas dilakukan pada hari ke-0, 7, 14, 21 dan 28. Analisis hasil penelitian menggunakan analisis kemometrik dengan teknik kalibrasi multivariat PLS (*Partial Least Square*s) dan PCR (*Principle Component Regression*) yang memanfaatkan *Software* Minitab®.

Hasil penelitian menunjukkan bahwa uji stabilitas sediaan racikan pulveres kombinasi parasetamol, tramadol HCl dan tiamin HCl tidak memenuhi uji stabilitas yang dilihat dari adanya perubahan kondisi organoleptis dan terjadi penurunan kadar parasetamol 20,105%, tramadol HCl 19,068% dan tiamin HCl 20,636% dalam waktu penyimpanan 28 hari. Namun, sediaan ini masih dapat mempertahankan stabilitas sampai hari ke-11.

Kata kunci: parasetamol, tramadol HCl, , tiamin HCl, kemometrik, organoleptik, penetapan kadar.

ABSTRACT

The combination of paracetamol, tramadol HCl, and thiamine HCl is made in the form of a pulveres compound for pain therapy. However, the salt content of tramadol HCl and thiamine HCl causes them to tend to be hygroscopic which causes a decrease in the stability of the preparation. This study aims to determine the physical and chemical stability of the pulveres preparation of a combination of paracetamol, tramadol HCl and thiamine HCl during 28 days of storage.

This research is a pure experimental research type. The parameters used in the pulveres stability test are physical stability tests with organoleptic observations such as color, odor and dosage form, while chemical stability tests are carried out by calculating the decrease in sample levels using a set of UV spectrophotometric tools. Stability testing was carried out on days 0, 7, 14, 21 and 28. Analysis of the results used chemometric analysis with multivariate calibration techniques PLS (Partial Least Squares) and PCR (Principle Component Regression) using Minitab® Software.

The results showed that the stability test for the pulveres mixture of paracetamol, tramadol HCl and thiamine HCl did not meet the stability test as seen from the changes in organoleptic conditions and decreased levels of paracetamol 20.105%, tramadol HCl 19.068% and thiamine HCl 20.636% within 28 days of storage. However, this preparation was still able to maintain stability until the 11th day.

Keywords: paracetamol, tramadol HCl, thiamine HCl, chemometrics, organoleptic, assay.