ABSTRAK

Peracikan obat merupakan proses penyiapan sediaan yang disesuaikan dengan kebutuhan pasien, salah satunya dalam bentuk kapsul racikan. Variasi jumlah sediaan yang diracik dapat mempengaruhi kestabilan dan masa simpan obat. Penelitian ini bertujuan untuk mengetahui pengaruh variasi jumlah sediaan kapsul racikan kombinasi parasetamol dan amitriptilin terhadap *Beyond Use Date* (BUD). Penelitian menggunakan rancangan eksperimental murni dengan variasi jumlah kapsul sebanyak 10, 30, 60, dan 90 kapsul. Proses peracikan dilakukan menggunakan *pulverizer* selama 1 menit, kemudian kapsul disimpan pada suhu 30°C dan kelembaban relatif 75±5%. Evaluasi dilakukan melalui uji organoleptis, uji *moisture content*, uji derajat kehalusan, serta penetapan kadar zat aktif menggunakan spektrofotometri UV-Vis dengan analisis kemometri metode *Partial Least Squares* (PLS). Penentuan BUD dilakukan melalui perhitungan *shelf-life* (t_{90}). Hasil penelitian menunjukkan bahwa variasi jumlah sediaan mempengaruhi nilai *Beyond Use Date* (BUD) kapsul racikan kombinasi parasetamol dan amitriptilin. Nilai *shelf-life* (t_{90}) pada variasi 10, 30, 60, dan 90 kapsul berturut-turut yaitu 138 hari; 86 hari; 59 hari; dan 79 hari. Hasil tersebut menunjukkan bahwa jumlah sediaan yang diracik mempengaruhi kestabilan dan masa simpan kapsul racikan kombinasi parasetamol dan amitriptilin.

Kata kunci: *Beyond Use Date* (BUD), kapsul racikan, parasetamol, amitriptilin, variasi jumlah sediaan.

ABSTRACT

Drug compounding is the process of preparing pharmaceutical formulations tailored to individual patient needs, one of which is compounded capsules. Different batch sizes may influence the stability and shelf life of these preparations. This study aimed to determine the effect of varying batch sizes of compounded capsules containing a combination of paracetamol and amitriptyline on the Beyond Use Date (BUD). A true experimental design was employed with batch sizes of 10, 30, 60, and 90 capsules. The compounding process was carried out using a pulverizer for 1 minute, and the samples were subsequently stored at 30°C and 75±5% relative humidity. Evaluations included organoleptic testing, moisture content analysis, particle size distribution, and assay of active ingredients using UV-Vis spectrophotometry combined with chemometric analysis using the Partial Least Squares (PLS) method. The BUD was determined based on shelf-life (t_{90}) calculations. The results demonstrated that batch size influenced the Beyond Use Date of compounded capsules containing paracetamol and amitriptyline. The t_{90} values for batch sizes of 10, 30, 60, and 90 capsules were 138 days; 86 days; 59 days; and 79 days, respectively. These findings indicate that batch size affects the stability and shelf life of compounded capsules containing paracetamol and amitriptyline.

Keywords: *Beyond Use Date (BUD), compounded capsules, paracetamol, amitriptyline, batch size variation.*