

## INTISARI

Parasetamol merupakan obat analgesik-antipiretik yang banyak digunakan oleh masyarakat dan sering diresepkan dalam bentuk sediaan pulveres. Parasetamol dalam bentuk sediaan pulveres sudah berada di luar kemasan primer, sehingga *expiration date* pada obat sudah tidak berlaku, melainkan diganti *beyond use date* (BUD) atau batas waktu penggunaan. Penelitian ini bertujuan untuk menghitung BUD sediaan racikan pulveres parasetamol 3 merek berbeda dan membandingkannya dengan perhitungan menurut *United States of Pharmacopeia* (USP).

Perhitungan BUD pada penelitian ini dilakukan dengan uji stabilitas dipercepat menggunakan 3 peringkat suhu. Pulveres disimpan selama 1 bulan pada suhu 40°C, 50°C, dan 60°C, kemudian ditetapkan kadarnya pada hari ke-0, 7, 14, 21, dan 28 serta diamati organoleptisnya untuk mengevaluasi stabilitas fisik. Selanjutnya, dari hubungan kadar dan waktu ditetapkan orde reaksi dan kecepatan degradasi untuk mengetahui nilai kecepatan degradasi pada suhu 25°C ( $k_{25}$ ) dan energi aktivasi ( $E_a$ ) menggunakan persamaan Arrhenius. Nilai  $k_{25}$  dimasukkan ke dalam persamaan  $t_{90}$  sesuai orde reaksinya, yang menggambarkan BUD sediaan. Hasil BUD dibandingkan dengan nilai BUD menurut USP.

Hasil perhitungan BUD untuk 3 merek pulveres parasetamol berbeda, sampel A memiliki BUD 31 hari, sampel B 13 hari, dan sampel C 13 hari. Hasil perhitungan berbeda dengan hasil penentuan BUD berdasarkan ketentuan USP yaitu BUD untuk sampel A, B, dan C adalah 6 bulan. Secara fisik, pulveres parasetamol tidak mengalami perubahan karakteristik fisik kecuali terdapat 3 sampel pulveres yang mengalami penggumpalan karena adanya pengaruh kelembaban.

**Kata kunci :** *beyond use date*, uji stabilitas, pulveres, parasetamol

## ABSTRACT

*Paracetamol is a commonly used analgetic antipiretic drug and often being prescribed in pulveres dosage form. Parasetamol in pulveres dosage form has been taken from its primary packaging, so expiration date (ED) stated in its packaging is no longer used, therefore we use beyond use date (BUD) instead. This study aim to observe the beyond use date of 3 different brand of paracetamol in pulveres dosage form. The result then compared to beyond use date by United States of Pharmacopeia (USP) convention.*

*Method used to calculate BUD in this study is accelerated stability testing using 3 stage of temperature. Pulveres were stored at 40°C, 50°C, and 60°C for 1 month then the content assay was done at day 0, 7, 14, 21, and 28. Physical characteristics also been observed along with the chemical assay. From the correlation of concentration and time, reaction rate and degradation rate at each temperatue was known to calculate the degrdation rate at 25°C ( $k_{25}$ ) and activation energy (Ea) using Arrhenius equation.  $K_{25}$  then used to calculate time when drug remained 90% ( $t_{90}$ ) by using  $t_{90}$  equation based on its reaction rate, which represent BUD of the drug. The result the compared to beyond use date by United States of Pharmacopeia (USP) convention*

*The result of this study showed that the 3 brand of paracetamol in pulveres dosage form have different BUD based on calculation of  $t_{90}$  value, sample A is 31 days, sample B is 13 days, and sample C is 13 days. The calculation is also different with the USP convention for BUD, that is 6 months for sample A, B, and C. Meanwhile, the result of physiscal characterization is that paracetamol in pulveres dosage form has not changed physically during storage period.*

**Keyword :***beyond use date, stability testing, pulveres, paracetamol.*