ABSTRAK

Polivinilpirolidon (PVP) K-30 merupakan bahan pengikat yang umum digunakan dalam pembuatan tablet, salah satunya tablet parasetamol. Dalam industri farmasi terdapat kemungkinan dilakukannya proses *reworking*, salah satunya pengempaan ulang. Namun, proses pengempaan ulang kemungkinan memberikan pengaruh terhadap potensi PVP K-30 sebagai bahan pengikat dalam menyatukan kembali bahan-bahan penyusun tablet. Adapun, perbedaan konsentrasi PVP K-30 kemungkinan dapat menghasilkan sifat fisik granul dan tablet yang berbeda. Penelitian ini bertujuan untuk mengetahui ada tidaknya pengaruh pengempaan ulang dan perbedaan konsentrasi PVP K-30 terhadap kualitas tablet parasetamol 300 mg. Pengaruh pengempaan ulang dan konsentrasi PVP K-30 dilihat berdasarkan ada atau tidaknya perbedaan bermakna pada sifat fisik campuran bahan penyusun tablet (kecepatan alir dan kompresibilitas campuran) dan sifat fisik tablet (kompaktibilitas, kekerasan, kerapuhan,dan waktu hancur tablet) dari formula dengan konsentrasi PVP K-30 2% b/b dan 4% b/b setelah mengalami 2 kali pengempaan ulang. Tablet parasetamol dibuat dengan metode granulasi basah melalui tahapan granulasi, lubrikasi, pengujian sifat fisik campuran, pengempaan, pengujian sifat fisik tablet, penghancuran, dan pengempaan ulang. Analisis data dilakukan secara statistik menggunakan uji normalitas *Shapiro-Wilk*, lalu dilanjutkan dengan uji *two-way Analysis of Variance* (ANOVA) atau Kruskal-Wallis dan uji *Post Hoc Mann Whitney*. Hasil menunjukan bahwa terdapat pengaruh pengempaan ulang dan konsentrasi PVP K-30 terhadap kemampuan PVP K-30 sebagai bahan pengikat dilihat dari perbedaan bermakna pada sifat fisik campuran dan tablet tiap kelompok uji.

Kata Kunci : polivinilpirolidon (PVP) K-30, tablet parasetamol, granulasi basah, pengempaan ulang.

ABSTRACT

Polyvinylpyrrolidone (PVP) K-30 is a commonly used binder in tablet production, including paracetamol tablets. In the pharmaceutical industry, there is a possibility of reworking, including tablet recompression. Nevertheless, the recompression process may have affected the potential of PVP K-30 as a binder to reunite the particles of tablet ingredients. However, the difference of PVP K-30 concentration might be resulting in the differences of granule and tablet characteristics. This study aims to determine whether there is an effect of recompression and the difference of PVP K-30 on the quality of paracetamol tablets. The effect of recompression and the difference of PVP K-30 was seen based on whether there is a significant different on physical properties of the mixture of tablet ingredients (mixture's flow rate and compressibility) and the tablets (compactibility and tablet's hardness, friability, and disintegration time) from the formula with a concentration of 2% w/w and 4% w/w PVP K-30 after experiencing 2 times of recompression. Paracetamol tablets were made by wet granulation method through the stages of granulation, lubrication, physical properties testing of the mixture, tablet compression, physical properties testing of tablets, crushing, and recompression. Data analysis was performed statistically using the Shapiro-Wilk normality test, followed by two-way Analysis of Variance (ANOVA) or Kruskal-Wallis test and Post Hoc Mann Whitney test. The results showed there was an effect of recompression and different concentration of PVP K-30 on the potential of PVP K-30 as a binder as seen from significant differences in the physical properties of the mixture and tablets in each test group.

Keywords: polyvinylpyrrolidone (PVP) K-30, paracetamol tablets, wet granulation, recompression