

ABSTRAK

Tablet adalah sediaan padat yang mengandung bahan aktif dan eksipien, banyak digunakan karena fleksibilitas dan kepraktisannya, namun selama proses manufaktur dapat terjadi cacat produk sehingga hasilnya tidak memenuhi spesifikasi. Pengerjaan ulang (*reworking*) menjadi salah satu upaya dalam mengatasi permasalahan tersebut. Bahan pengikat berperan penting dalam formulasi tablet, khususnya untuk API seperti kalsium laktat dengan sifat alir dan kompresibilitas buruk, sehingga pemilihan *binder* yang tepat serta modifikasi metode pembuatan, yakni granulasi basah pada eksipien dan kempa langsung diterapkan untuk memperbaiki sifat tersebut. Penelitian ini bertujuan untuk mengevaluasi pengaruh pengempaan berulang dan kadar pengikat Avicel PH 101-CMC Na terhadap kualitas tablet kalsium laktat. Penelitian eksperimental murni dilakukan dengan rancangan penelitian acak lengkap dua arah. Uji evaluasi sifat fisik campuran (kecepatan waktu alir, kompresibilitas, kompaktibilitas) dilakukan pada campuran baik pencampuran kempa awal maupun campuran penggerusan tablet, lalu uji evaluasi sifat fisik tablet (kekerasan, kerapuhan, waktu hancur) dilakukan baik pada hasil kempa awal hingga kempa ulang. Data penelitian dianalisis menggunakan uji normalitas *Shapiro-Wilk*, jika berdistribusi normal dilanjutkan dengan uji *Two-Way Analysis of Variance* (ANOVA) namun, jika data tidak terdistribusi normal, dilakukan uji *Kruskal-Wallis* dan uji *Post-Hoc Mann-Whitney* pada *software* SPSS. Hasil menunjukkan bahwa pengempaan berulang memengaruhi sifat fisik campuran, kekerasan, dan kerapuhan tablet, sedangkan kadar pengikat Avicel PH 101-CMC Na hanya memengaruhi sifat fisik campuran dan kekerasan tablet serta tidak memengaruhi kerapuhan. Akan tetapi, keduanya tidak berpengaruh pada waktu hancur tablet.

Kata Kunci: tablet, Avicel PH 101-CMC Na, kalsium laktat, granulasi basah, *reworking*, kempa ulang.

ABSTRACT

Tablets are solid dosage forms containing active ingredients and excipients, widely used due to their flexibility and practicality. However, during the manufacturing process, product defects may occur, resulting in products that do not meet specifications. Reworking is one strategy to address this issue. Binders are essential in tablet formulation, especially for APIs like calcium lactate, which have poor flow and compressibility. Therefore, appropriate binder selection and manufacturing modifications, such as wet granulation of excipients and direct compression, are applied to improve these properties. This study aims to evaluate the effect of repeated compression and the concentration of Avicel PH 101-CMC Na as a binder on the quality of calcium lactate tablets. A pure experimental study with a two-way completely randomized design was used. Physical property evaluations of the mixture (flow time, compressibility, compactibility) were conducted on both the initial mixture and the tablet grinding mixture. Tablet properties (hardness, friability, disintegration time) were evaluated after initial and repeated compression. Data were analyzed statistically with the Shapiro-Wilk normality test, normally distributed data were tested with two-way ANOVA, while non-normal data used the Kruskal-Wallis and Mann-Whitney post-hoc tests in SPSS software. The results showed that repeated compression affected the physical properties of the mixture, tablet hardness, and tablet friability, while the Avicel PH 101-CMC Na binder content only affected the physical properties of the mixture and tablet hardness and did not affect tablet friability. However, neither affected tablet disintegration time.

Keywords: tablets, Avicel PH 101-CMC Na, calcium lactate, wet granulation, reworking, recompression.