

INTISARI

Laktosa merupakan salah satu jenis bahan pengisi (*filler*) yang umum digunakan dalam pembuatan sediaan tablet. Namun, laktosa memiliki kompaktibilitas yang buruk sehingga berpotensi membentuk tablet yang rapuh. Maka dari itu, teknik *co-processing* dikembangkan guna menghasilkan excipien baru dengan sifat yang lebih unggul. Kollidon® VA 64 merupakan salah satu jenis bahan pengikat (*binder*) yang berpotensi besar untuk dikombinasikan dengan laktosa menjadi suatu *co-processed excipients* karena sifat alir, kompaktibilitas, dan kompresibilitasnya yang baik. *Co-processed excipients* dapat diaplikasikan dalam pembuatan *Fast Disintegrating Tablet* (FDT). Penambahan stevia sebagai bahan pemanis alami dapat menjadi alternatif excipien yang lebih sehat. Penelitian ini bertujuan untuk mengetahui proporsi laktosa dan Kollidon® VA 64 yang optimal dengan pemanis stevia sebagai kandidat *co-processed excipients filler-binder* dalam formula FDT.

Co-processed excipients laktosa, Kollidon® VA 64, dan stevia dibuat dengan metode granulasi basah dan dievaluasi sifat-sifat fisiknya meliputi sifat alir, kompaktibilitas, kompresibilitas, ukuran partikel, daya serap air, dan *Loss on Drying* granul. Optimasi formula *co-processed excipients* didasarkan pada hasil pengujian sifat fisik yang diolah menggunakan metode *factorial design*. *Co-processed excipients* yang optimal dianalisis gugus fungsinya menggunakan *Fourier Transform Infrared Spectroscopy* (FTIR) dan morfologinya menggunakan *Scanning Electron Microscopy* (SEM).

Hasil penelitian menunjukkan bahwa peningkatan jumlah laktosa mampu menurunkan sudut diam sehingga memperbaiki sifat alir granul. Peningkatan Kollidon® VA 64 dapat meningkatkan kecepatan alir, kompaktibilitas, kompresibilitas, ukuran partikel, dan *Loss on Drying* granul, serta menurunkan daya serap air granul. *Co-processed excipients* yang optimal mengandung jumlah laktosa sebesar 75% w/w dan Kollidon® VA 64 sebesar 5% w/w. Karakterisasi menggunakan FTIR menunjukkan kemiripan antara spektrum *co-processed excipients* dan ketiga bahan penyusunnya. Karakterisasi menggunakan SEM menampilkan morfologi granul *co-processed excipients* sebagai gabungan dari morfologi laktosa, Kollidon® VA 64, dan stevia sekaligus menunjukkan potensi perbaikan sifat fisik *co-processed excipients*.

Kata kunci: laktosa, Kollidon® VA 64, stevia, *co-processed excipients*, *factorial design*

ABSTRACT

Lactose is one of the most commonly used fillers in tablet formulation. However, lactose has poor compactibility, which can potentially result in high friability tablets. Therefore, co-processing methods have been developed to produce new excipients with better properties. Kollidon[®] VA 64 is a binder with great potential to be combined with lactose into co-processed excipients due to its good flowability, compactibility, and compressibility. Co-processed excipients can be applied in the manufacture of Fast Disintegrating Tablets (FDTs). The addition of stevia as a natural sweetener can serve as a healthier alternative excipient. This study aims to determine the optimal proportion of lactose and Kollidon[®] VA 64 with stevia as a sweetener in filler-binder co-processed excipients candidate for FDT formulation.

The co-processed excipients of lactose, Kollidon[®] VA 64 and stevia were prepared using wet granulation and evaluated for their physical properties, including granule flowability, compactibility, compressibility, particle size, water absorption rate, and Loss on Drying. The optimization of the co-processed excipient formula was based on the results of physical property tests, which were analyzed using the factorial design method. The optimal products were analyzed for their functional groups using Fourier Transform Infrared Spectroscopy (FTIR) and their morphology using Scanning Electron Microscopy (SEM).

The research implied that increasing the amount of lactose reduced the angle of repose, thereby improving the flow properties of the granules. An increase in Kollidon[®] VA 64 enhanced granule flow rate, compactibility, compressibility, particle size, and Loss on Drying, while reducing the water absorption rate of the granules. The optimal co-processed excipients contain 75% w/w lactose and 5% w/w Kollidon[®] VA 64. Characterization using FTIR shows similarities between the spectres of the co-processed excipients and its three components. SEM characterization revealed that the morphology of the granules was a combination of the morphologies of all components, also indicating potential improvements in its physical properties.

Keywords: *lactose, Kollidon[®] VA 64, stevia, co-processed excipients, factorial design*