OPTIMASI GRANULASI DAN KARAKTERISASI ASAM MEFENAMAT HASIL PROSES *HIGH SHEAR MIXER* DAN *FLUID BED GRANULATOR* TERHADAP EFISIENSI PENGEMPAAN TABLET

TESIS

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C 242 007

PROGRAM STUDI MAGISTER FARMASI
SEKOLAH TINGGI FARMASI INDONESIA
YAYASAN HAZANAH
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Agustus 2026

Disetujui Oleh:

Pembimbing	Pembimbing
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Kutipan atau saduran baik sebagian ataupun seluruh naskah, harus menyebut nama pengarang dan sumber aslinya, yaitu Sekolah Tinggi Farmasi Indonesia

Layaknya proses granulasi yang mengikat partikel-partikel kecil menjadi satu kesatuan yang solid dan efisien saat dikempa, dukungan kalianlah yang memadatkan tekad dan semangat saya hingga penelitian ini selesai. Tesis ini saya persembahkan dengan penuh rasa syukur kepada:

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Keluarga, Sahabat dan teman atas ikatan persaudaraan dan semangat yang terus menguatkan.

ABSTRAK

Asam mefenamat merupakan zat aktif dengan kelarutan rendah dan sifat alir yang buruk, sehingga sering kali menurunkan efisiensi kecepatan mesin pada proses pengempaan tablet. Penelitian ini bertujuan untuk mendapatkan granul yang menunjang percepatan dan kelancaran proses pengempaan, memperoleh karakteristik fisik granul dari metode *High Shear Mixer* (HSM) dan *Fluid Bed Granulator* (FBG), serta menetapkan metode yang paling optimal. Pembuatan granul asam mefenamat dilakukan menggunakan HSM (dengan variasi waktu putar 2, 3, dan 4 menit) dan FBG (dengan variasi kecepatan spray 100 rpm dan 200 rpm). Karakterisasi granul meliputi evaluasi sudut istirahat, kerapatan ruahan, kerapatan mampat, *compressibility index*, *Hausner ratio*, dan *moisture content*. Granul kemudian dikempa menjadi tablet untuk dievaluasi parameter bobot, kekerasan, kerenyahan, kadar, disolusi, dan keseragaman sediaan. Hasil karakterisasi menunjukkan granul dari kedua metode memiliki sifat alir kategori sangat baik. Hasil evaluasi tablet menunjukkan bahwa perlakuan FBG 200 rpm memberikan laju disolusi yang superior (85,49%), tingkat akurasi dan presisi bobot yang masuk kategori *World-Class Industrial Capability* (Cpk = 1,51), nilai keseragaman sediaan (NP) 2,06, serta efisiensi waktu siklus operasional berkat sistem *one-pot processing*. Berdasarkan hasil tersebut, dapat disimpulkan bahwa metode FBG dengan kecepatan spray 200 rpm merupakan metode yang paling optimal untuk produksi tablet asam mefenamat skala komersial tanpa perlu melakukan perubahan formula.

Kata kunci: asam mefenamat, granulasi, *high shear mixer*, *fluid bed granulator*, efisiensi pengempaan

ABSTRACT

Mefenamic acid is an active pharmaceutical ingredient characterized by low solubility and poor flowability, which often limits machine speed efficiency during the tablet compression process. This study aimed to produce granules that support faster and smoother compression processes, to determine the physical characteristics of granules produced by High Shear Mixer (HSM) and Fluid Bed Granulator (FBG) methods, and to identify the most optimal granulation method. Mefenamic acid granules were prepared using HSM (with rotation times of 2, 3, and 4 minutes) and FBG (with spray *rates of 100 rpm and 200 rpm). Granule characterization included the evaluation of angle of repose, bulk density, tapped density, compressibility index, Hausner ratio, and moisture content. The granules were subsequently compressed into tablets and evaluated for weight, hardness, friability, assay, dissolution, and content uniformity. Characterization results indicated that granules from both methods exhibited excellent flow properties. Tablet evaluation demonstrated that the FBG 200 rpm treatment provided a superior dissolution rate (85.49%), weight accuracy and precision levels categorized as World-Class Industrial Capability (Cpk = 1.51), a content uniformity acceptance value (NP) of 2.06, and cycle time efficiency due to its one-pot processing system. Based on these findings, it can be concluded that the FBG method with a* spray *rate of 200 rpm is the most optimal approach for the commercial-scale production of mefenamic acid tablets without necessitating formula modifications.*

Keywords: *mefenamic acid, granulation, high shear mixer, fluid bed granulator, compression efficiency*

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