

## EFFECT OF MILLING PROCESS ON PHYSICAL CHARACTERISTICS OF FENOFIBRATE

Aditya Trias Pradana<sup>1\*</sup>, Amelia Susetyo<sup>1</sup>, Christina Avanti<sup>1</sup>

<sup>1</sup>*Department of Pharmaceutics, College of Pharmacy, University of Surabaya, Indonesia.*

\*Corresponding author: Aditya Trias Pradana, phone: +62312981110, fax: +62312981111 [aditya\\_trias@staff.ubaya.ac.id](mailto:aditya_trias@staff.ubaya.ac.id)

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### ABSTRACT

Particle size is one of the most important characteristics of active drug substance that affects solubility and bioavailability. Fenofibrate, as a class II drug based on biopharmaceutical classification system, which has poor aqueous solubility has been chosen to be drug model of particle size reduction. Fenofibrate was mixed with mannitol as stabilizer with the ratio 1:9 in physical mixture form. The size reduction was conducted by a ball mill, with the milling rate of 100, 200 and 300 rpm, respectively. Characterization of the solid dispersion was analyzed by organoleptic and instrumental methods. The instrumental tools used were Fourier Transform Infrared Spectroscopy (FTIR) and Differential Scanning Calorimetry (DSC) which showed that there were no changes in fenofibrate molecules during the milling process. Scanning Electron Microscope results showed that fenofibrate-mannitol produced non-spherical forms. Milling rate improvement produced smaller particle size with rough morphology that decreased the flow properties. Based on the solubility test and reflected in UV/Vis spectra, it showed that particle size reduction with 200 rpm milling rate determined 3 times higher absorbance value compared with pure fenofibrate.