UNIVERSITI TEKNOLOGI MARA

IMPROVEMENT OF GRANULES CHARACTERIZATION USING POLY-ETHYLENE GLYCOL (PEG) AS A BINDER VIA MELT GRANULATION IN PRESSURE SWING GRANULATOR FLUIDIZED BED

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ABSTRACT

Melt granulation of producing core granules was conducted using Pressure Swing Granulation (PSG) technique to produce spherical shape, narrow size distribution of granules, high granule strength and good content uniformity. Core granule of lactose-poly-ethyl ene glycol (PEG) with mass ratio of 85 wt%:15 wt% was produced in this study. Two-stage core granules was conducted by supplying hot fluidizing air for 120 minutes at 80 °C which was higher than PEG melting point. As a comparison, the core granules from first stage of PSG were heated in an oven at same temperature and duration. Lactose granules were also produced to represent granules without binder and heating treatment. Next, binderless granulation of mefenamic acid particles was conducted to produce spherical shape, narrow size distribution of granules, high granule strength and good content uniformity by using Pressure Swing Granulation (PSG) technique. Also to investigate compaction behavior of granulated mefenamic acid (MA) into tablet and study the characteristic of MA tablet. Two types of granules namely lactose-mefenamic acid and lactose-PEG-mefenamic acid with mass ratio of 30:70 and 25:5:70 were produced in this study respectively. The later type of granules is heated for 80 °C above the PEG melting point. All granules are uniform, spherical and narrow size distribution whereby the granules size is less than 500 urn. The tensile strength of two-stage core granules is higher than settled-bed core granules due to densification effect during fluidization. The tensile strength of the lactose-PEG-MA is higher than tensile strength of lactose-MA due to heating process. The content of lactose in two-stage core granules is similar to the feed mixture before introduced to granulation process. The drug contents in both types of granules were uniform and almost similar to the drug content introduced before granulation which was 70%. Then, mefenamic tablet were formed by using compression of tableting machine. The prepared tablets then were characterized by using dissolution testing, tensile strength, weight variation and also uniformity. As a result, with the different compression forces, the dissolution rate is high for the samples and gives a percent drug release more than 80 % after 60 minutes. Besides, the hardness and strength of tablet is high and sufficient to withstand to the pharmaceutical process. The weight variation of the tablet product is smaller and the uniformity is high showed that the flow property of the MA is increased.

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