

ABSTRACT

FORMULATION AND EVALUATION OF CO-PROCESSED EXCIPIENTS WITH COMPARISON OF PEG 4000 10% AND 20% AS MELTABLE BINDER MADE BY MELT GRANULATION METHOD

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Co-processed excipients were made using the melting granulation technique or Melt Granulation. Melt Granulation is a method of forming a solid dispersion in the form of granules with a meltable binder above room temperature. The method can be used to form granules having a binder material. The co-processed excipient additives consist of Lactose, PEG 4000 and primogel. PEG 4000 which serves as a meltable binder or binder that melts easily so no solvent is required, Lactose serves as a filler and Primogel serves as a disintegrant. Based on the results of the study, granules that have met each of the requirements include flow velocity test, rest angle test, compressibility test, and hausner ratio test. The results obtained average flow velocity of granules F1 and F2 have met the flow time requirements, namely the flow time of granules in 100 grams of granules ≤ 10 seconds or flow velocity of 10g/second, the results of the chisel angle test. The results obtained meet the requirements because the requirement of a very good rest angle is 25°, the results of the compressibilitas test and the hausner ratio of granules based on the relationship with flow properties, then F1 can be said to have rather good flow properties, while F2 has fairly good flow properties. While the results of the water content test only F1 met the requirements while F2 did not meet the requirements, because the water content requirement was good 2 5%. Then the results of the evaluation were statistically tested using the SPSS Independent T test and the results showed that between Formula 1 and Formula 2 there was no significant difference. Thus, it can be concluded that excipients made by the melt granulation method can be formulated into preparations from co-processed excipients. And from the results of the evaluation, granules are eligible for flow velocity test, rest angle test, compressibility test and hausner ratio test, respectively. While from the statistical test results there was no significant difference between peg 4000 10% and peg 4000 20% as a meltable binder to the physical characteristics of co-processed excipients made using the Melt Granulation method except for the water content parameter. Therefore, in the next study, further formulations need to be carried out with different concentrations of peg to see the effect on co-processed excipients.

Keywords: Co-processed excipients, PEG 4000, meltable binder, melt granulation