

**ABSTRACT**

**THE EFFECT OF POLYPLASDONE XL-10 ON  
CHARACTERISTICS OF MANNITOL – POLYPLASDONE  
XL-10 – GELATIN CO-PROCESSED EXCIPIENT FOR  
ORALLY DISINTEGRATING TABLET  
(Produced by Fluid Bed Granulation Method)**

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There is a strong trend in the pharmaceutical industry toward developing Orally Disintegrating Tablets (ODTs), because they have various benefits for the patient compared with regular tablets. ODTs disintegrate rapidly in the mouth without any water, usually in a matter of seconds. In the present research, co-processed excipients for Orally Disintegrating Tablets (ODTs) were designed with a view to develop ODT by direct compression method.

Granules of co-processed excipients were produced by Fluid Bed Granulation method, containing mannitol as filler and sweetener, Polyplasdone XL-10 as superdisintegrant in two different concentrations: 5% and 10%, and gelatin as binder in 2% concentration.

The characteristics of the granules were evaluated including moisture content, particle-size distribution, density, flow rate, angle of repose, % compressibility, compactibility, disintegrating time, dilution potential, and Scanning Electron Microscope (SEM).

The result was analyzed by SPSS 20 statistic programme using *Independent Two Sample t-test*. Statistical analysis showed that there was a significant difference on characteristics among formulas, except the compactibility. It can be concluded that the optimum formula was the formula with 10% of Polyplasdone XL-10, with flow rate of 10,11 g/s, compactibility and disintegrating time in the force of 1 ton of 12,80 kP and 60,19 second, and dilution potential in the ratio of 50 : 50 co-processed excipient : paracetamol of 5,44 kP.

Keyword: co-processed excipient, orally disintegrating tablets, fluid bed granulation, Polyplasdone XL-10, and characteristics.