ABSTRACT

Influence of Lactose Concentration on the Release of Ketoprofen from Controlled Release Tablets with Hydroxypropyl Methyl Cellulose K4M as a Matrix

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Most controlled release forms are designed so that the administration of a single dosage unit provides the immediate release of an amount of drug that promptly produces the desired therapeutic effect and gradual and continual release of additional amounts of drug to maintain this level of effect over an extended period, usually 8 to 12 hours. Controlled release forms has many advantages such as reducing fluctuations in drug levels in the blood, reducing the frequency of drug use, improve patient compliance and convenience and reduce side effects.

The purpose of this research was to determine concentration of lactose that can produce controlled release tablets of ketoprofen with HPMC K4M as matrix, with physical quality according to regulation, with release of the drug that appropriate with Welling regulation and also achieve a zero order release. HPMC K4M matrix tablet of ketoprofen using lactose channeling agent were prepared by wet granulation method.

In this research, there were four formulas that contain different lactose concentration. Formula 1 as a control. Formula 2, 3, and 4 contains lactose 20%, 25%, 30%. Various concentration of lactose as channeling agent is to observe the significant difference in physical quality of granulate include moisture content, flow rate, angle of response, and the number of fines, physical quality of tablets include hardness, friability, variety of weight and dissolution rate.

The result showed that with increasing concentration of lactose will produce granules with a lower moisture content, granule flow properties better, and tablets with higher hardness and lower friability and the physical quality of granule and tablets was different for each formula. Dissolution test were evaluated for 480 minutes by USP dissolution apparatus 2 with phosphate buffer medium pH 6.8 at temperature 37 ± 0.5°C. In total release, with increasing concentration of lactose in the formula will increase the total release. The release showed that total release F4 was the higher than F1, F2 and F3. In the statistical test on the total release of 480 minutes, there was a significant difference between the formulas.

Release of ketoprofen from matrix tablet none of them appropriate with Welling regulation. In order of kinetics profile, all of the formula following first order and all of formulas indicate the drug was release by non fickian diffusion.

Key words: Ketoprofen, HPMC K4M, Channeling Agent, Lactose, Controlled release tablet