

## INTISARI

Kalium diklofenak merupakan *Non-Steroidal Anti Inflammatory Drugs* (NSAID) yang poten dan telah digunakan secara klinis untuk terapi inflamasi. Akan tetapi, kalium diklofenak memiliki ketersediaan hayati yang rendah sebesar 60% dan dapat mengiritasi lambung apabila dikonsumsi oral. *Fast dissolving film* (FDF) dapat hancur secara cepat di rongga mulut dan memberikan efek melalui absorpsi oromukosal, sehingga dapat meningkatkan ketersediaan hayati dan menghindari risiko iritasi lambung.

Pada penelitian ini dioptimasi formula FDF kalium diklofenak menggunakan metode *simplex lattice design* dengan kombinasi *plasticizer* PEG 400 dan PEG 1000. Pembuatan FDF dilakukan dengan metode *solvent casting* menggunakan pelarut akuades. Sediaan FDF diuji karakteristiknya yang meliputi keseragaman kandungan, kuat tarik, elongasi, *moisture content*, waktu hancur, dan ketebalan. Formula optimum hasil prediksi program diverifikasi dengan membandingkan hasil uji karakteristik FDF formula optimum yang dibuat dengan data hasil prediksi program menggunakan uji t (*one sample t test*) dengan taraf kepercayaan 95%.

Berdasarkan hasil analisis, penggunaan PEG 400, PEG 1000, dan kombinasinya memberikan pengaruh signifikan pada karakteristik sediaan. Formula optimum FDF diperoleh pada kombinasi 5,1% PEG 400 dan 4,9% PEG 1000. Penggunaan *plasticizer* dengan perbandingan optimum mengurangi ketebalan FDF, meningkatkan kuat tarik, elongasi, dan *moisture content*, serta mempercepat waktu hancur sediaan.

*Kata kunci : kalium diklofenak, fast dissolving film, PEG 400, PEG 1000*

## ABSTRACT

Diclofenac potassium is a potent non-steroidal anti-inflammatory drug (NSAID) and has been used clinically for inflammatory therapy. However, potassium diclofenac has a low bioavailability at 60% and can irritate the stomach when taken orally. Fast dissolving film (FDF) disintegrate quickly in the oral cavity and give effect through oromukosal absorption, so that it can increase bioavailability and avoid the risk of stomach irritation.

In this study, the FDF potassium diclofenac formula was optimized using the simplex lattice design method with a combination of PEG 400 and PEG 1000 *plasticizers*. FDF made using solvent casting method with distilled water as the solvent. FDF tested for characteristics including uniformity of content, tensile strength, elongation, moisture content, disintegration time, and thickness. The optimum formula for the results of program predictions then verified by comparing the results of the FDF characteristic test, the optimum formula made with the program prediction data using the t test (one sample t test) with a confidence level of 95%.

Based on the results of the analysis, the use of PEG 400, PEG 1000, and its combination had a significant effect on the characteristics of the preparation. The optimum formula for FDF obtained from a combination of 5.1% PEG 400 and 4.9% PEG 1000. The use of an optimum *plasticizer* reduced FDF thickness, increased tensile strength, elongation, and moisture content, and accelerated the preparation time.

*Keywords: diclofenac potassium, fast dissolving film, PEG 400, PEG 1000*