ABSTRAK

Irbesartan merupakan obat antihipertensi golongan antagonis reseptor angiotensin II (subtipe AT1) yang termasuk BCS kelas II dengan kelarutan dalam air yang sangat rendah (0,00884 mg/mL), sehingga menyebabkan absorpsi tidak konsisten dan variabilitas bioavailabilitas antarpasien. Penelitian ini bertujuan untuk mengetahui pengaruh variasi rasio PEG 6000 : poloxamer 188 dalam sistem dispersi padat irbesartan menggunakan metode *solvent evaporation* terhadap kelarutan dan laju disolusi. Dispersi padat dibuat dengan dua variasi rasio PEG 6000 : poloxamer 188, yaitu 98:2 (Formula 1) dan 99:1 (Formula 2), kemudian dibandingkan dengan campuran fisik masing-masing formula melalui uji kelarutan dan uji disolusi dalam medium HCl 0,1 N selama 120 menit. Parameter disolusi dinyatakan sebagai *Dissolution Efficiency* (DE%) dan analisis statistik menggunakan uji normalitas Shapiro-Wilk dilanjutkan dengan *independent t-test* apabila data terdistribusi normal atau *Mann-Whitney test* apabila tidak normal pada taraf kepercayaan 95%. Hasil uji menunjukkan dispersi padat Formula 1 memiliki kelarutan tertinggi (9,79±0,04 µg/mL) dengan nilai DE_{120} tertinggi (90,893%), diikuti Formula 2 (8,80±0,03 µg/mL; DE_{120} 89,144%). Kedua formula tersebut berbeda bermakna dibandingkan dengan campuran fisik masing-masing ($p < 0,001$). Terdapat perbedaan yang bermakna secara statistik antara dispersi padat Formula 1 dan Formula 2 ($p < 0,001$).

Kata Kunci: Irbesartan, dispersi padat, PEG 6000, poloxamer 188, kelarutan, disolusi.

ABSTRACT

Irbesartan is an antihypertensive drug belonging to the angiotensin II (subtype AT1) receptor antagonist class and classified as a BCS class II drug with very low water solubility (0.00884 mg/mL), resulting in inconsistent absorption and inter-patient variability in bioavailability. This study aimed to determine the effect of variations in the PEG 6000 : poloxamer 188 ratio in an irbesartan solid dispersion system using the solvent evaporation method on solubility and dissolution rate. Solid dispersions were prepared using two variations of the PEG 6000 : poloxamer 188 ratio, namely 98:2 (Formula 1) and 99:1 (Formula 2), and were then compared with the physical mixtures of each formula via solubility and dissolution tests in 0.1 N HCl medium for 120 minutes. Dissolution parameters were expressed as Dissolution Efficiency (DE%), and statistical analysis used the Shapiro-Wilk normality test followed by an independent t-test if the data were normally distributed, or the Mann-Whitney test if not, at a 95% confidence level. The results showed that the Formula 1 solid dispersion had the highest solubility (9.79±0.04 µg/mL) with the highest DE_{120} value (90.893%), followed by Formula 2 (8.80±0.03 µg/mL; DE_{120} 89.144%). Both formulations differed significantly from their respective physical mixtures ($p < 0.001$). A statistically significant difference was observed between solid dispersion Formula 1 and Formula 2 ($p < 0.001$).

Keywords: Irbesartan, solid dispersion, PEG 6000, poloxamer 188, solubility, dissolution.