ABSTRAK

Telah dilakukan penelitian tentang uji disolusi terbanding amlodipin dari berbagai sediaan tablet yang beredar dipasaran. Evaluasi mutu fisik tablet yang dilakukan meliputi keseragaman bobot, keseragaman ukuran, kerapuhan, waktu hancur, nilai HFR/DT, % penyimpangan bobot. Secara fisik memiliki nilai yang sesuai dengan persyaratan yang tertera dalam Farmakope Indonesia dan relatif sama antar tablet amlodipin inovator dan generik, kecuali untuk kekerasan tablet inovator memiliki hasil lebih tinggi dari syarat (4-8 kg/cm²). Konsentrasi amlodipin diukur dengan kromatografi cair kinerja tinggi pada detektor 237 nm menggunakan fase gerak buffer fosfat pH 3,0 : metanol HPLC grade : asetonitril pro HPLC (50:35:15), pelarut metanol HPLC grade, laju alir 1 mL/menit, dan run time 30 menit. Penetapan kadar zat aktif dalam tablet amlodipin inovator berkisar 94,5730±2,1957 %; tablet generik A 89,8894±1,8175 %; dan tablet generik B 88,6854±3,4395 % memperlihatkan hanya tablet inovator yang memenuhi syarat USP (90-110%). Faktor kemiripan disolusi tablet inovator dengan generik A f2=62,7938 memenuhi syarat f2 karena berada pada kisaran 50-100, sedangkan faktor kemiripan dari tablet inovator dengan tablet generik B tidak memenuhi persyaratan dengan hasil f2=23,1034. Profil disolusi digambarkan dari plot antara % terdisolusi terhadap waktu, dan linieritas diperoleh berdasarkan kinetika pelepasan menurut persamaan Higuchi. Pengujian berdasarkan statistik F menunjukkan perbedaan nyata antara jenis sediaan dan waktu dengan hasil kadar disolusi ($P<0,05$), serta berdasarkan uji fisher tidak ada perbedaan proporsi antara kedua jenis tablet.

ABSTRACT

A research of comparative dissolution testing of various dosage amlodipine tablets in circulation. Quality evaluation was conducted on the physical tablet weight uniformity, uniformity of size, friability, disintegration time, the value corresponding to the requirements described in the pharmacopoeia Indonesia, and relatively similar between amlodipine tablets innovators have higher yields than condition (4-8 kg/cm²). Kromatografri amlodipine concentrations were measured by high performance liquid detector 273 nm using a mobile phase of phosphate buffer pH 3.0: methanol HPLC grade: acetonitrile pro HPLC (50:35:15), PHPLC grade methanol, flow rate 1 mL / min, and runtime 30 minutes. Assay of the active substance in the tablets of amlodipine innovator ranges from around 94.5730±2.1957%, tablets of generic A 89.8894±1.8175%, and tablets of generic B 88,6854±3.4395% and showed innovator tablets eligible only to USP (90-110%). Factor similarity dissolution of innovator tablet with generic A f2 = 62.7938 qualify because being in the range of 50-100, while the factor of similarity with the innovator tablet generic B does not meet the requirements with the results of f2 = 23.1034. Dissolution profiles depicted from the plot between % dissolved versus time, and linearity obtained by release kinetics according the equation of Higuchi. The test is based on the F statistic which showed differences significant between the type of preparation and time with the results of dissolution levels ($P < 0.05$), and base on fisher test there is nothing difference of proportion between both of them.