ABSTRAK

Kaptopril merupakan obat antihipertensi dengan waktu paruh yang pendek. Adanya inovasi tablet *sustained release* kaptopril dapat meningkatkan kepatuhan pasien dalam terapi. Metode analisis hasil disolusi tablet *sustained release* kaptopril belum pernah dikembangkan, padahal disolusi merupakan parameter penting pada kontrol kualitas sediaan, sehingga penelitian ini bertujuan melakukan pengembangan dan validasi metode analisis hasil disolusi tablet *sustained release* kaptopril secara Kromatografi Cair Kinerja Tinggi (KCKT).

Metode analisis yang dikembangkan menggunakan instrumen KCKT (Hitachi®) dengan kolom LiChrospher® 100 RP-8 (250 mm x 4,6 mm *i.d.*, 5 µm), fase gerak metanol : air yang mengandung asam fosfat 0,001% (1:1) dengan laju alir 1 mL/menit dan detektor UV 205 nm. Parameter validasi metode analisis meliputi uji selektivitas, presisi, akurasi, linearitas dan *range*, stabilitas, *ruggedness*, dan *robustness*.

Menurut hasil penelitian, metode analisis bersifat selektif sebab tidak terdapat interferensi pada waktu retensi kaptopril (t_R=3,8 menit), bersifat akurat dengan nilai *recovery* 99%, bersifat teliti dengan nilai RSD 1,7%, dan linear dengan nilai r = 0,999. Uji *robustness* dan *ruggedness* memenuhi syarat dengan nilai RSD ≤ 5,3%. Kaptopril dinyatakan stabil dalam media disolusi HCl 0,01 N pada uji stabilitas selama 300 menit. Metode analisis yang dikembangkan bersifat valid, sehingga dapat digunakan sebagai alternatif metode analisis hasil disolusi tablet *sustained release* kaptopril.

Kata kunci : kaptopril, *sustained release*, disolusi, validasi

ABSTRACT

Captopril has been used for treatment of hypertension but it has a short biological half life. There is innovation for captopril sustained-release tablets that can improve patient compliance in treatment. The analytical method for dissolution samples of captopril sustained-release tablets has not been reported before, so it should be developed and validated by High Performance Liquid Chromatography (HPLC).

The method was developed using HPLC instruments with LiChrospher® 100 RP-8 (250 mm x 4.6 mm i.d., 5 µm), methanol and water containing phosphoric acid 0,001 % (1:1) as mobile phase, at flow rate 1.0 mL/minute, and UV detector 205 nm. Validation parameters that should be done are selectivity, accuracy, precision, linearity and range, stability, ruggedness, and robustness.

The results showed that the method was selective because there is no peak at the retention time of captopril (t_R = 3.8 minutes), accurate with recovery value 99%, and precise with RSD value 1.7%. The linearity test shows the value of r = 0.999. The RSD value of robustness and ruggedness test within 5.3%. The stability test showed that captopril was stable in dissolution media HCl 0,01 N for 300 minutes. The method meets all the requirements so that it can be used as an alternative method for analyzing dissolution samples of captopril sustained-release tablets.

Keywords : captopril, sustained release, dissolution, validation