Validasi metode analisis esomeprazol dalam plasma in vitro secara kromatografi cair kinerja tinggi photodiode array = Validation of esomeprazole in human plasma by high performance liquid chromatography photodiode array

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Abstrak

ABSTRAK
Esomeprazol merupakan salah satu obat penghambat pompa proton yang efektif untuk mempertahankan pH lambung. Esomeprazol dibuat dalam bentuk tablet salut selaput sehingga termasuk obat wajib Uji Bioekivalensi menurut Peraturan Kepala Badan Pengawas Obat dan Makanan Republik Indonesia tentang Obat Wajib Uji Ekivalensi. Uji Bioekivalensi obat harus menggunakan metode bioanalisis yang tervalidasi. Penelitian ini bertujuan untuk mengembangkan metode analisis esomeprazol dalam plasma mulai dari kondisi kromatografi optimum, metode preparasi plasma optimum, hingga validasi metode analisis. Kondisi kromatografi optimum adalah kolom C-18 (Waters, SunfireTM 5 µm; 250 x 4,6 mm), suhu kolom 40 oC; fase gerak asetonitril ? dapar fosfat pH 7,6 (40 : 60 %v/v); laju alir 1,00 mL/menit; detektor photodiode array pada panjang gelombang 300 nm; dan lansoprazol sebagai baku dalam. Preparasi sampel menggunakan metode ekstraksi cair-cair dengan pelarut diklorometan lalu dikeringkan dengan gas nitrogen pada suhu 40 oC selama 30 menit; dan direkonstitusi dengan fase gerak sebanyak 100 µL. Hasil validasi terhadap metode analisis esomeprazol yang dilakukan memenuhi persyaratan validasi berdasarkan EMEA Bioanalytical Guideline tahun 2011. Metode yang diperoleh linear pada rentang konsentrasi 5,0 ? 450,0 ng/mL dengan r > 0,9997.
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ABSTRAK
Esomeprazole is a proton pump inhibitor drug that is effective to maintain the pH of the stomach. Esomeprazole was formulated as film coated tablet that includes mandatory drug testing bioequivalence according to Regulation Head of National Agency of Drug and Food of the Republic of Indonesia about Mandatory Drug Testing equivalences. Drug bioequivalence trials should use validated bioanalytical method. This research aimed to develop analytical methods esomeprazole in human plasma from optimum chromatographic conditions, the optimum plasma preparation method, until the validation of analytical methods. The optimum chromatographic condition was obtain using C-18 column (Waters, Sunfire? 5 μm; 250 x 4.6 mm), column temperature 40 °C; mobile phase acetonitrile - phosphate buffer pH 7.6 (40: 60% v/v); a flow rate of 1.00 mL/min; photodiode array detector at a wavelength of 300 nm; and lansoprazole as internal standard. Sample preparation using liquid-liquid extraction with dichloromethane as solvent and then dried with nitrogen gas at a temperature of 40 °C for 30 minutes; and reconstituted with mobile phase of 100 mL. The results of validation fulfilled the acceptance criteria of validation method based on EMEA Bioanalytical Guideline 2011. The method was linear at concentration range of 5.0 to 450.0 ng / mL with r > 0.9997.