Incurred sample stability metformin hidroklorida dalam plasma 6 orang subjek sehat secara kromatografi cair kinerja tinggi = Incurred sample stability of metformin hydrochloride in plasma of 6 healthy subject by high performance liquid chromatography

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Abstrak

Metformin merupakan obat yang memerlukan respon pasti critical use drug , sehingga termasuk obat wajib uji bioekivalensi. Uji Bioekivalensi dapat dilakukan melalui studi farmakokinetika yang memerlukan metode bioanalisis yang tervalidasi untuk penentuan kadar obat dalam plasma. Pada pelaksanaan validasi metode bioanalisis diantaranya terdapat parameter stabilitas yang dilakukan secara in vitro. Pada keadaan in vivo analit dapat dipengaruhi oleh berbagai senyawa endogen dan proses metabolisme. Analisis metformin dilakukan pada 6 subjek sehat yang mengkonsumsi tablet metformin hidroklorida 850 mg sebagai bentuk pengaplikasian in vivo metode yang telah tervalidasi. Pengambilan darah pada subjek akan dilakukan sebanyak 12 titik pada beberapa interval waktu hingga jam ke-12. Penelitian ini bertujuan untuk menganalisis incurred sample stability pada 6 subjek sehat pada hari ke 7, 14, dan 30 pada fase Cmax dan eliminasi. Kondisi kromatografi optimum yang digunakan adalah kolom C-18 Waters, SunfireTM 5 m; 250 x 4,6 mm , suhu kolom 40°C; fase gerak asetonitril ndash; dapar fosfat pH 7,0 40 : 60 v/v ; laju alir 1 mL/menit; detektor photodiode array pada panjang gelombang 234 nm; dan kalsium atorvastatin sebagai baku dalam. Hasil stabilitas incurred sample metformin HCl pada hari ke 7 , 14, dan 30 subjek 1 hingga subjek 6 menunjukan kestabilan yang memenuhi persyaratan berdasarkan EMEA Bioanalytical Guideline tahun 2011 yaitu nilai diff tidak boleh lebih dari 20. Metode yang diperoleh linear pada rentang konsentrasi 20,0 ndash; 5000,0 ng/mL dengan r =0,9999.

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Metformin HCl is one of the biguanid drugs for diabetes mellitus DM type 2. Metformin is a drug that requires a valid response critical use drug , so it is included as a drug that required bioekivalensi test. Bioquivalence tests can be performed through pharmacokinetics studies that require validated bioanalysis methods for the determination of plasma drug levels. In the implementation of validation of bioanalytical methods, there are some stability parameters that performed in vitro. At the in vivo condition, analit can be affected by various endogenous compounds and metabolism processes. Metformin analysis was performed on 6 healthy subjects who consumed 850 mg metformin hydrochloride tablet as a form of applying validated in vivo method. Blood sampling on the subject will be done as many as 12 points at several time intervals up to the 12th hour. This study aims to analyze incurred sample stability in 6 healthy subjects on day 7th, 14th, and 30th. The optimum chromatographic conditions that used were C 18 columns Waters, SunfireTM 5 m, 250 x 4.6 mm , column temperature 40°C Acetonitrile phosphate buffer phase pH 7.0 40 60 v v Flow rate of 1 mL min Photodiode array detector at 234 nm wavelength And calcium atorvastatin as an inner standard. The results of stability of incurred samples of metformin HCl on day 7th, 14th, and 30th from subject 1 to subject 6 show stability that meets the requirement based on the EMEA Bioanalytical Guideline in 2011, that diff value cannot be more than 20 . The method that obtained is linear in the concentration range 20.0 5000.0 ng mL with r 0.9999.