Profil farmakokinetika dan incurred sample stability esomeprazol pada sampel dried blood spot subjek sehat menggunakan kromatografi cair kinerja tinggi - photodiode array = Pharmacokinetic profile and incurred sample stability of esomeprazole in dried blood spot sample of healthy subjects using high performance liquid chromatography - photodiode array

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Abstrak

Esomeprazol adalah salah satu obat golongan penghambat pompa proton yang tidak stabil terhadap pH asam, panas, kelembaban dan oksidasi, sehingga seringkali membuat esomeprazol terdegradasi saat penyimpanan. Pada umumnya, teknik biosampling yang digunakan dalam studi farmakokinetik esomeprazol adalah venipuncture. Namun pada penelitian ini, teknik biosampling yang digunakan adalah Dried Blood Spot DBS yang lebih dapat menjaga stabilitas esomeprazol dan lebih nyaman bagi subjek dibandingkan teknik venipuncture. Penelitian ini bertujuan untuk menganalisis stabilitas in vivo esomeprazol dalam sampel DBS dengan menguji Incurred Sample Stability ISS esomeprazol terhadap 6 subjek sehat pada hari ke 7, 14 dan 28. 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 7,6 40:60 v/v ; laju alir 1,00 mL/menit; detektor photodiode array pada panjang gelombang 300 nm; dan lansoprazol sebagai baku dalam. Nilai diff terbesar yang diperoleh dalam uji ISS esomeprazol pada hari ke 7, 14, dan 28, dari seluruh subjek adalah 9,81. Hasil ini memenuhi persyaratan ISS dari EMEA yaitu nilai diff tidak lebih dari 20 dan minimal 67 dari total sampel memenuhi persyaratan tersebut. Sehingga dapat disimpulkan esomeprazol stabil secara in vivo dalam sampel DBS hingga hari ke 28.

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Esomeprazole is one of the proton pump inhibitor that is unstable against pH, heat, moisture and oxidation, which often makes esomeprazole degraded at the time of storage. Basically, in bioequivalence test of esomeprazole, biosampling technique used is venipuncture. In this research, biosampling technique used was Dried Blood Spot DBS, which will give better stability and provide more comfort to subject than venipuncture technique. This research aimed to analyse in vivo stability of esomeprazole by testing Incurred Sample Stability ISS of esomeprazole on day 7, 14 and 28. The optimum chromatographic condition was obtained using C 18 column Waters, Sunfire trade 5 m 250 x 4.6 mm, column temperature was 40°C mobile phase was acetonitrile phosphate buffer pH7.6 40:60 v/v flow rate was 1.00 mL min photodiode array detector at a wavelength of 300 nm and lansoprazole as internal standard. The highest diff value of esomeprazoles ISS on day 7, 14, and 28 from all subjects were 8,91 that fulfilled the acceptance criteria of validation method based on EMEA, which is the diff should not be greater than 20 and 67 of total samples have to fulfill this criteria. So, the ISS result showed that esomeprazole were stable as in vivo in DBS sample until 28 days.