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Determination of Sulthiame in Plasma by High-Performance Liquid Chromatography*

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Sulthiame, N-(4'-sulfamoylphenyl)-1,4-butanedisulfonamide, is an antiepileptic agent. Several pharmaceutical preparations containing sulthiame have been used clinically. The therapeutic effects of the preparations may be related to its concentration in plasma. Thus, for comparison of the bioavailabilities of the preparations and for drug monitoring during therapy, a rapid and sensitive method of assay was required.

We found that high-performance liquid chromatography (HPLC) with UV detection meets the requirement. Plasma sample was acidified with aqueous HCl and extracted with CHCl_3 . The CHCl_3 layer was separated and evaporated to dryness in vacuo. The residue was dissolved in CHCl_3 containing aminopyrine, a reference standard, and injected into a liquid chromatograph. The compounds were separated by normal phase chromatography on Zorbax-SIL. The standard curve obtained by plotting the ratio of the peak height of sulthiame to that of the reference standard against the amount of sulthiame was linear and passed through the origin.

The present method permits the accurate determination of sulthiame in plasma at concentrations as low as 150 ng/ml and is suitable for monitoring the drug in the therapeutic dose range and for investigation of the bioavailabilities of preparations of the drug. The bioequivalence of sulthiame-containing tablets (Ospolot Tablets) of two formulas, which were the same in content of sulthiame but different in the kind and contents of inactive ingredients, was demonstrated in dogs.

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