ІПКСФ НФаУ

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Національний фармацевтичний університет
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ФАРМАЦЕВТИЧНІ ТЕХНОЛОГІЇ, СТАНДАРТИЗАЦІЯ ТА ЗАБЕЗПЕЧЕННЯ ЯКОСТІ ЛІКАРСЬКИХ ЗАСОБІВ

Харків, 22 травня 2025

DEVELOPMENT OF SULPIRIDE IDENTIFICATION METHODS SUITABLE FOR CHEMICAL-TOXICOLOGICAL ANALYSIS

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Introduction. Sulpiride 5-(aminosulfonyl)-N-[(1-ethyl-2-pyrrolidinyl)methyl]-2-methoxybenzamide is an antipsychotic drug.

Sulpiride is a substituted benzamide derivative and a selective dopamine D2 antagonist indicated to treat acute and chronic schizophrenia. It has a short duration of action as it is given twice daily, and a wide therapeutic window as patients have survived single doses as high as 16g. Patients should be counselled regarding increased motor agitation, extrapyramidal reactions, and neuroleptic malignant syndrome. Sulpiride is a selective dopamine D2 and D3 receptor antagonist. It is estimated that D2 receptors should be 65-80% occupied for optimal treatment and minimal adverse effects. Numerous cases of lethal intoxications due to sulpiride overdosage were reported in the literature. The postmortem blood concentrations ranged from 3.9 to 38.7 mg/l, liver concentration of 11.0 μg/g has been reported. The average volume of distribution of sulpiride is 2.72 ± 0.66 L/kg.

Aim of the study. To develop sensitive and accessible methods for sulpiride detection and identification with help of colour reactions, thin layer chromatography and UV-spectrophotometry.

Materials of the study. Interaction of sulpiride with 10 chromogenic reagents was studied, their sensitivity was determined. Rf values of sulpiride in 12 mobile phases including those recommended by The International Association of Forensic Toxicologists (TIAFT) for TLC drug screening for 4 types of chromatographic plates (plates manufactured in Estonia with KSKG sorbent, Sorbfil, Silufol, Merk) were determined. UV spectrum of sulpiride was studied in 0.1 M hydrochloric acid solution.

Results of the study. Dragendorff's reagent with Munier modification and iodine vapour were the most sensitive (2.0 μg/spot). Marqui's reagent (green, sensitivity was of 15.0 μg), Froehde reagent (green, sensitivity was of 20.0 μg) were selective relating the endogenous biological matrix components. Three mobile phases of chloroform–methanol (90:10) (R_f=0.04), methanol–25% ammonia (100:1.5) (R_f=0.37) (or chloroform–dioxane–acetone–25% ammonia (47.5:45:5:2.5) (R_f=0.36)), ethyl acetate–methanol–25% ammonia (85:10:5) (R_f=0.54) had a low correlation of R_f values. R_f values are given for Merk plates. According to the TIAFT recommendations, the joint use of low-correlation chromatographic systems increases the reliability of drug identification by TLC. Sulpiride in 0.1 M hydrochloric acid had absorption maximum in UV region of spectrum at the wavelength of 293±2 nm (A_1^1 60,0).

Conclusions. Sensitive and selective techniques developed using colour reactions, thin layer chromatography and UV spectrophotometry are suitable for the purpose of chemical-toxicological analysis.