

POSTER PRESENTATIONS

HPLC AND CAPILLARY ELECTROPHORESIS IN THE ANALYSIS OF THE TEFESTROL SUBSTANCE

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At the Institute of the Chemistry of Plant Substances of the Academy of Sciences of the Republic of Uzbekistan (ICPS AS RUz), an original medicinal product, Tefestrol, has been developed for the treatment of gynecological disorders. The active pharmaceutical ingredient of Tefestrol (TF), isolated from the roots of *Ferula tenuisecta*, exhibits pronounced estrogenic activity. The roots of this plant contain esters of sesquiterpene alcohols with aromatic acids (ESAAs), including ferutin, ferutin, teferin, and related compounds. Ferutin accounts for not less than 95% of the total ESAA content. The medicinal product has been approved by the Ministry of Health of the Republic of Uzbekistan for widespread clinical use. The active pharmaceutical ingredient is manufactured at the Institute's pilot production facility, while the finished dosage form is supplied as tablets containing 5 mg of the active substance.

Sensitive and selective methods are required for the quantitative determination of TF in new dosage forms. In this study, micellar electrokinetic chromatography (MEKC) was used, with neutral hydrophobic TF molecules partitioning into sodium dodecyl sulfate (SDS) micelles. The optimized conditions were 10 mM sodium tetraborate with 80 mM SDS, 260 nm detection wavelength, 25 kV voltage, and 25°C. The electropherogram of a 100 µg/mL TF solution is shown in Figure 1, where the ferutin and impurity peaks are clearly resolved.

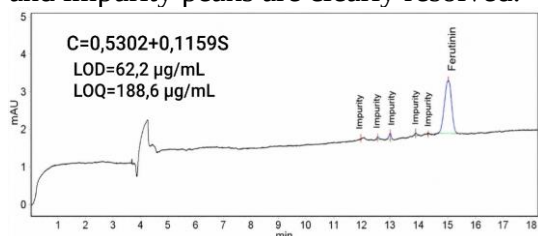


Figure 1- Electropherogram of Tefestrol (100 µg/mL)

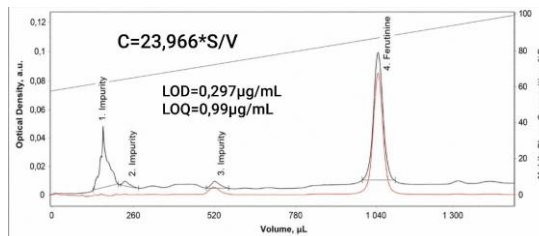


Figure 2 - Chromatogram of Tefestrol (100 µg/mL)

A quantitative HPLC method for TF was also developed using a Milichrom A-02 microcolumn chromatograph equipped with a reversed-phase ProntoSil-120-5-C18 AQ microcolumn (75 × 2 mm, 5 µm). Gradient elution was performed using a water–acetonitrile mobile phase (60–100% B) at a flow rate of 200–150 µL/min.

In summary, novel selective methods for the quantitative determination of the phytosubstance Tefestrol were developed using both CE and HPLC on the Milichrom A-02 microcolumn chromatograph. These methods provide efficient and selective quantification of TF and are suitable for quality control of the pharmaceutical formulation as well as stability studies of the active pharmaceutical ingredient.