

THE DETERMINATION OF KETOROLAC TROMETHAMINE IN PHARMACEUTICAL
PREPARATIONS BY FLOW INJECTION ANALYSIS
USING UV DETECTION

UV DETEKTÖR KULLANILARAK FLOW İNJEKSİYON ANALİZ YÖNTEMİ İLE
FARMASÖTİK PREPARATLARDA KETOROLAK TROMETHAMİNİN TAYİNİ

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A flow-injection analysis (FIA) of ketorolac tromethamine (KT) using UV detection is described. The best solvent system was found to be 0.1 mol.l⁻¹ acetate buffer at pH 5.2. A flow rate of 1 ml.min⁻¹ was pumped and active material was detected at 323 nm. The calibration equation was linear in the range of 1x10⁻⁵ to 5x10⁻⁵ mol.l⁻¹. Limit of detection (LOD) and limit of quantitation (LOQ) were calculated to be 2.8x10⁻⁶ and 8.2x10⁻⁶ mol.l⁻¹ respectively. The proposed method was applied to the determination of KT in pharmaceutical preparations. The results were compared with those obtained by UV-spectrophotometry. The validation studies were realised by the related applications and the results were evaluated statistically and insignificant differences were observed between the methods.

Ketorolak tromethaminin (KT), UV detektörü kullanılarak Flow İnjeksiyon Analiz (FIA) yöntemi ile tayini geliştirilmiştir. En iyi çözücü sisteminin 0.1 mol.l⁻¹ asetat tamponu (pH:5.2) olduğu bulunmuştur. Aktif materyal 1 ml.dak⁻¹ akış hızında pompalanmış ve 323 nm de detekte edilmiştir. 1 x10⁻⁵ ile 5x10⁻⁵ mol.l⁻¹ derişim aralığında doğrusallık elde edilmiştir. Şaptama ve tayin sınırları sırasıyla, 2.8x10⁻⁶ ve 8.2x10⁻⁶ mol.l⁻¹ olarak hesaplanmıştır. Yöntem KT içeren farmasötik preparatlara da uygulanmış, sonuçlar UV-spektrofotometrik yöntemle karşılaştırılmıştır. Uygulamalar üzerinde validasyon çalışmaları yapılmış, sonuçlar istatistiksel açıdan değerlendirilmiş ve yöntemler arasında anlamlı bir fark gözlenmemiştir.

Keywords: Ketorolac tromethamine; Flow Injection Analysis; Pharmaceutical Application

Anahtar Kelimeler: Ketorolak tromethamin; Flow İnjeksiyon Analiz Yöntemi; Farmasötik Uygulamalar

Introduction

Ketorolac tromethamine (KT) [(±)-5-benzoyl, 2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, 2-amino-2-hydroxymethyl-1,3-propane-diol (1:1), is a nonnarcotic analgesic with

cyclooxygenase inhibitory activity. It has been evaluated for the treatment of moderate to severe pain, such as postoperative pain. Like other compounds inhibiting prostaglandin

* Correspondence

The validity of this method was examined by applying to commercial tablets. The ingredients in the tablets did not interfere in the experiments. All results of the assays were evaluated statistically as presented in table 2.

Table 2. The assay results of KT in tablets.*

	FIA	UV- Spectrophotometry
mean	9.8	9.9
n	8	8
RSD%	1.3	0.8
CL	±0.16	±0.12
F-test of insignificant	3.18	$F_{0.05}=4.28(\text{table})$
t- test of insignificant	1.85	$t_{0.05}=2.18(\text{table})$

*Each tablet contains 10 mg of KT

High reproducibility and insignificant differences between FIA and UV-spectrophotometry were observed at the 95% probability level. As a conclusion, the method proposed in this study is simple, accurate, precise and rapid. Therefore, the suggested method is more practical, regarding the time of analysis, consumption of solvents and size of sample required for the routine analysis of KT.

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