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# A Simple High-Throughput Method for Determination of Pregabalin in Pharmaceutical Dosage Forms using a Microplate Fluorescence Reader

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Pregabalin is a structural analogue of γ-aminobutyric acid approved for treatment of neuropathic pain, as adjunctive therapy for partial seizures, and in generalized anxiety disorder. It has no significant UV or visible absorption, therefore most often derivatization methods have to be employed for its determination. Previusly published methods for pregabalin determination in pharmaceutical dosage forms are either time-consuming [1] or use chromatographic separation [2]. Herein, we propose a novel high-throughput method utilizing a simple derivatization with fluorescamine and fluorescence detection with a microplate reader. The derivatization process is fast (5 min), proceeds at a room temperature in borate buffer at pH 9.5. Using fluorescent detection (λex 395 nm, λem 476 nm), the method was linear ($r^2$ > 0.997) over the concentration range (0.75–30 μg/ml). The intraday and interday precision of quality control samples was < 4.5%, and accuracy was 97.3–105.3%. Evaluation of the method robustness revealed that the emission wavelength and fluorescamine concentration are the most influential parameter. The method was applied to the analysis of pregabalin in 25 mg capsules. The content of pregabalin did not differ from the declared amount by more than 3.7%. Additionally, the method was applied to dissolution studies using USP 29 Apparatus 2 and FDA recommendation for dissolution testing of pregabalin capsules. It was demonstarted that more than 80% of pregabaline released in 10 min and more than 99.7% in 45 min. Finally, the universality of the method was proven by analyzing the content and dissolution profiles of pregabalin structural analogues vigabatrin, and gabapentin in pharmaceutical dosage forms.

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[2] Jadhav AS, Pathare DB, Shingare MS. Validated Enantioselective LC Method, with Precolumn Derivatization with Marfey's Reagent, for Analysis of the Antiepileptic Drug Pregabalin in Bulk Drug Samples. Chromatographia. 2007; 65: 253–256. doi:10.1365/s10337-006-0152-z