Research Paper

International Journal of Pharmaceutical Sciences and Nanotechnology
Volume 10 • Issue 1 • January – February 2017
MS ID: IJPSN-10-20-16-NAGESHWARA RAO

A New Method for Determination of Tolterodine and its Related Impurities in Active Pharmaceutical Ingredient by HPLC

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Received October 20, 2016; accepted December 25, 2016

ABSTRACT

Tolterodine is used to treat overactive bladder symptoms such as loss of bladder control (incontinence) or a frequent need to urinate. A simple and inexpensive method was developed with high performance liquid chromatography with PDA detection for determination of tolterodine and related impurities. The chromatographic separations were achieved on (250 × 4.6 mm), 5.0 µm make: symmetry, C8 column employing methanol and 0.1% orthophosphoric acid in water, in the ratio of 90:10 as mobile phase with gradient programmed at flow rate 1.0 mL/min was chosen. Three impurities were eluted within 35 minutes. The column temperature was maintained at 35◦C and a detector wavelength of 220 nm was employed. The method was successfully validated by establishing system suitability, specificity, linearity, accuracy, LOD and LOQ. The validated method is useful for tolterodine assay in pharmaceutical products.

KEYWORDS: HPLC; Method validation; Tolterodine; LOD and LOQ.