Available online at **www.joac.info**

ISSN: 2278-1862

Journal of Applicable Chemistry

2024, 13 (1): 18-26

(International Peer Reviewed Journal)

Simultaneous Determination of Impurities and Degradation Product in Fluralaner Antiparasitic Drugs Using Reverse Phase High-Performance Liquid Chromatography Method

Nitin S. Pagar[1]*, Sushant B. Dhanawade[2] and Vibhavari K. Belhe[1]

1. Post Graduate Department of Chemistry, Sir Parashurambhau College (Autonomous), Affiliated to Savitribai Phule Pune University, Pune-411030, **INDIA**.
2. Research and Development Division, NGL Fine Chemical Ltd, Mumbai, 400060, **INDIA**.

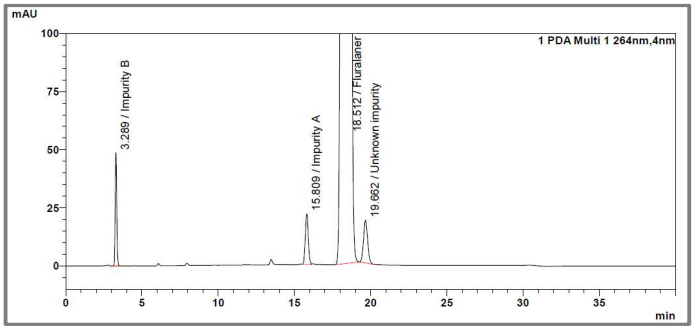
Email: nitin.pagar@spcollegepune.ac.in, nspagar@gmail.com

Accepted on 5th December, 2023

ABSTRACT

A simple, selective and fast Reversed-Phase High-Performance Liquid Chromatographic (RP-HPLC) approach for identifying related compounds in fluralaner, an Active Pharmaceutical Ingredient (API), has been developed and validated. The chromatographic system consisted of LC-2030C 3D with PDA detector and auto-sampler. The chromatographic separation was performed by gradient elution method using Hypersil BDS C_{18} column (250 mm×4.6 mm, 5 µm) as a stationary phase and mobile phase comprising of phosphate buffer (pH 4.0), acetonitrile (60:40) v/v in phase A and acetonitrile and methanol (50:50) v/v as phase B at a flow rate of 1.0 mL min^{-1}.Using an ultraviolet absorbance detector, the samples were detected and quantified at 264 nm.The method was found selective and a peak of the fluralaner was well separated with other impurities. For fluralaner the proposed method is linear (r^2 = 0.999), accurate (with 99.0% recovery) and precise (%RSD<2%). The method has been utilized to determine related substances in commercial products and was found to be accurate within a limit. .

Graphical Abstract:



Impurity spike chromatogram.

Keywords: Fluralaner, Impurity, Method validation, RP-HPLC.