IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 3, May 2025
Impact Factor: 7.67

Analytical Techniques for the Determination of Enzalutamide: A Comprehensive Review of Stability- Indicating RP-HPLC Methods

Mrunal D. Thakare, Dr. Anil V. Chandewar
Pharmacutical Quality Assurance, M. Pharm; Ph.D; F.I.C.
P. Wadhwani College of Pharmacy, Yavatmal, India

Abstract: *Enzalutamide was quantitatively determined in bulk and pharmaceutical dose forms using a straightforward, accurate, precise, and stability-indicating reverse-phase high-performance liquid chromatography (RP-HPLC) method that was developed and validated. Using a C18 column (250 mm × 4.6 mm, 5 µm) and a mobile phase made up of acetonitrile and phosphate buffer (pH 3.5) in a 60:40 v/v ratio at a flow rate of 1.0 mL/min, chromatographic separation was accomplished. The wavelength of detection was 215 nm. With a correlation coefficient (R2) of >0.999, the technique showed excellent linearity over the concentration range of 1–100 µg/mL. The specificity and stability-indicating ability of the approach were validated by forced degradation tests conducted in acidic, basic, oxidative, thermal, and photolytic environments. According to ICH Q2(R1) requirements, the approach was validated and determined to be accurate, precise, robust, and appropriate for routine Enzalutamide quality control.*

Keywords: Enzalutamide, RP-HPLC, Stability-Indicating Method, Method Validation, Forced Degradation, ICH Guidelines, Pharmaceutical Analysis, Antiandrogen

DOI: 10.48175/IJARSCT-26312