

**Stability Indicating RP-HPLC Method Development
and Validation for Psychostimulant Drugs
in Syrup Dosage Form**

Submitted By

Patel Krupaben Kirtikumar

Supervised By

Dr. Suresh M. Jain

M. Pharm., PhD.

Associate Professor and HOD, Dept. of Pharmaceutical Quality Assurance

Torrent Research Center

Bhat, Ta. & Dist. Gandhinagar 382428

ABSTRACT

A Stability Indicating RP-HPLC method was developed and validated for estimation of Psychostimulant drugs in syrup dosage form. The RP-HPLC method has shown adequate separation of drug A from its degradation products. The separation was achieved on an Inertsil ODS C₁₈ (250mm X 4.6 mm i.d., 5 µm particle size) with an isocratic mixture of 0.5 M Tetrabutyl ammonium hydrogen sulphate buffer pH 6.0 adjusted with glacial acetic acid: acetonitrile in the ratio of 90:10 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 20µl and wavelength of detection was kept at 270nm. The retention time for Drug A was 4.235±0.1min. The linearity of the proposed method for drug A was investigated in the range of 1-75µg/ml and correlation coefficient was 0.9985. The limit of detection was 0.059µg/ml and the limit of quantification was 0.180µg/ml. Force degradation study was carried out on reference/working standard and syrup dosage form as per ICH guideline and it was exposed to hydrolytic (acid and base hydrolysis), oxidative, thermal and photo

degradation conditions to apply stress. Proposed methods were validated as per ICH guidelines for linearity, accuracy, precision, specificity and robustness for estimation of drug A in commercially available syrup dosage form and results were found to be satisfactory. Thus the developed and validated stability indicating method can be used successfully for marketed formulations.

Key words: Drug A, stability indicating RP-HPLC method, Force degradation